PFIZER INC
Form 10-K
February 28, 2019
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 1-3619

PFIZER INC.

(Exact name of registrant as specified in its charter)

Delaware	13-5315170
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
235 East 42nd Street New York, New York	10017
(Address of principal executive offices)	(Zip Code)

(212) 733-2323

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, $.05 par value	New York Stock Exchange
Floating Rate Notes due 2019	New York Stock Exchange
0.000% Notes due 2020	New York Stock Exchange
0.250% Notes due 2022	New York Stock Exchange
1.000% Notes due 2027	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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 x No o

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 x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. x

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.

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

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. o

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, July 1, 2018, was approximately $212 billion. This excludes shares of common stock held by directors and executive officers at July 1, 2018. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. The registrant has no non-voting common stock.

The number of shares outstanding of the registrant's common stock as of February 26, 2019 was 5,551,804,790 shares of common stock, all of one class.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2018 Annual Report to Shareholders	Parts I, II and IV
Portions of the Proxy Statement for the 2019 Annual Meeting of Shareholders	Part III

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DEFINED TERMS

Unless the context requires otherwise, references to “Pfizer,” “the Company,” “we,” “us” or “our” in this 2018 Form 10-K (defined below) refer to Pfizer Inc. and its subsidiaries. We also have used several other terms in this 2018 Form 10-K, most of which are explained or defined below.

2018 Financial Report	Exhibit 13 to this 2018 Form 10-K
2018 Form 10-K	This Annual Report on Form 10-K for the fiscal year ended December 31, 2018
2019 Proxy Statement	Proxy Statement for the 2019 Annual Meeting of Shareholders
ACA	U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act
ACIP	Advisory Committee on Immunization Practices
Alliance revenues	Revenues from alliance agreements under which we co-promote products discovered or developed by other companies or us
Anacor	Anacor Pharmaceuticals, Inc.
ANDA	Abbreviated New Drug Application
Astellas	Astellas Pharma Inc., Astellas US LLC and Astellas Pharma US, Inc.
Bain Capital	Bain Capital Private Equity and Bain Capital Life Sciences
BLA	Biologics License Application
BMS	Bristol-Myers Squibb Company
Cerevel	Cerevel Therapeutics, LLC
cGMPs	current Good Manufacturing Practices
DEA	U.S. Drug Enforcement Agency
Developed Markets	U.S., Western Europe, Japan, Canada, South Korea, Australia, Scandinavian countries, Finland and New Zealand
EFPIA	European Federation of Pharmaceutical Industries and Associations
EH	Essential Health
EMA	European Medicines Agency
Emerging Markets	Includes, but is not limited to, the following markets: Asia (excluding Japan and South Korea), Latin America, Eastern Europe, Africa, the Middle East, Central Europe and Turkey
EU	European Union
Exchange Act	Securities Exchange Act of 1934, as amended
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FFDCA	U.S. Federal Food, Drug and Cosmetic Act
GPD	Global Product Development organization
GSK	GlaxoSmithKline plc
HIS	Hospira Infusion Systems
Hospira	Hospira, Inc.
ICU Medical	ICU Medical, Inc.
IH	Innovative Health
IPR&D	In-process Research and Development
LIBOR	London Interbank Offered Rate
LOE	Loss of Exclusivity
MCO	Managed Care Organization
Medivation	Medivation, Inc.
NDA	New Drug Application
NMPA	National Medical Product Administration (formerly known as China Food and Drug Administration or CFDA)

NYSE	New York Stock Exchange
OTC	over-the-counter
PBM	Pharmacy Benefit Manager
PGS	Pfizer Global Supply
PMDA	Pharmaceuticals and Medical Device Agency in Japan
R&D	Research and Development
SEC	U.S. Securities and Exchange Commission
Tax Cuts and Jobs Act	Legislation commonly referred to as the U.S. Tax Cuts and Jobs Act of 2017
U.K.	United Kingdom
U.S.	United States
VAI	Voluntary Action Indicated
WRD	Worldwide Research and Development

~$53.6 Billion in Revenues in 2018

10 Products with Direct Product and/or Alliance Revenues of Greater than $1 Billion in 2018

2 Distinct Business Segments in 2018 —
Pfizer Innovative Health (~$33.4 Billion 2018 Revenues) / Pfizer Essential Health (~$20.2 Billion 2018 Revenues)

6 Primary Therapeutic Areas in Pfizer Innovative Health in 2018 —
Internal Medicine, Vaccines, Oncology, Inflammation & Immunology, Rare Disease and Consumer Healthcare

4 Pfizer Essential Health Product Categories in 2018 —
Global Brands (Legacy Established Products & Peri-LOE Products), Sterile Injectable Pharmaceuticals, Biosimilars and Pfizer CentreOne

>125 Countries Where We Sell Our Products

100 Projects in Clinical Research & Development*

~$8 Billion 2018 R&D Expense

58 Manufacturing Sites Worldwide Operated by PGS

~92,400 Employees Globally

Unless indicated otherwise, the information contained in this summary is as of December 31, 2018. This summary does not include information that will be incorporated by reference into Part III of this 2018 Form 10-K from our 2019 Proxy Statement.

* As of January 29, 2019

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PART I
ITEM 1. BUSINESS
ABOUT PFIZER

Pfizer Inc. is a research-based, global biopharmaceutical company. We apply science and our global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products. We work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. We collaborate with healthcare providers, governments and local communities to support and expand access to reliable, affordable healthcare around the world. Our revenues are derived from the sale of our products and, to a much lesser extent, from alliance agreements, under which we co-promote products discovered or developed by other companies or us. The majority of our revenues come from the manufacture and sale of biopharmaceutical products. The Company was incorporated under the laws of the State of Delaware on June 2, 1942.

We believe that our medicines provide significant value for both healthcare providers and patients, not only from the improved treatment of diseases but also from a reduction in other healthcare costs, such as emergency room or hospitalization costs, as well as improvements in health, wellness and productivity. We continue to actively engage in dialogues about the value of our medicines and how we can best work with patients, physicians and payers to prevent and treat disease and improve outcomes. We continue to work within the current legal and pricing structures, as well as continue to review our pricing arrangements and contracting methods with payers, to maximize patient access and minimize any adverse impact on our revenues. We remain firmly committed to fulfilling our company's purpose: Breakthroughs that change patients' lives. By doing so, we expect to create value for the patients we serve and for our shareholders.

We are committed to capitalizing on growth opportunities by advancing our own pipeline and maximizing the value of our in-line products, as well as through various forms of business development, which can include alliances, licenses, joint ventures, collaborations, equity- or debt-based investments, dispositions, mergers and acquisitions. We view our business development activity as an enabler of our strategies, and we seek to generate earnings growth and enhance shareholder value by pursuing a disciplined, strategic and financial approach to evaluating business development opportunities.

Our significant recent business development activities include:

- On December 19, 2018, we announced that we entered into a definitive agreement with GSK under which we and GSK have agreed to combine our respective consumer healthcare businesses into a new consumer healthcare joint venture that will operate globally under the GSK Consumer Healthcare name. The joint venture is expected to be a category leader in pain relief, respiratory, vitamin and mineral supplements, digestive health, skin health and therapeutic oral health and will be the largest global OTC consumer healthcare business. In exchange for contributing our Consumer Healthcare business, we will receive a 32% equity stake in the company and GSK will own the remaining 68%. The transaction is expected to close in the second half of 2019, subject to customary closing conditions including GSK shareholder approval and required regulatory approvals.

- On February 3, 2017, we completed the sale of Pfizer's global infusion systems net assets, HIS, to ICU Medical for up to approximately $900 million, composed of cash and contingent cash consideration, ICU Medical common stock and seller financing. HIS, which was acquired as part of the Hospira acquisition in September 2015, includes intravenous pumps, solutions and devices.

On December 22, 2016, for $1,040 million we acquired the development and commercialization rights to AstraZeneca's small molecule anti-infectives business, primarily outside the U.S., which includes the marketed products Zavicefta™ (ceftazidime-avibactam), Merrem™/Meronem™ (meropenem) and Zinforo™ (ceftaroline fosamil), and the clinical development assets aztreonam-avibactam and ceftaroline fosamil-avibactam.

- On September 28, 2016, we acquired Medivation for approximately $14.3 billion in cash ($13.9 billion, net of cash acquired). Medivation is a biopharmaceutical company focused on developing and commercializing small molecules for oncology.

- On June 24, 2016, we acquired Anacor for approximately $4.9 billion in cash ($4.5 billion net of cash acquired), plus $698 million debt assumed. Anacor is a biopharmaceutical company focused on novel small-molecule therapeutics derived from its boron chemistry platform.

For a further discussion of our strategy and our business development initiatives, see the Notes to Consolidated Financial Statements—Note 2. Acquisitions, Divestitures, Assets and Liabilities Held for Sale, Licensing Arrangements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Privately Held Investment and the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy and —Our Business Development Initiatives sections in our 2018 Financial Report.

Our businesses are heavily regulated in most of the countries in which we operate. In the U.S., the principal authority regulating our operations is the FDA. The FDA regulates the safety and efficacy of the products we offer and our research, quality, manufacturing processes, product promotion, advertising and product labeling. Similar regulations exist in most other countries, and in many countries the government also regulates our prices. In the EU, the EMA conducts the scientific evaluation, supervision and safety monitoring of our products, and employs a centralized procedure for approval of medicines for the EU and the European Economic Area countries. In China, the NMPA (formerly CFDA) is the primary regulatory authority for approving and supervising medicines. In Japan, the PMDA is involved in a wide range of regulatory activities, including clinical studies, approvals, post-marketing reviews and pharmaceutical safety. Health authorities in many middle and lower income countries require marketing approval by a recognized regulatory authority (i.e., similar to the authority of the FDA or EMA) before they begin to conduct their application review process and/or issue their final approval. For additional information, see the Item 1. Business—Government Regulation and Price Constraints section below.

Note: Some amounts in this 2018 Form 10-K may not add due to rounding. All percentages have been calculated using unrounded amounts.

AVAILABLE INFORMATION AND PFIZER WEBSITE

Our website is located at www.pfizer.com. This 2018 Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are, or will be, available (free of charge) on our website, in text format and, where applicable, in interactive data file format, as soon as reasonably practicable after we electronically file this material with, or furnish it to, the SEC.

Throughout this 2018 Form 10-K, we "incorporate by reference" certain information from other documents filed or to be filed with the SEC, including our 2019 Proxy Statement and the 2018 Financial Report, portions of which are filed as Exhibit 13 to this 2018 Form 10-K, and which also will be contained in Appendix A to our 2019 Proxy Statement. The SEC allows us to disclose important information by referring to it in that manner. Please refer to this information. Our 2018 Annual Report to Shareholders consists of the 2018 Financial Report and the Corporate and Shareholder Information attached to the 2019 Proxy Statement. Our 2018 Financial Report will be available on our website on or about February 28, 2019. Our 2019 Proxy Statement will be available on our website on or about March 14, 2019.

We may use our website as a means of disclosing material information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included on our website in the “Investors” or “News” sections. Accordingly, investors should monitor these portions of our website, in addition to following Pfizer’s press releases, SEC filings, public conference calls and webcasts, as well as Pfizer’s social media channels (Pfizer’s Facebook, YouTube and LinkedIn pages and Twitter accounts (@Pfizer and @Pfizer_News)).

Information relating to corporate governance at Pfizer, including our Corporate Governance Principles; Director Qualification Standards; Pfizer Policies on Business Conduct (for all of our employees, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer); Code of Business Conduct and Ethics for Members of the Board of Directors; information concerning our Directors; ways to communicate by e-mail with our Directors; Board Committees; Committee Charters; Charter of the Lead Independent Director; and transactions in Pfizer securities by Directors and Officers are available on our website. We will provide any of the foregoing information without charge upon written request to our Corporate Secretary, Pfizer Inc., 235 East 42nd Street, New York, NY 10017. We will disclose any future amendments to, or waivers from, provisions of the Pfizer Policies on Business Conduct affecting our Chief Executive Officer, Chief Financial Officer and Controller on our website as promptly as practicable, as may be required under applicable SEC and NYSE rules. Information relating to shareholder services, including the Computershare Investment Program, book-entry share ownership and direct deposit of dividends, is also available on our website.

The information contained on our website, our Facebook, YouTube and LinkedIn pages or our Twitter accounts does not, and shall not be deemed to, constitute a part of this 2018 Form 10-K. Pfizer’s references to the URLs for websites are intended to be inactive textual references only.

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COMMERCIAL OPERATIONS

From the second quarter of our 2016 fiscal year until the end of 2018, we managed our commercial operations through two distinct business segments: Pfizer Innovative Health (IH) and Pfizer Essential Health (EH). The IH and EH operating segments were each led by a single manager. Each operating segment had responsibility for its commercial activities and for certain IPR&D projects for new investigational products and additional indications for in-line products that generally have achieved proof-of-concept. Each business had a geographic footprint across developed and emerging markets.

At the beginning of our fiscal year 2019, we began to manage our commercial operations through a new global structure consisting of three businesses, each of which is led by a single manager—Pfizer Biopharmaceuticals Group (Biopharma), Upjohn and Consumer Healthcare. We designed this new global structure to take advantage of new growth opportunities driven by the evolving and unique dynamics of relevant markets.

Some additional information about each business follows:

- Pfizer Biopharmaceuticals Group - a science-based Innovative Medicines business that includes our Innovative Health business units (except Consumer Healthcare) as well as a new Hospital business unit that commercializes our global portfolio of sterile injectable and anti-infective medicines. We also incorporated our biosimilar portfolio into our Oncology and Inflammation & Immunology therapeutic areas;
- Upjohn - an off-patent branded and generic established medicines business headquartered in China that includes 20 of our off-patent solid oral dose legacy brands, including Lyrica, Lipitor, Norvasc, Viagra and Celebrex, as well as certain generic medicines; and
- Consumer Healthcare - an over-the-counter medicines business, which we announced on December 19, 2018 will be contributed to, and combined with, GSK's consumer healthcare business to form a new consumer healthcare joint venture.

Results for 2018 and prior periods in our 2018 Form 10-K are reported on the basis under which we managed our businesses in 2018 and do not reflect the 2019 reorganization. Beginning with our first-quarter 2019 financial results, our financial reporting will reflect the new organizational structure.

For additional information regarding our new global structure, as well as our Organizing for Growth initiative, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Organizing for Growth section in our 2018 Financial Report.

Some additional information about our business segments as of December 31, 2018 (prior to our new 2019 commercial organizational re-alignment) follows:

IH focused on developing and commercializing novel, value-creating medicines and vaccines that significantly improve patients' lives, as well as products for consumer healthcare. Key therapeutic areas included internal medicine, vaccines, oncology, inflammation & immunology, rare disease and consumer healthcare.	EH included legacy brands that have lost or will soon lose market exclusivity in both developed and emerging markets, branded generics, generic sterile injectable products, biosimilars and select branded products including anti-infectives. EH also included an R&D organization, as well as our contract manufacturing business. Through February 2, 2017, EH also included HIS.
Leading brands included: - Prevnar 13/Prevenar 13 - Xeljanz	Leading brands included: - Lipitor - Norvasc

- Eliquis
- Lyrica (U.S., Japan and certain other markets)
- Enbrel (outside the U.S. and Canada)
- Ibrance
- Xtandi
- Chantix/Champix
- Several OTC consumer healthcare products (e.g., Centrum and Advil)
- Lyrica (Europe, Russia, Turkey, Israel and Central Asia countries)
- Celebrex
- Viagra*
- Inflectra/Remsima
- Sulperazon
- Several sterile injectable products

* Viagra lost exclusivity in the U.S. in December 2017. In 2018, revenues for Viagra in the U.S. and Canada, which were reported in IH through 2017, were reported in EH (which reported all other Viagra revenues excluding the U.S. and Canada through 2017). Therefore, in 2018, total Viagra worldwide revenues were reported in EH.

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For a further discussion of these operating segments, see the Innovative Health and Essential Health sections below and the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information, including the tables therein captioned Selected Income Statement Information, Geographic Information and Significant Product Revenues, the table captioned Revenues by Segment and Geography in the Analysis of the Consolidated Statements of Income section, and the Analysis of Operating Segment Information section in our 2018 Financial Report, which are incorporated by reference.

INNOVATIVE HEALTH

The key therapeutic areas comprising our IH business segment included:

Therapeutic Area	Description	Key Products
Internal Medicine	Included innovative brands from two therapeutic areas, Cardiovascular Metabolic and Pain, as well as regional brands.	Lyrica (outside Europe, Russia, Turkey, Israel and Central Asia countries), Chantix/Champix and Eliquis (jointly developed and commercialized with BMS)
Vaccines	Included innovative vaccines brands across all ages—infants, adolescents and adults—in pneumococcal disease, meningitis and tick-borne encephalitis, with a pipeline focus on healthcare-acquired infections and maternal health.	Prevnar 13/Prevenar 13 (pediatric/adult), Trumenba and FSME-IMMUN
Oncology	Included innovative oncology brands of biologics, small molecules and immunotherapies across a wide range of cancers.	Ibrance, Sutent, Xalkori, Inlyta and Xtandi (jointly developed and commercialized with Astellas)
Inflammation and Immunology	Included innovative brands for chronic immune and inflammatory diseases.	Enbrel (outside the U.S. and Canada), Xeljanz and Eucrisa
Rare Disease	Included innovative brands for a number of rare diseases, including hematology, neuroscience, and inherited metabolic disorders.	BeneFix, Genotropin and Refacto AF/Xyntha
Consumer Healthcare*	Included over-the-counter (OTC) brands with a focus on dietary supplements, pain management, gastrointestinal and respiratory and personal care. In 2018, according to Nicholas Hall's retail sales data (based on moving annual total data through the third quarter of 2018), Pfizer's Consumer Healthcare business was the fifth-largest branded multi-national, OTC consumer healthcare business in the world and produced two of the ten largest selling consumer healthcare brands (Centrum and Advil) in the world.	Dietary Supplements: Centrum brands, Caltrate and Emergen-C Pain Management: Advil brands and ThermaCare Gastrointestinal: Nexium 24HR/Nexium Control and Preparation H Respiratory and Personal Care: Robitussin, Advil Cold & Sinus and ChapStick

* On December 19, 2018, we announced that we entered into a definitive agreement with GSK under which we and GSK have agreed to combine our respective consumer healthcare businesses into a new consumer healthcare joint venture, which will operate globally under the GSK Consumer Healthcare name. Assets and liabilities associated with our Consumer Healthcare business were reclassified as held for sale in the consolidated balance sheet as of

December 31, 2018. We expect to complete the transaction during the second half of 2019, subject to customary closing conditions, including GSK shareholder approval and required regulatory approvals. For additional information, see the Notes to Consolidated Financial Statements—Note 2C. Acquisitions, Divestitures, Assets and Liabilities Held for Sale, Licensing Arrangements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Privately Held Investment: Assets and Liabilities Held for Sale.

We recorded direct product and/or alliance revenues of more than $1 billion for each of eight IH products in 2018, and seven IH products in 2017 and 2016:

Innovative Health $1B+ Products

2018	2017	2016
Prevnar 13/Prevenar 13	Prevnar 13/Prevenar 13	Prevnar 13/Prevenar 13
Lyrica IH	Lyrica IH	Lyrica IH
Ibrance	Ibrance	Enbrel
Eliquis*	Eliquis*	Ibrance
Enbrel	Enbrel	Eliquis*
Xeljanz	Xeljanz	Viagra IH
Chantix/Champix	Sutent	Sutent
Sutent		

* Eliquis includes alliance revenues and direct sales in 2018, 2017 and 2016.

For a discussion of certain IH products and additional information regarding the revenues of our IH business, including revenues by geography and of significant IH products, see the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information and the Analysis of the Consolidated Statements of Income—Revenues—Overview, —Revenues by Segment and Geography and —Revenues—Selected Product Discussion sections in our 2018 Financial Report; and for additional information on the key operational revenue drivers of our IH business, see the Analysis of Operating Segment Information—Innovative Health Operating Segment section of our 2018 Financial Report. For a discussion of the risks associated with our dependence on certain of our major products, see Item 1A. Risk Factors—Dependence on Key In-Line Products below.

ESSENTIAL HEALTH

The product categories in our EH business segment included:

Product Category	Description	Key Products
Global Brands—Legacy Established Products	Included products that have lost patent protection (excluding Sterile Injectable Pharmaceuticals and Peri-LOE Products).	Lipitor, Premarin family and Norvasc
Global Brands—Peri-LOE Products	Included products that have recently lost or are anticipated to soon lose patent protection.	Lyrica (Europe, Russia, Turkey, Israel and Central Asia), Viagra*, Celebrex, Pristiq, Zyvox, Vfend, Revatio and Inspra
Sterile Injectable Pharmaceuticals	Included generic injectables and proprietary specialty injectables (excluding Peri-LOE Products).	Medrol, Sulperazon, Fragmin and Tygacil
Biosimilars	Included recombinant and monoclonal antibodies, primarily in inflammation, oncology and supportive care.	Inflectra/Remsima (biosimilar infliximab) (U.S., Canada, the EU, Australia and certain international markets), Nivestim/Nivestym (biosimilar filgrastim) (U.S. and certain European, Asian and Africa/Middle East markets), Retacrit (biosimilar epoetin alfa-epbx/epoetin zeta) (U.S. and certain European and Africa/Middle East markets) and Ixifi Infliximab BS for I.V. Infusion 100mg (Japan)

Pfizer CentreOne	Included revenues from our contract manufacturing and active pharmaceutical ingredient sales operation, including sterile injectables contract manufacturing, and revenues related to our manufacturing and supply agreements, including with Zoetis Inc.	--

* Viagra lost exclusivity in the U.S. in December 2017. In 2018, revenues for Viagra in the U.S. and Canada, which were reported in IH through 2017, were reported in EH (which reported all other Viagra revenues excluding the U.S. and Canada through 2017). Therefore, in 2018, total Viagra worldwide revenues were reported in EH.

We recorded direct product revenues of more than $1 billion for two EH products in 2018, one EH product in 2017, and two EH products in 2016:

Essential Health $1B+ Products		
2018	2017	2016
Lipitor	Lipitor	Lipitor
Norvasc		Premarin family of products

For a discussion of certain EH products and additional information regarding the revenues of our EH business, including revenues by geography and of significant EH products, see the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information and the Analysis of the Consolidated Statements of Income—Revenues—Overview, —Revenues by Segment and Geography and —Revenues—Selected Product Discussion sections in our 2018 Financial Report; and for additional information on the key operational revenue drivers of our EH business, see the Analysis of Operating Segment Information—Essential Health Operating Segment section of our 2018 Financial Report. For a discussion of the risks associated with our dependence on certain of our major products, see Item 1A. Risk Factors—Dependence on Key In-Line Products below.

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COLLABORATION AND CO-PROMOTION AGREEMENTS

We are party to collaboration and/or co-promotion agreements relating to certain biopharmaceutical products, including, among others, Eliquis, Xtandi and Bavencio. Revenues from Eliquis (except in certain markets where we have direct sales), Xtandi and Bavencio are included in alliance revenues.

Eliquis has been jointly developed and is being commercialized in collaboration with BMS. Pfizer funds between 50% and 60% of all development costs depending on the study. Profits and losses are shared equally on a global basis, except in certain countries where Pfizer commercializes Eliquis and pays BMS compensation based on a percentage of net sales. We have full commercialization rights in certain smaller markets. BMS supplies the product to us at cost plus a percentage of the net sales to end-customers in these markets. Eliquis is part of the Novel Oral Anticoagulant market; the agents in this class were developed as alternative treatment options to warfarin in appropriate patients.

Xtandi is being developed and commercialized through a collaboration with Astellas. The two companies share equally in the gross profits (losses) related to U.S. net sales of Xtandi. Subject to certain exceptions, Pfizer and Astellas also share equally all Xtandi commercialization costs attributable to the U.S. market. In addition, Pfizer and Astellas share certain development and other collaboration expenses, and Pfizer receives tiered royalties as a percentage of international Xtandi net sales (recorded in Other (Income)/Deductions—Net). Xtandi is an androgen receptor inhibitor that blocks multiple steps in the androgen receptor signaling pathway within tumor cells.

Bavencio (avelumab) is being developed and commercialized in collaboration with Merck KGaA. Both companies jointly fund the majority of development and commercialization costs, and split equally any profits generated from selling any products containing avelumab from this collaboration. Bavencio is currently approved in metastatic Merkel cell carcinoma and for patients with locally advanced or metastatic urothelial carcinoma in certain countries and in development as a potential treatment for multiple other types of cancer.

RESEARCH AND DEVELOPMENT

Innovation is critical to the success of our company, and drug discovery and development is time-consuming, expensive and unpredictable. Our goal is to discover, develop and bring to market innovative products that address major unmet medical needs.

Our R&D Priorities and Strategy

Our R&D priorities include:

- delivering a pipeline of differentiated therapies and vaccines with the greatest medical and commercial potential;
- advancing our capabilities that can position Pfizer for long-term leadership; and
- creating new models for biomedical collaboration that will expedite the pace of innovation and productivity.

To that end, our research and development primarily focuses on:

- Inflammation and Immunology;
- Internal Medicine;
- Oncology;
- Rare Diseases;
- Vaccines; and
- Biosimilars.

In January 2018, we announced our decision to end internal neuroscience discovery and early development efforts and re-allocate funding to other areas where we have stronger scientific leadership. The development of tanezumab and potential treatments for rare neuromuscular disorders is not impacted by this decision. In June 2018, we announced our plan to invest up to $600 million in biotechnology and other emerging growth companies through Pfizer Ventures,

our venture investment vehicle. In September 2018, we and Bain Capital entered into a transaction to create a new biopharmaceutical company, Cerevel, to continue development of a portfolio of clinical and preclinical stage neuroscience assets primarily targeting disorders of the central nervous system, including Parkinson's disease, epilepsy, Alzheimer's disease, schizophrenia and addiction. For additional information on the transaction with Bain Capital, see the Notes to Consolidated Financial Statements—Note 2B. Acquisitions, Divestitures, Assets and Liabilities Held for Sale, Licensing Arrangements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Privately Held Investment: Divestitures in our 2018 Financial Report.

While a significant portion of R&D is done internally, we continue to seek out promising chemical and biological lead molecules and innovative technologies developed by third parties to incorporate into our discovery and development processes or projects, as well as our product lines, by entering into collaboration, alliance and license agreements with other companies, as well as leveraging acquisitions and equity- or debt-based investments. These agreements enable us to co-develop, license or acquire promising compounds, technologies or capabilities. We also enter into agreements pursuant to which a third party agrees to fund a portion of the development costs of one or more of our pipeline products in exchange for rights to receive potential milestone payments, revenue sharing payments, profit sharing payments and/or royalties. Collaboration, alliance, license and funding agreements and equity- or debt-based investments allow us to share risk and cost and to access external scientific and technological expertise, and provide us the opportunity to advance our own products as well as the in-licensed or acquired products.

Our R&D Operations

We conduct R&D internally and also through contracts with third parties, through collaborations with universities and biotechnology companies and in cooperation with other pharmaceutical firms. In 2018, we continued to strengthen our global R&D organization and pursue strategies intended to improve innovation and overall productivity in R&D to achieve a sustainable pipeline that is positioned to deliver value in the near term and over time.

Our R&D spending in 2018 was conducted through a number of matrix organizations:

- Research Units within our WRD organization were generally responsible for research and early-stage development assets for our IH business (assets that have not yet achieved proof-of-concept).
- Our R&D organization within the EH business supported the large base of EH products and helped develop potential new sterile injectable drugs and therapeutic solutions, as well as biosimilars.
- Our Global Product Development organization, a unified center for late-stage development for our innovative products that was generally responsible for the operational execution of clinical trials for both early-stage assets in the WRD portfolio as well as late-stage assets in the Innovative portfolio. For WRD assets, GPD worked in close collaboration with the Early Clinical Development group, which has expertise in various disciplines such as Biostatistics, Clinical Pharmacology and Digital Medicine.
- Our science-based and other platform-services organizations, where a significant portion of our R&D spending occurred, provided technical expertise and other services to the various R&D projects, and were organized into science-based functions (which were part of our WRD organization), such as Pharmaceutical Sciences, Medicine Design, Regulatory and Drug Safety, and non-science-based functions, such as Facilities, Business Technology and Finance.

At the beginning of 2019, we reorganized our R&D operations as part of our Organizing for Growth reorganization:

- WRD is renamed Worldwide Research, Development and Medical (WRDM) as we have created a new Worldwide Medical & Safety organization that incorporates the former Chief Medical Office as well as the Worldwide Safety function;
- The R&D organization within the EH business has been integrated into the WRDM, GPD and Upjohn organizations, including moving biosimilars into WRDM and GPD and realigning them with the relevant therapeutic areas (e.g., Oncology and Inflammation & Immunology);
- The Regulatory function has been moved from the WRDM organization into the GPD organization; and
- Late-stage portfolio spend has been moved from IH to GPD and from EH to GPD and Upjohn.

For discussion regarding these R&D matrix organizations and additional information on our R&D operations and expenses, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Description of Research and Development Operations and Costs and Expenses—Research and Development (R&D) Expenses sections in our 2018 Financial Report.

Our R&D Pipeline and Competition

The discovery and development of safe, effective new products, as well as the development of additional uses for existing products, are necessary for the continued strength of our businesses. Drug candidates can fail at any stage of the process, and candidates may not receive regulatory approval even after many years of research and development. The process from discovery to development to regulatory approval can take more than ten years.

As of January 29, 2019, we had the following number of projects in various stages of R&D:
Development of a single compound is often pursued as part of multiple programs. While these drug candidates may or may not eventually receive regulatory approval, new drug candidates entering clinical development phases are the foundation for future products. In addition to discovering and developing new products, our R&D efforts seek to add value to our existing products by improving their effectiveness, enhancing ease of dosing and by discovering potential new indications for them.

Information concerning several of our drug candidates in development, as well as supplemental filings for existing products, is set forth in the Analysis of the Consolidated Statements of Income—Product Developments—Biopharmaceutical section in our 2018 Financial Report, which is incorporated by reference.

Our competitors also devote substantial funds and resources to R&D. We also compete against numerous small biotechnology companies in developing potential drug candidates. The extent to which our competitors are successful in their research could result in erosion of the sales of our existing products and potential sales of products in development, as well as unanticipated product obsolescence. In addition, several of our competitors operate without large R&D expenses and make a regular practice of challenging our product patents before their expiration. For additional information, see the Competition and Item 1A. Risk Factors—Competitive Products sections below.
INTERNATIONAL OPERATIONS

We have significant operations outside the U.S. In 2018, operations in developed and emerging markets were managed through our two business segments: IH and EH. Emerging markets are an important component of our strategy for global leadership, and our commercial structure recognizes that the demographics and rising economic power of the fastest-growing emerging markets are becoming more closely aligned with the profile found within developed markets. Urbanization in emerging markets, particularly in Asia, is creating additional access opportunities for our medicines.

We sell our products in over 125 countries. Revenues from operations outside the U.S. of $28.3 billion accounted for 53% of our total revenues in 2018. By total revenues, China and Japan are our two largest national markets outside the U.S. For a geographic breakdown of revenues, see the table captioned Geographic Information in the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information in our 2018 Financial Report, and the Analysis of the Consolidated Statements of Income—Revenues—Overview and —Revenues by Segment and Geography sections in our 2018 Financial Report.

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Our international operations are subject, in varying degrees, to a number of risks inherent in carrying on business in other countries, including, among other things, currency fluctuations, capital and exchange control regulations and expropriation and other restrictive government actions. See Item 1A. Risk Factors—International Operations below. Our international businesses are also subject to government-imposed constraints, including laws and regulations on pricing, reimbursement, and access to our products. See Item 1. Business—Government Regulation and Price Constraints—Outside the United States below for a discussion of these matters.

Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or decrease the reported dollar value of our net assets and results of operations. While we cannot predict with certainty future changes in foreign exchange rates or the effect they will have on us, we attempt to mitigate their impact through operational means and by using various financial instruments, depending upon market conditions. For additional information, see the Notes to Consolidated Financial Statements—Note 7F. Financial Instruments: Derivative Financial Instruments and Hedging Activities in our 2018 Financial Report, as well as the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2018 Financial Report. Those sections of our 2018 Financial Report are incorporated by reference.

MARKETING

In our global biopharmaceutical businesses, we promote our products to healthcare providers and patients. Through our marketing organizations, we explain the approved uses, benefits and risks of our products to healthcare providers, such as doctors, nurse practitioners, physician assistants and pharmacists; MCOs that provide insurance coverage, such as hospitals, Integrated Delivery Systems, Pharmacy Benefit Managers and health plans; and employers and government agencies who hire MCOs to provide health benefits to their employees. We also market directly to consumers in the U.S. through direct-to-consumer advertising that seeks to communicate the approved uses, benefits and risks of our products while motivating people to have meaningful conversations with their doctors. In addition, we sponsor general advertising to educate the public on disease awareness, prevention and wellness, important public health issues, and our patient assistance programs.

Our prescription pharmaceutical products are sold principally to wholesalers, but we also sell directly to retailers, hospitals, clinics, government agencies and pharmacies, and, in the case of our vaccines products in the U.S., we primarily sell directly to the U.S. Centers for Disease Control and Prevention, wholesalers, individual provider offices, retail pharmacies, and integrated delivery networks. We seek to gain access for our products on healthcare authority and PBM formularies, which are lists of approved medicines available to members of the PBMs. PBMs use various benefit designs, such as tiered co-pays for formulary products, to drive utilization of products in preferred formulary positions. We may also work with payers to assist them with disease management, patient education and other tools that help their medical treatment routines.

In 2018, our top three biopharmaceutical wholesalers accounted for approximately 37% of our total revenues (and approximately 76% of our total U.S. revenues).

% of 2018 Total Revenues and U.S. Revenues from
Major Biopharmaceutical Wholesalers and Other Customers

Our global Consumer Healthcare business uses its own sales and marketing organizations to promote its products, and occasionally uses distributors and agents, principally in smaller markets. The advertising and promotions for our Consumer Healthcare business are generally disseminated to consumers through television, print, digital and other media advertising, as well as through in-store promotion. Consumer Healthcare products are sold through a wide variety of channels, including distributors, pharmacies, retail chains and grocery and convenience stores. Our Consumer Healthcare business generates a significant portion of its sales from several large customers, the loss of any one of which could have a material adverse effect on the Consumer Healthcare business.

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PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

Our products are sold around the world under brand-name, logo and certain product design trademarks that we consider, in the aggregate, to be of material importance to Pfizer. Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms.

We own or license a number of U.S. and foreign patents. These patents cover pharmaceutical and other products and their uses, pharmaceutical formulations, product manufacturing processes and intermediate chemical compounds used in manufacturing.

Patents for individual products extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. Further, patent term extension may be available in many major countries to compensate for a regulatory delay in approval of the product. For additional information, see Item 1. Business—Government Regulation and Price Constraints—Outside the United States—Intellectual Property below.

In various markets, a period of regulatory exclusivity may be provided to certain therapeutics upon approval. The scope and term of such exclusivity will vary but, in general, the period of regulatory exclusivity will run concurrently with the term of any existing patent rights associated with the therapeutic.

In the aggregate, our patent and related rights are of material importance to our businesses in the U.S. and most other countries. Based on current product sales, and considering the vigorous competition with products sold by our competitors, the patent rights we consider most significant in relation to our business as a whole, together with the year in which the basic product patent expires (including, where applicable, the additional six-month pediatric exclusivity period and/or the granted patent term extension), are those for the medicines set forth in the table below. Unless otherwise indicated, the years set forth in the table below pertain to the basic product patent expiration for the respective products. Patent term extensions, supplementary protection certificates and pediatric exclusivity periods are not reflected in the expiration dates listed in the table below, unless they have been granted by the issuing authority. In some instances, there are later-expiring patents relating to our products directed to particular forms or compositions, to methods of manufacturing, or to use of the drug in the treatment of particular diseases or conditions. However, in some cases, such patents may not protect our drug from generic or, as applicable, biosimilar competition after the expiration of the basic patent.

Drug	U.S. Basic Product Patent Expiration Year	Major EU Basic Product Patent Expiration Year	Japan Basic Product Patent Expiration Year
Lyrica	2019[1]	2014[2]	2022[3]
Chantix/Champix	2020	2021	2022
Sutent	2021	2021	2024
Ibrance	2023	2028	2028
Inlyta	2025	2025	2025
Xeljanz	2025	2028[4]	2025
Prevnar 13/Prevenar 13	2026	2026[5]	2029
Eucrisa	2026	N/A[6]	N/A[6]
Eliquis[7]	2026	2026	2026
Xtandi[8]	2027	*[8]	*[8]
Besponsa	2027	2023	2028[9]
Xalkori	2029	2027	2028

Bavencio[10]	2033	2032	2033

(1) In November 2018, the FDA granted pediatric exclusivity for Lyrica in the U.S. for an additional six months to June 2019; pediatric exclusivity applies to both the basic product patent for Lyrica and a method of treatment patent, both of which expired in the U.S. in December 2018.

(2) Lyrica regulatory exclusivity in the EU expired in July 2014.

(3) Lyrica is covered by a Japanese method-of-use patent which expires in 2022. The patent is currently subject to an invalidation action.

(4) Xeljanz EU expiry is provided by regulatory exclusivity.

(5) The EU patent that covers the combination of the 13 serotype conjugates of Prevenar 13 has been revoked following an opposition proceeding. This first instance decision has been appealed. There are other EU patents and pending applications covering the formulation and various aspects of the manufacturing process of Prevenar 13 that remain in force.

(6) Eucrisa is not approved in the EU or Japan.

(7) Eliquis was developed and is being commercialized in collaboration with BMS.

(8) Xtandi is being developed and commercialized in collaboration with Astellas, which has exclusive commercialization rights for Xtandi outside the U.S.

(9) Besponsa Japan expiry is provided by regulatory exclusivity.

(10) Bavencio is being developed and commercialized in collaboration with Merck KGaA.

A number of our current products have experienced patent-based expirations or loss of regulatory exclusivity in certain markets in the last few years. For additional information, including further discussion of our products experiencing, or expected to experience in 2019, patent expirations or loss of regulatory exclusivity in the U.S., Europe or Japan, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—Industry-Specific Challenges—Intellectual Property Rights and Collaboration/Licensing Rights section in our 2018 Financial Report and Item 1A. Risk Factors—Dependence on Key In-Line Products below.

Companies have filed applications with the FDA seeking approval of product candidates that such companies claim do not infringe our patents; these include candidates that would compete with, among other products, Eliquis, Xeljanz and Xtandi. We also are often involved in other proceedings, such as inter partes review, post-grant review, re-examination or opposition proceedings, before the U.S. Patent and Trademark Office, the European Patent Office, or other foreign counterparts relating to our intellectual property or the intellectual property rights of others. For additional information, see the Notes to Consolidated Financial Statements—Note 17A1. Contingencies and Certain Commitments—Legal Proceedings—Patent Litigation in our 2018 Financial Report.

The expiration of a basic product patent or loss of patent protection resulting from a legal challenge normally results in significant competition from generic products against the originally patented product and can result in a significant reduction in revenues for that product in a very short period of time. In some cases, however, we can continue to obtain commercial benefits from product manufacturing trade secrets; patents on uses for products; patents on processes and intermediates for the economical manufacture of the active ingredients; patents for special formulations of the product or delivery mechanisms; or conversion of the active ingredient to OTC products.

Biologic Products

Our biologic products, including BeneFIX, ReFacto, Xyntha, Bavencio, Prevnar 13/Prevenar 13 and Enbrel (we market Enbrel outside the U.S. and Canada), may face in the future, or already face, competition from biosimilars (also referred to as follow-on biologics). In the U.S., such biosimilars would reference our originator biologic products approved under the U.S. Public Health Service Act. Additionally, the FDA has approved a follow-on recombinant human growth hormone that referenced our biotechnology product, Genotropin, that was approved under the FFDCA.

Biosimilars are versions of biologic medicines that have been developed and proven to be highly similar to the original biologic in terms of safety and efficacy and that have no clinically meaningful differences in safety, purity or potency. Biosimilars have the potential to offer high-quality, lower-cost alternatives to biologic medicines. Abbreviated legal pathways for the approval of biosimilars exist in certain international markets and, since the passage of the ACA in 2010, a framework for such approval exists in the U.S. In Europe, the European Commission grants marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals.

As part of our business strategy, we are capitalizing on our expertise in biologics manufacturing, as well as our regulatory and commercial strengths, to develop and commercialize biosimilar medicines. See Item 1A. Risk Factors—Biologic Products below.

We may face litigation with respect to the validity and/or scope of patents relating to our biologic products. Likewise, as we develop, manufacture and seek to launch biosimilars, patents may be asserted against us.

International

One of the main limitations on our operations in some countries outside the U.S. is the lack of effective intellectual property protection for our products. Under international and U.S. free trade agreements in recent years, we have seen some improvement in global protection of intellectual property rights. For additional information, see Item 1. Business—Government Regulation and Price Constraints—Outside the United States—Intellectual Property below.

COMPETITION

Our businesses are conducted in intensely competitive and often highly regulated markets. Many of our prescription pharmaceutical products face competition in the form of branded or generic drugs or biosimilars that treat similar diseases or indications. The principal forms of competition include efficacy, safety, ease of use, and cost effectiveness. Though the means of competition vary among product categories and business groups, demonstrating the value of our products is a critical factor for success in all of our principal businesses.

Our competitors include other worldwide research-based biopharmaceutical companies, smaller research companies with more limited therapeutic focus, generic and biosimilar drug manufacturers and consumer healthcare manufacturers. We compete with other companies that manufacture and sell products that treat diseases or indications similar to those treated by our major products.

This competition affects our core product business, which is focused on applying innovative science to discover and market products that satisfy unmet medical needs and provide therapeutic improvements. Our emphasis on innovation is underscored by our multi-billion-dollar investment in R&D, as well as our business development transactions, both designed to result in a strong product pipeline. Our investment in research does not stop with drug approval; we continue to invest in further understanding the value of our products for the conditions they treat, as well as potential new applications. We seek to protect the health and well-being of patients by striving to ensure that medically sound knowledge of the benefits and risks of our medicines is understood and communicated to patients, physicians, payers and global health authorities. We also seek to continually enhance the organizational effectiveness of all of our biopharmaceutical functions, including coordinating support for our salespersons' efforts to accurately and ethically launch and promote our products to our customers.

Operating conditions have become more challenging under mounting global pressures of competition, industry regulation and cost containment. We continue to take measures to evaluate, adapt and improve our organization and business practices to better meet customer and public needs. We believe that we have taken an industry-leading role in evolving our approaches to U.S. direct-to-consumer advertising; interactions with, and payments to, healthcare professionals; and medical education grants. We also continue to sponsor programs to address patient affordability and access barriers, as we strive to advance fundamental health system change through support for better healthcare

solutions.

Our vaccines business may face competition from the introduction of alternative or next generation vaccines. For example, Prevnar 13 may face competition in the form of alternative 13-valent or additional valent next-generation pneumococcal conjugate vaccines prior to the expiration of its patents, which may adversely affect our future results.

Our generics and biosimilars businesses compete with branded products from competitors, as well as other generics and biosimilars manufacturers. Globally, Pfizer sells generic versions of Pfizer's, as well as certain competitors', solid oral dose and sterile injectable pharmaceutical products, as well as biosimilars. We seek to maximize the opportunity to establish a "first-to-

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market" or early market position for our generic injectable drugs and biosimilars, as a "first-to-market" position provides customers a lower-cost alternative immediately when available and also may provide us with potentially higher levels of sales and profitability until other generic or biosimilar competitors enter the market.

Our Consumer Healthcare business faces competition from OTC business units in other major pharmaceutical and consumer packaged goods companies, and retailers who carry their own private label brands. Our competitive position is affected by several factors, including the amount and effectiveness of our and our competitors' promotional resources; customer acceptance; product quality; our and our competitors' introduction of new products, ingredients, claims, dosage forms, or other forms of innovation; and pricing, regulatory and legislative matters (such as product labeling, patient access and prescription to OTC switches).

Managed Care Organizations

The evolution of managed care in the U.S. has been a major factor in the competitive makeup of the healthcare marketplace. Approximately 298 million people in the U.S. now have some form of health insurance coverage. Due to the expansion of health insurance coverage (see Item 1. Business—Government Regulation and Price Constraints—In the United States below), the marketing of prescription drugs to both consumers and the entities that manage this expanded coverage in the U.S. continues to grow in importance.

The influence of MCOs has increased in recent years due to the growing number of patients receiving coverage through MCOs. At the same time, those organizations have been consolidating into fewer, even larger entities. This consolidation enhances both their ability to negotiate, as well as their importance to Pfizer.

The growth of MCOs has increased pressure on drug prices as well as revenues. One objective of MCOs is to contain and, where possible, reduce healthcare expenditures. MCOs typically negotiate prices with pharmaceutical providers by using formularies (which are lists of approved medicines available to members of the MCOs), 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), volume purchasing, long-term contracts and their ability to influence volume and market share of prescription drugs. In addition, by placing branded medicines on higher-tier status in their formularies (leading to higher patient co-pays) or non-preferred tier status, MCOs transfer a portion of the cost of the medicine to the patient, resulting in significant out-of-pocket expenses for the patient, especially for chronic treatments. This financial disincentive is a tool for MCOs to manage drug costs and channel patients to medicines preferred by the MCOs. MCOs also use additional measures such as new-to-market blocks, exclusion lists, indication-based pricing, "copay accumulator" programs and value-based pricing/contracting to improve their cost containment efforts. We are closely monitoring these newer approaches and developing appropriate strategies to respond to them.

Due to their generally lower cost, generic medicines typically are placed in lowest cost tiers of MCO formularies. The breadth of the products covered by formularies can vary considerably from one MCO to another, and many formularies include alternative and competitive products for treatment of particular medical problems. MCOs are currently evaluating the appropriate placement of biosimilars on their formularies.

Exclusion of a product from a formulary or other MCO-implemented restrictions can significantly impact drug usage in the MCO patient population. Consequently, pharmaceutical companies compete to gain access to formularies for their products. Unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, are generally beneficial to achieving access to formularies. However, lower overall cost of therapy is also an important factor. We have been generally, although not universally, successful in having our major products included on MCO formularies. However, increasingly our branded products are being placed on the higher tiers or in a non-preferred status.

MCOs also emphasize primary and preventive care, out-patient treatment and procedures performed at doctors' offices and clinics as another way to manage costs. Hospitalization and surgery, typically the most expensive forms of treatment, are carefully managed. Since the use of certain drugs can reduce the need for hospitalization, professional therapy, or even surgery, such drugs can become favored first-line treatments for certain diseases.

The ACA has accelerated payment reform by distributing risk across MCOs and other stakeholders in care delivery with the intent of improving quality while reducing costs, which creates pressure on MCOs to tie reimbursement to defined outcomes. We anticipate continued Congressional interest in modifying provisions of the ACA, particularly given the recent ruling in Texas v. Azar to invalidate the law as unconstitutional, though we believe it is unlikely Congress will find bipartisan consensus to advance any significant changes to the ACA until the legal process unfolds. We are monitoring any such actions to see if any changes to the ACA will be enacted that would impact our business.

Generic Products

One of the biggest competitive challenges that our branded products face is from generic pharmaceutical manufacturers. Upon the expiration or loss of patent protection for a product, especially a small molecule product, we can lose the major portion of revenues for that product in a very short period of time. Several competitors make a regular practice of challenging our product

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patents before their expiration. Generic competitors often operate without large R&D expenses, as well as without costs of conveying medical information about products to the medical community. In addition, the FDA approval process exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy data of the innovator product. Generic competitors can market a competing version of our product after the expiration or loss of our patent and often charge much less. In China, for example, we are expected to face strong competition by certain generic manufacturers in 2019, which may result in price cuts and volume loss of some of our products.

In addition, our patent-protected products can face competition in the form of generic versions of competitors' branded products that lose their market exclusivity.

As noted above, MCOs that focus primarily on the immediate cost of drugs often favor generics over brand-name drugs. Many governments also encourage the use of generics as alternatives to brand-name drugs in their healthcare programs, including Medicaid in the U.S. Laws in the U.S. generally allow, and in some cases require, pharmacists to substitute, for brand-name drugs, generic drugs that have been rated under government procedures to be chemically and therapeutically equivalent to brand-name drugs. In a small subset of states, prescribing physicians are able to expressly prevent such substitution. Favoring generics may reduce sales of our branded products.

RAW MATERIALS

Raw materials essential to our businesses are purchased worldwide in the ordinary course of business from numerous suppliers. In general, these materials are available from multiple sources. In 2018, we experienced periodic shortages of select materials due to constrained capacity or operational challenges with the associated suppliers. Supplier management activities are ongoing to work to ensure the necessary supply to meet our requirements for these materials. No significant impact to our operations is anticipated in 2019.

GOVERNMENT REGULATION AND PRICE CONSTRAINTS

Pharmaceutical companies are subject to extensive regulation by government authorities in the countries in which they do business. Certain laws and regulations that govern Pfizer's business are discussed below.

General. Our business has been and will continue to be subject to numerous laws and regulations. Failure to comply with these laws and regulations, including those governing the manufacture and marketing of our products, could subject us to administrative and legal proceedings and actions by various governmental bodies. For additional information on these proceedings and actions, see the Notes to Consolidated Financial Statements—Note 17A. Contingencies and Certain Commitments—Legal Proceedings in our 2018 Financial Report. Criminal charges, substantial fines and/or civil penalties, warning letters and product recalls or seizures, delays in product approvals, as well as limitations on our ability to conduct business in applicable jurisdictions, could result from such proceedings and actions.

In the United States

Drug Regulation. In the U.S., biopharmaceutical products are subject to extensive pre- and postmarket regulation by the FDA, including regulations that govern, among other things, the safety and efficacy of our medicines, clinical trials, advertising and promotion, manufacturing, labeling and record keeping. Our products are also subject to postmarket surveillance under the FFDCA and its implementing regulations with respect to drugs, as well as the Public Health Service Act and its implementing regulations with respect to biologics. Our Consumer Healthcare products are also subject to FDA regulation.

Other U.S. federal agencies, including the DEA, also regulate certain of our products. The U.S. Federal Trade Commission has the authority to regulate the advertising of consumer healthcare products, including OTC drugs and

dietary supplements. Many of our activities also are subject to the jurisdiction of the SEC.

Biopharmaceutical companies seeking to market a product in the U.S. must first test the product to demonstrate that it is safe and effective for its intended use. If, after evaluation, the FDA determines the product is safe (i.e., its benefits outweigh its known risks) and effective, then the FDA will approve the product for marketing, issuing a NDA or BLA as appropriate. Companies seeking to market a generic prescription drug must scientifically demonstrate that the generic drug is bioequivalent to the innovator drug. The ANDA, or generic drug application, must show, among other things, that the generic drug is pharmaceutically equivalent to the brand, the manufacturer is capable of making the drug correctly, and the proposed label is the same as that of the innovator/brand drug's label.

Even after a drug or biologic is approved for marketing, it may still be subject to postmarketing commitments or postmarketing requirements. Postmarketing commitments are studies or clinical trials that the drug or biologic sponsor has agreed to conduct, but are not required by law and/or regulation. Postmarketing requirements include studies and clinical trials that sponsors are required to conduct, by law and/or regulation, as a condition of approval. Postmarketing studies or clinical trials can be required in order to assess a known risk or demonstrate clinical benefit for drugs or biologics approved pursuant to accelerated approval. If a company fails to meet its postmarketing requirements, the FDA may assess a civil monetary penalty, issue a warning letter or deem the drug or biologic misbranded. Once a drug or biologic is approved, any modifications to the product must be notified to the FDA and may also require a manufacturer to submit additional studies or conduct clinical trials. In addition, we are also required to report adverse events and comply with cGMPs, as well as advertising and promotion regulations. Failure to comply with the FFDCA may subject us to administrative and/or judicial sanctions, including warning letters, product recalls, seizures, delays in product approvals, injunctions, fines, civil penalties and/or criminal prosecution.

Biosimilar Regulation. The ACA created a framework for the approval of biosimilars (also known as follow-on biologics) following the expiration of 12 years of exclusivity for the innovator biologic, with a potential six-month pediatric extension. Under the ACA, biosimilar applications may not be submitted until four years after the approval of the reference innovator biologic.

The FDA is responsible for implementation of the legislation and approval of new biosimilars. Through FDA approvals and the issuance of draft and final guidance, the FDA has addressed a number of issues related to the biosimilars approval pathway, such as the labeling expectations for biosimilars. Over the next several years, the FDA is expected to issue additional draft and final guidance documents impacting biosimilars, including updated draft or final guidance regarding the standards for demonstrating interchangeability with a U.S.-licensed reference product. In addition, in 2017, the Biosimilar User Fee Act was reauthorized for a five-year period, which should lead to a significant increase in the FDA's biosimilar user fee revenues, thereby providing the FDA with additional resources to process biosimilar applications. For example, in the first year under the newly authorized fee structure, the FDA estimates its revenues from biosimilar user fees will increase by more than $10 million.

Sales and Marketing Laws and Regulations. The marketing practices of U.S. biopharmaceutical companies are generally subject to various federal and state healthcare laws that are intended, among other things, to prevent fraud and abuse in the healthcare industry and to protect the integrity of government healthcare programs. These laws include anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a biopharmaceutical company from soliciting, offering, receiving, or paying anything of value to generate business, including purchasing or prescribing of a particular product. False claims laws generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for goods (including drugs or biologics) or services to third-party payers (including Medicare and Medicaid) that are false or fraudulent and generally treat claims generated through kickbacks as false or fraudulent. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions and/or exclusion from federal healthcare programs (including Medicare and Medicaid). The federal government and various states also have enacted laws to regulate the sales and marketing practices of pharmaceutical companies. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers, require disclosure to the federal or state government and the public of such interactions, and/or require the

adoption of compliance standards or programs. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalties under the pertinent laws and regulations.

Pricing and Reimbursement. Pricing and reimbursement for our pharmaceutical products depends in part on government regulation. Pfizer must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid Drug Rebate Program, the "federal ceiling price" drug pricing program, the 340B drug pricing program and the Medicare Part D Program. Pfizer must also report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose Pfizer to penalties. See the discussion regarding rebates in the Analysis of the Consolidated Statements of Income—Revenues—Overview section in our 2018 Financial Report and in the Notes to Consolidated Financial Statements—Note 1G. Basis of Presentation and Significant Accounting Policies: Revenues and Trade Accounts Receivable in our 2018 Financial Report, which are incorporated by reference.

Government and private third-party payers routinely seek to manage utilization and control the costs of our products. For example, the majority of states use preferred drug lists to restrict access to certain pharmaceutical products under Medicaid. Restrictions exist for some Pfizer products under certain state Medicaid programs. As another example, access to our products under the Medicaid managed care program is typically determined by the health plans with which state Medicaid agencies contract to provide services to Medicaid beneficiaries. Given certain states' current and potential ongoing fiscal crises, a growing number of states are considering a variety of cost-control strategies, including capitated managed care plans that typically contain cost by restricting access to certain treatments. In addition, we expect that consolidation and integration of pharmacy chains and wholesalers, who are the primary purchasers of our pharmaceutical products in the U.S., will increase pricing pressures on pharmaceutical manufacturers, including us.

Efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation, could adversely affect our business if implemented. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. At the federal level, for example, in May 2018, President Trump released his Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint). Certain proposals in the Blueprint, and related drug pricing measures proposed since the Blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in October 2018, the Centers for Medicare and Medicaid Services solicited public comments on potential changes to payment for certain Medicare Part B drugs, including reducing the Medicare payment amount for selected Medicare Part B drugs to more closely align with international drug prices. In addition, in January 2019, the White House Office of Management and Budget released the long awaited proposed rule submitted by the Office of Inspector General of the Department of Health and Human Services to remove safe harbor protections for drug rebates paid to insurance plans and PBMs for Medicare Part D and Managed Medicaid and to create new safe harbors. Among other changes, the proposed rule would explicitly exclude the reductions in price offered by drug manufacturers to PBMs in Medicare Part D and Managed Medicaid plans from protection under the "discount" safe harbor. It would also create a new safe harbor designed specifically for price reductions in pharmaceutical products, but only those that are fully reflected in the price to the patient at the pharmacy counter. Additionally, a new safe harbor was proposed to protect administrative fees paid to PBMs, which must be at fair market value, a fixed fee and not based upon a percentage of volume or list price. Manufacturers could continue to negotiate price reductions with PBMs and Medicare Part D and Managed Medicaid plans if their reductions meet that criterion. The proposed rule represents a large step toward significantly altering the current rebate model in place with MCOs. We are in the process of evaluating the implications of the proposed rule on our operations and processes, as well as the infrastructure that will be required in order to implement the rule once it is finalized. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around

drug costs or limiting drug prices. Certain state legislation has been subject to legal challenges. Adoption of new legislation regulating drug pricing at the federal or state level could further affect demand for, or pricing of, our products.

We believe medicines are the most efficient and effective use of healthcare dollars based on the value they deliver to the overall healthcare system. We will continue to work with lawmakers and advocate for solutions that effectively improve patient health outcomes, lower costs to the healthcare system, and ensure access to medicines within an efficient and affordable healthcare system.

Healthcare Reform. There have been significant efforts at the federal and state levels to reform the healthcare system by enhancing access to healthcare, improving the delivery of healthcare and further rationalizing payment for healthcare. For example, we face uncertainties due to federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. For example, tax reform legislation enacted at the end of 2017 eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). We anticipate continued Congressional interest in modifying provisions of the ACA, particularly given the recent ruling in Texas v. Azar to invalidate the law as unconstitutional. At this time, the law remains in effect pending appeals of the decision. Given the outcomes of the 2018 U.S. midterm elections with Democrats taking over the U.S. House of Representatives and Republicans growing their majority in the U.S. Senate, we believe it is unlikely Congress will find bipartisan consensus to advance any significant changes to the ACA until the legal process unfolds. The revenues generated for Pfizer by the health insurance exchanges and Medicaid expansion under the ACA are not material, so the impact of the change in law and similar recent administration actions is expected to be limited. Any future replacement, modification or repeal of the ACA may adversely affect our business and financial results, particularly if the legislation reduces incentives for employer-sponsored insurance coverage. As another example, the Bipartisan Budget Act of 2018, which increased the discount we pay in the Medicare Part D “coverage gap” from 50% to 70%, will modestly increase our future Medicare Part D rebates. Any future healthcare reform efforts may adversely affect our business and financial results.

Anti-Corruption. The FCPA prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Outside the United States

We encounter similar regulatory and legislative issues in most other countries.

New Drug Approvals. In the EU, the approval of new drugs may be achieved using the Mutual Recognition Procedure, the Decentralized Procedure or the EU Centralized Procedure. These procedures apply in the EU member states, plus the European Economic Area countries, Norway, Iceland and Liechtenstein. The Centralized Procedure, managed by the EMA, results in one single authorization for the whole EU, which provides the most rapid and efficient means of gaining approval across the EU and is the one most commonly used for new products.

In China, the regulatory system historically presented numerous challenges for the pharmaceutical industry, as its requirements for drug development and registration were often inconsistent with U.S. or other international standards. In recent years, however, China has introduced reforms and draft reforms, which are discussed in more detail below, that attempt to address these challenges. 2018 was another active year in this respect, with a number of reforms coming into effect, and more proposals and drafts being issued for consultation. Also, in 2018, a significant government restructuring resulted in the creation of the National Medical Product Administration (NMPA), replacing the former CFDA.

In Japan, the PMDA is the point of entry for businesses looking to sell drugs in the country. The PMDA, which is involved in a wide range of regulatory activities, including clinical studies, approvals, postmarketing reviews and pharmaceuticals safety, must approve an application before a new drug product may be marketed in Japan. The PMDA also offers consultations on clinical trials of new drugs and provides advice on product classifications and approvals.

Health authorities in many middle and lower income countries require marketing approval by a recognized regulatory authority (i.e., similar to the authority of the FDA or the EMA) before they begin to conduct their application review process and/or issue their final approval. Many authorities also require local clinical data in the country's population in order to receive final marketing approval.

Pharmacovigilance. In the EU, detailed legislation and guidance on pharmacovigilance has increased and strengthened in recent years. The EMA's Pharmacovigilance Risk Assessment Committee has the responsibility for reviewing and making recommendations on product safety issues for the EU authorities. EU regulators may require pharmaceutical companies to conduct post-authorization safety and efficacy studies at the time of approval, or at any time afterwards in light of scientific developments. There are also additional extensive requirements regarding adverse drug reaction reporting and additional monitoring of products. Outside developed markets such as the EU and Japan, pharmacovigilance requirements vary and are generally not as extensive, but there is a trend toward increasing regulation.

Pricing and Reimbursement. In Europe, Japan, China, Canada, South Korea and some other international markets, governments provide healthcare at low-to-zero direct cost to consumers at the point of care and have significant power as large single payers to regulate pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored healthcare system, particularly under recent global economic pressures. Governments may use a variety of cost-containment measures for our pharmaceutical products, including price cuts, mandatory rebates, health technology assessments, forced localization as a condition of market access and international reference pricing (i.e., the practice of a country linking its regulated medicine prices to those of other countries). This international patchwork of price regulation and differing economic conditions and incomplete value assessments across countries has led to varying health outcomes and some third-party trade in our products between countries.

In particular, international reference pricing adds to the regional impact of price cuts in individual countries and hinders patient access and innovation. Price variations, exacerbated by international reference pricing systems, also have resulted from exchange rate fluctuations. The downward pricing pressure resulting from this dynamic can be expected to continue as a result of reforms to international reference pricing policies and measures targeting pharmaceuticals in some European countries.

In addition, several important multilateral organizations, such as the United Nations (UN), including the World Health Organization (WHO), and the Organization for Economic Cooperation and Development (OECD), are increasing scrutiny of international pharmaceutical pricing through issuing reports and policy recommendations (e.g., 2016 UN High Level Panel Report on Access to Medicines). Late in 2018, two new reports critical of the pharmaceutical industry's pricing practices were published: OECD's Pharmaceutical Innovation and Access to Medicines and WHO's Pricing of Cancer Medicines and its Impacts. These reports and upcoming public forums focused on their recommendations will continue to exert additional pricing pressures.

In China, pricing pressures have increased in recent years. Top Chinese government officials have consistently emphasized the importance of improved health outcomes, the need for healthcare reform and decreased drug prices as a key indicator of progress towards reform. Even though the government provides basic health insurance for the vast majority of Chinese citizens, the insurance is not adequate to cover innovative medicines. Alternative funding sources for innovative medicines remain suboptimal, as private health insurance growth is restrained by issues with access to healthcare data, potential corruption concerns and control over providers.

In 2017 and 2018, Chinese authorities entered into special negotiations with China's National Medical Security Bureau to add approximately 60 high-value drugs (mainly oncology medicines) to the National Reimbursement Drug List. Prices for drugs were reduced dramatically through these negotiations, some by as much as 70 percent. While these negotiations included a path to access for companies, market access is not strictly assured. In addition, significant questions about the processes and negotiations for provincial tendering remain. In addition, multi-layered negotiations are required across provincial, municipal and hospital levels, and the linkage of price negotiations to reimbursement is inconsistent. In the off-patent space, in 2013, China began to implement a quality consistency (QCE) process in order to improve the quality of domestically-manufactured generic drugs, primarily by requiring such drugs to pass a test to assess their bioequivalence to a qualified reference drug (typically the originator drug). In 2018, numerous local generics were officially deemed bioequivalent under the QCE. A pilot project for centralized procurement of 31 categories of drugs covering 11 major Chinese cities now drives patients to generics that have passed the QCE, which has resulted in dramatic price cuts for off-patent drugs.

In Japan, the access environment for innovative medicines continued to deteriorate in 2018 with tighter restrictions around the criteria to gain a price maintenance premium and a push by the Japanese government to adopt healthcare technology assessments based on rigid cost-effectiveness criteria for re-pricing of reimbursed medicines. Additionally, the Japanese government has officially requested the Ministry of Health, Labour and Welfare to look into using cost-effectiveness analyses to make reimbursement decisions at the launch of a drug.

EU Regulatory Changes. The EU adopted a new Clinical Trials Regulation in May 2014, which is expected to come into effect sometime in late 2019. This regulation is aimed at simplifying and harmonizing the governance of clinical trials in the EU and will require increased public posting of clinical trial results.

Brexit. In June 2016, the U.K. electorate voted in a referendum to leave the EU, which is commonly referred to as "Brexit". In March 2017, the U.K. government formally notified the European Council of its intention to leave the EU after it triggered Article 50 of the Lisbon Treaty to begin the two-year negotiation process establishing the terms of the exit and outlining the future relationship between the U.K. and the EU. Formal negotiations officially started in June 2017. This process continues to be highly complex and the end result of these negotiations may pose certain implications to our research, commercial and general business operations in the U.K. and the EU, including the approval and supply of our products. The EMA will be relocating from London, U.K. to Amsterdam, Netherlands by the scheduled date of Brexit at the end of March 2019. At present, it is still unclear whether and to what extent the U.K. will remain within or aligned to the EU system of medicines regulation, and/or what separate requirements will be imposed in the U.K. after it leaves the EU. However, both the U.K. and the EU have issued detailed guidance for the industry on how medicines, medical devices and clinical trials will be separately regulated in their respective territories in the event of a 'hard Brexit', meaning an outcome where no negotiated settlement is reached. For additional information on Brexit, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—The Global Economic Environment in our 2018 Financial Report.

China Regulatory Changes. In an effort to encourage drug innovation and reduce backlogs for existing applications for drug approval, the NMPA has unveiled numerous reform initiatives for China's drug approval system, and engaged in significant efforts to build its capabilities. The NMPA now divides drugs into new drugs and generics, with the definition for new drugs changed from "China New" to "Global New." This means that drugs previously approved in other markets (such as the U.S. or Europe) will not be considered new drugs under China's regulatory regime. This change in definition creates more opportunities for China's domestic drug manufacturers than for multinational firms, because multinational firms have historically had significant competitive advantage in successfully achieving regulatory approvals for drugs first approved outside of China. Revisions in 2017 made clear, however, that regulatory approval from the FDA or the EMA would no longer be required for approval of imported drugs, though a notable exception persists for imported vaccines, which still require prior approval from a relevant regulatory agency. The "marketing authorization holder" system, which will allow for more flexibility in contract manufacturing arrangements and asset transfers, is now being piloted in ten Chinese provinces, but not yet for imported drugs.

While challenges remain, a number of other policy changes are streamlining and accelerating approvals of domestic and imported drugs in China. These reforms, along with China's June 2018 entry into the Management Committee of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, are expected to pave the way for integration of Chinese regulations with global practices. These changes include introducing an umbrella clinical trial authorization for all three phases of registration studies (instead of the original phase-by-phase approvals), a filing/recordation system for bioequivalence studies on generics (instead of the original review and approval system), admitting more categories of drugs as innovative drugs eligible for the fast track/"green channel" approval pathway and ongoing implementation of previously announced regulatory reforms. In 2018, the review timeline for clinical trial authorizations was shortened to 60 working days due to the introduction of a clinical trial notification system, and China's Fast Track Policy was finalized, for a specific group of products selected by the Center for Drug Evaluation, part of the NMPA.

In addition, China's Human Genetic Resources Administrative Office strictly scrutinizes clinical trials involving the collection, storage, export and use of human genetic resources and relevant deriving data from the Chinese population, adding an extra layer of review in addition to that of the NMPA.

Healthcare Provider Transparency and Disclosures. A number of countries have implemented laws requiring (or their industry associations have recommended) disclosure of transfers of value made by pharmaceutical companies to healthcare providers. For example, the EFPIA's disclosure code requires all members, including Pfizer, to disclose transfers of value to healthcare professionals and healthcare organizations.

Intellectual Property. The World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) required participant countries to amend their intellectual property laws to provide patent protection for pharmaceutical products by 2005, with an extension until 2033 for least-developed countries. While we still face patent grant, enforcement and other intellectual property challenges around the world, some countries have made improvements. We include stronger patent protection among the factors we consider for continued business expansion in other participant countries.

While the global intellectual property environment has generally improved following WTO-TRIPS and bilateral/multilateral trade agreements, our future business growth depends on further progress in intellectual property protection. In emerging market countries in particular, governments have used intellectual property policies as a tool for reducing the price of imported medicines, as well as to protect their local pharmaceutical industries. Considerable political and economic pressure exists to weaken current intellectual property protection and resist implementation of any further protection, which has led to policies such as more restrictive standards for obtaining patents and more difficult procedures for patenting biopharmaceutical inventions, restrictions on patenting certain types of inventions (e.g., new medical treatment methods), revocation of patents, issuance (and threat of issuance) of compulsory licenses, weak intellectual property enforcement and failure to implement effective regulatory data protection. Our industry advocacy efforts focus on seeking a more balanced business environment for foreign manufacturers, as well as on underscoring the importance of strong intellectual property systems for local innovative industries. In developed countries as well, including the EU, we are facing an increasingly challenging intellectual property environment.

Canada's intellectual property regime for drugs provides some level of patent protection and data exclusivity (currently eight years plus six-month pediatric extension), but it lacks the predictability and stability that otherwise comparable countries provide. Through intense negotiations as part of the Canada/EU Comprehensive Economic & Trade Agreement (CETA), Canadian authorities have amended the Patent Medicines (Notice of Compliance) Regulations to provide the innovator a right of appeal, and Canada now provides sui generis protection for patent term extensions of up to two years for basic patents. Furthermore, the US-Mexico-Canada Agreement (USMCA), if ratified and implemented, would establish 10 years of data protection for biologics and patent term adjustment for unreasonable or unnecessary delays in the grant of patents.

In China, the intellectual property environment has improved, although effective enforcement and adequate legal remedies remain areas of concern. The government has taken steps to protect intellectual property rights in conformity with World Trade Organization provisions, and several companies, including Pfizer, have established R&D centers in China due to increased confidence in China's intellectual property environment. Despite this, China remained on the U.S. Trade Representative's Priority Watch List for 2018. Further, the standards for patentability in China remain more restrictive than in other major markets, including the U.S., Europe and Japan. Also, while a framework exists for protecting patents for 20 years, enforcement mechanisms are often lacking or inconsistent. For example, the absence of effective patent linkage mechanisms and preliminary injunctions, impractical evidentiary burdens, and heightened sufficiency standards have been used to invalidate patents at the enforcement stage.

In Brazil and other Latin American countries, the role of health regulatory authorities in reviewing patents (e.g., National Health Surveillance Agency in Brazil), restrictive patentability rules, ambiguity regarding the term of certain patents and backlogs at patent agencies may limit our ability to protect our products through patents. The lack of regulatory data protection and difficulties in protecting certain types of inventions, such as new medical uses of drug products, may limit the commercial lifespan of some pharmaceutical products. Additionally, an increased threat of issuance of compulsory licenses for biopharmaceutical products exists, which adds to business uncertainty.

In India, we have seen some progress in terms of expediting patent approval processes to reduce pendency rates and implementing training programs to enhance enforcement. Despite these positive steps, gaps remain in terms of addressing longstanding intellectual property concerns. For example, policies favoring compulsory licensing of patents, the tendency of the Indian Patent Office to revoke pharmaceutical patents in opposition proceedings (both pre- and post-grant), and restrictive standards for patentability of pharmaceutical products have made it difficult to safeguard many of our inventions and our investments in innovation. These policies heighten the risk of additional patent challenges targeting innovative pharmaceutical products, especially in areas perceived as being important to the public health of the population. Challenges against Pfizer patents in India are ongoing.

ENVIRONMENTAL MATTERS

Most of our operations are affected by national, state and/or local environmental laws. We have made, and intend to continue to make, the expenditures necessary for compliance with applicable laws. We also are cleaning up environmental contamination from past industrial activity at certain sites. See the Notes to Consolidated Financial Statements—Note 17A3. Contingencies and Certain Commitments—Legal Proceedings—Commercial and Other Matters in our 2018 Financial Report. As a result, we incurred capital and operational expenditures in 2018 for environmental compliance purposes and for the clean-up of certain past industrial activity as follows:

- environment-related capital expenditures— $33 million; and
- other environment-related expenses— $162 million.

While capital expenditures or operating costs for environmental compliance cannot be predicted with certainty, we do not currently anticipate they will have a material effect on our capital expenditures or competitive position.

Climate change presents risks to our operations, including the potential for additional regulatory requirements and associated costs, and the potential for more frequent and severe weather events and water availability challenges that may impact our facilities and those of our suppliers. For example, in 2017, our manufacturing and commercial operations in Puerto Rico were impacted by hurricanes. For additional information, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business—Impact of Hurricanes in Puerto Rico section of the 2018 Financial Report. We cannot provide assurance that physical risks to our facilities and supply chain due to climate change will not occur in the future; however, we have a program for reviewing our vulnerability to potential weather-related risks and we update our assessments periodically. To date, we have concluded that, because of our facility locations, our existing distribution networks and our controls, we do not anticipate that these risks will have a material impact on Pfizer in the near term.

TAX MATTERS

The discussion of tax-related matters in the Notes to Consolidated Financial Statements—Note 5. Tax Matters in our 2018 Financial Report is incorporated by reference.

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EMPLOYEES

In our innovation-intensive business, our employees are vital to our success. We generally believe we have good relationships with our employees. As of December 31, 2018, we employed approximately 92,400 people in our operations throughout the world.

DISCLOSURE PURSUANT TO SECTION 219 OF THE IRAN THREAT REDUCTION AND SYRIA HUMAN RIGHTS ACT OF 2012

Section 219 of Iran Threat Reduction and Syria Human Rights Act of 2012 (ITRSHRA) requires disclosure by public companies of certain transactions involving the Government of Iran, as well as entities and individuals designated under Executive Order 13382 and Executive Order 13224 (the Executive Orders). In some instances, ITRSHRA requires companies to disclose these types of transactions, even if they were permissible under U.S. law or were conducted by a non-U.S. affiliate in accordance with the local law under which such entity operates.

As a global biopharmaceutical company, we conduct business in multiple jurisdictions throughout the world. During 2018, our activities included supplying life-saving medicines, medical products and consumer products (Pfizer products) for patient and consumer use in Iran. We ship Pfizer products to Iran, and conduct related activities, in accordance with licenses issued by the U.S. Department of the Treasury’s Office of Foreign Assets Control and other U.S. and non-U.S. governmental entities, and in line with our corporate policies. We will continue our global activities to improve the health and well-being of patients and consumers in a manner consistent with applicable laws and our corporate policies. To our knowledge, none of our activities during 2018 are required to be disclosed pursuant to ITRSHRA.

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ITEM 1A. RISK FACTORS

The statements in this Section describe the major risks to our business and should be considered carefully. In addition, these statements constitute our cautionary statements under the Private Securities Litigation Reform Act of 1995.

Our disclosure and analysis in this 2018 Form 10-K and in our 2018 Annual Report to Shareholders contain forward-looking statements. From time to time, we also provide forward-looking statements in other materials we release to the public, as well as oral forward-looking statements. Such forward-looking statements involve substantial risks and uncertainties. We have tried, wherever possible, to identify such statements by using words such as “will,” “may,” “could,” “likely,” “ongoing,” “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe,” “assume,” “targ “guidance,” “goal,” “objective,” “aim,” “seek” and other words and terms of similar meaning or by using future dates in connection with any discussion of, among other things, our anticipated operating and financial performance, business plans and prospects, in-line products and product candidates, including anticipated regulatory submissions, data read-outs, study starts, approvals, performance, timing of exclusivity and potential benefits of Pfizer’s products and product candidates, strategic reviews, capital allocation, business-development plans, the benefits expected from the reorganization of our commercial operations into three businesses effective at the beginning of our 2019 fiscal year, our acquisitions and other business development activities, our ability to successfully capitalize on growth opportunities or prospects, manufacturing and product supply and plans relating to share repurchases and dividends. In particular, these include statements relating to future actions, business plans and prospects, our acquisitions and other business development activities, our proposed transaction with GSK to combine our respective consumer healthcare businesses into a new consumer healthcare joint venture, prospective products or product approvals, our product pipeline, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates, the outcome of contingencies, such as legal proceedings, plans relating to share repurchases and dividends, government regulation and financial results, including, in particular, the availability of raw materials for 2019 set forth in Item 1. Business—Raw Materials in this 2018 Form 10-K; the anticipated progress in remediation efforts at certain of our Hospira manufacturing facilities and the expectations related to our supply issues set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business—Product Manufacturing section in our 2018 Financial Report; the benefits expected from the reorganization of our commercial operations into three businesses effective at the beginning of our 2019 fiscal year and our expectations regarding growth set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Organizing for Growth section in our 2018 Financial Report; the expected timing of completion and benefits of our proposed transaction with GSK to combine our respective consumer healthcare businesses into a new consumer healthcare joint venture set forth in the Item 1. Business—About Pfizer and —Innovative Health, and Item 1A. Risk Factors sections in this 2018 Form 10-K and in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business, —Our Strategy and —Our Business Development Initiatives sections in our 2018 Financial Report; the anticipated costs related to our preparations for Brexit set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—The Global Economic Environment section in our 2018 Financial Report; our anticipated liquidity position set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—The Global Economic Environment and the Analysis of Financial Condition, Liquidity and Capital Resources sections in our 2018 Financial Report; our plans for increasing investment in the U.S. set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Capital Allocation and Expense Management—Increasing Investment in the U.S. section in our 2018 Financial Report; the financial guidance set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Financial Guidance for 2019 section in our 2018 Financial Report; the anticipated costs and savings, including from our cost-reduction/productivity initiatives, as well as from our Organizing for Growth initiative, set forth in the Costs and Expenses—Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives section in our 2018 Financial Report and in the Notes to Consolidated Financial Statements—Note 3. Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives; the benefits expected from our business development transactions; the planned capital spending set forth in the Analysis

of Financial Condition, Liquidity and Capital Resources—Selected Measures of Liquidity and Capital Resources—Contractual Obligations section in our 2018 Financial Report; and the contributions that we expect to make from our general assets to the Company's pension, postretirement and deferred compensation plans during 2019 set forth in the Analysis of Financial Condition, Liquidity and Capital Resources—Selected Measures of Liquidity and Capital Resources—Contractual Obligations section and in the Notes to Consolidated Financial Statements—Note 11. Pension and Postretirement Benefit Plans and Defined Contribution Plans in our 2018 Financial Report.

We cannot guarantee that any forward-looking statement will be realized. Achievement of anticipated results is subject to substantial risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. You should bear this in mind as you consider forward-looking statements, and you are cautioned not to put undue reliance on forward-looking statements.

We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law or by the rules and regulations of the SEC. You are advised, however, to consult any further disclosures we make on related subjects. Also note that we provide the following cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our businesses. These are factors that, individually or in the aggregate, may cause our actual results to differ materially from expected, projected or historical results. We note these factors

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for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

RISKS RELATED TO OUR BUSINESS, INDUSTRY AND OPERATIONS:

MANAGED CARE TRENDS

Private third-party payers and other managed care entities, such as pharmacy benefit managers, continue to take action to manage the utilization of drugs and control the cost of drugs. Consolidation among MCOs has increased the negotiating power of MCOs and other private third-party payers. Private third-party payers, as well as governments, increasingly employ formularies to control costs by taking into account discounts in connection with decisions about formulary inclusion or favorable formulary placement. Failure to obtain or maintain timely adequate pricing or favorable formulary placement for our products, or failure to obtain such formulary placement at favorable pricing, could adversely impact revenue. Private third-party payers, including self-insured employers, often implement formularies with copayment tiers to encourage utilization of certain drugs and have also been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private third-party payers are also implementing new initiatives like so-called “copay accumulators” (policies that provide that the value of copay assistance does not count as out-of-pocket costs that are applied toward deductibles) that can shift more of the cost burden to manufacturers and patients. This cost shifting has increased consumer interest and input in medication choices, as they pay for a larger portion of their prescription costs and may cause consumers to favor lower cost generic alternatives to branded pharmaceuticals. Private third-party payers also use additional measures such as new-to-market blocks, exclusion lists, indication-based pricing, and value-based pricing/contracting to improve their cost containment efforts. Private third-party payers 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. As the U.S. payer market consolidates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives.

GENERIC COMPETITION

Competition from manufacturers of generic drugs is a major challenge for our branded products around the world, and the loss or expiration of intellectual property rights can have a significant adverse effect on our revenues. The date at which generic competition commences may be different from the date that the patent or regulatory exclusivity expires. However, upon the loss or expiration of patent protection for one of our products, or upon the “at-risk” launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our patented products, we can lose the major portion of revenues for that product in a very short period of time, which can adversely affect our business. A number of our products are expected to face significantly increased generic competition over the next few years. In China, for example, we are expected to face strong competition by certain generic manufacturers in 2019, which may result in price cuts and volume loss of some of our products.

Also, generic manufacturers have filed applications with the FDA seeking approval of product candidates that such companies claim do not infringe our patents; these include candidates that would compete with, among other products, Eliquis, Xeljanz and Xtandi. Our licensing and collaboration partners also face challenges by generic drug manufacturers to patents covering products for which we have licenses or co-promotion rights. In addition, our patent-protected products may face competition in the form of generic versions of competitors’ branded products that lose their market exclusivity.

COMPETITIVE PRODUCTS

We cannot predict with accuracy the timing or impact of the introduction of competitive products, including new product entrants, in-line branded products, generic products, private label products, biosimilars and product candidates that treat diseases and conditions similar to those treated by our in-line drugs and drug candidates. The introduction of competitive products can result in erosion of the sales of our existing products and potential sales of products in development, as well as unanticipated product obsolescence. Competitive product launches have occurred in recent years, and certain potentially competitive products are in various stages of development. Some of these have been filed for approval with the FDA and with regulatory authorities in other countries.

We also produce generic and biosimilar pharmaceutical products that compete with products from competitors, including other generic and biosimilar manufacturers. The ability to launch a generic or biosimilar pharmaceutical product at or before the anticipated formation of the generic or biosimilar marketplace is important to that product's profitability. Prices for products typically decline, sometimes dramatically, following generic or biosimilar entry, and as additional companies receive approvals to market that product, competition intensifies. If a company's generic or biosimilar product can be "first-to-market" such that its only competition is the branded drug for a period of time, higher levels of sales and profitability can be achieved until other generic or biosimilar competitors enter the market. With increasing competition in the generic or biosimilar product market, the timeliness with which we can market new generic or biosimilar products will increase in importance. Our success will depend on our ability to bring new products to market quickly. The FDA, along with other regulatory agencies around the world, has been

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experiencing a backlog of generic drug applications, which may result in delayed approvals of new generic products. While the FDA is taking steps to address the backlog of pending applications, continued approval delays may be experienced by generic drug applicants over the next few years. Also, we may face access challenges for our biosimilar products where our product may not receive appropriate formulary access or remains in a disadvantaged position relative to the innovator product. For example, Inflectra/Remsima has experienced access challenges among commercial payers. In September 2017, Pfizer filed suit in the U.S. District Court for the Eastern District of Pennsylvania against Johnson & Johnson (J&J) alleging that J&J's exclusionary contracts and other anticompetitive practices concerning Remicade® (infliximab) violate federal antitrust laws.

DEPENDENCE ON KEY IN-LINE PRODUCTS

We recorded direct product and/or alliance revenues of more than $1 billion for each of ten biopharmaceutical products in 2018: Prevnar 13/Prevenar 13, Lyrica, Ibrance, Eliquis, Enbrel, Lipitor, Xeljanz, Chantix/Champix, Sutent and Norvasc. Those products accounted for 51% of our total revenues in 2018. If these products or any of our other major products were to become subject to problems such as loss of patent protection (if applicable), changes in prescription growth rates, material product liability litigation, unexpected side effects, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, pricing and access pressures, supply shortages or, if a new, more effective treatment should be introduced, the adverse impact on our revenues could be significant. A number of our current products have experienced patent-based expirations or loss of regulatory exclusivity in certain markets in the last few years (including some of our billion-dollar and previously billion-dollar products), and patents covering a number of our best-selling medicines are, or have been, the subject of pending legal challenges. For example, as a result of a patent litigation settlement, Teva Pharmaceuticals USA, Inc. launched a generic version of Viagra in the U.S. in December 2017. In addition, the basic product patent for Lyrica in the U.S. will expire in June 2019, which includes the FDA's grant of pediatric exclusivity that extended the period of market exclusivity in the U.S. for Lyrica for an additional six months from December 2018. In addition, our revenues could be significantly impacted by the timing and rate of commercial acceptance of key new products. For additional information, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—Industry-Specific Challenges—Intellectual Property Rights and Collaboration/Licensing Rights—Recent Losses and Expected Losses of Product Exclusivity section in our 2018 Financial Report. Further, our Alliance revenues will be adversely affected by the termination or expiration of collaboration and co-promotion agreements that we have entered into and that we may enter into from time to time.

RESEARCH AND DEVELOPMENT INVESTMENT

The discovery and development of safe, effective new products, as well as the development of additional uses for existing products, are necessary for the continued strength of our businesses. Our product lines must be replenished over time in order to offset revenue losses when products lose their market exclusivity, as well as to provide for earnings growth. Our growth potential depends in large part on our ability to identify and develop new products or new indications for existing products that address unmet medical needs and receive reimbursement from payers, either through internal R&D or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. However, balancing current growth, investment for future growth and the delivery of shareholder return remains a major challenge. The average costs of product development continue to rise, as do the regulatory requirements in many therapeutic areas, which may affect the number of candidates funded as well as the sustainability of the R&D portfolio. Our ongoing investments in new product introductions and in R&D for new products and existing product extensions could exceed corresponding sales growth.

Additionally, our R&D investment plans and resources may not be correctly matched between science and markets, and failure to invest in the right technology platforms, therapeutic segments, product classes, geographic markets and/or in-licensing and out-licensing opportunities could adversely impact the productivity of our pipeline. Further,

even if the areas with the greatest market attractiveness are identified, the scientific approach may not succeed for any given program despite the significant investment required for R&D, and the commercial potential of the product may not be as competitive as expected because of the highly dynamic market environment and the hurdles in terms of access and reimbursement.

We continue to strengthen our global R&D organization and pursue strategies intended to improve innovation and overall productivity in R&D to achieve a sustainable pipeline that is positioned to deliver value in the near-term and over time. These strategies may not deliver the desired result, which could affect growth and profitability in the future.

BIOLOGIC PRODUCTS

Abbreviated legal pathways for the approval of biosimilars exist in many international markets and, since the passage of the ACA, a framework for such approval exists in the U.S. If competitors are able to obtain marketing approval for biosimilars referencing our biologic products, our biologic products may become subject to competition from these biosimilars, with attendant competitive pressure, and price reductions could follow. For example, Enbrel faces ongoing biosimilar competition in most developed Europe markets. The expiration or successful challenge of applicable patent rights could trigger this competition, assuming any relevant regulatory exclusivity period has expired. We may face litigation with respect to the validity and/or scope of patents relating to our biologic products.

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We are developing biosimilar medicines. Risks related to our development of biosimilars include the potential for steeper than anticipated price erosion due to increased competitive intensity (or, as in the case of Inflectra/Remsima, exclusionary contracting by the originator that leads to a lack of payer coverage and lower uptake), coupled with high costs associated with clinical development or intellectual property challenges that may preclude timely commercialization of our potential biosimilar products. There is also a risk of lower uptake for biosimilars due to various factors that may vary for different biosimilars (e.g., anti-competitive practices, physician reluctance to prescribe biosimilars for existing patients taking the originator product, or misaligned financial incentives). See also the Competitive Products risk factor above.

RESEARCH STUDIES

Decisions about research studies made early in the development process of a drug or vaccine candidate can have a substantial impact on the marketing strategy and payer reimbursement possibilities if it receives regulatory approval. For example, a wider range of studies can lead to approval for a broader set of indications that may impact the marketing and payer reimbursement process. However, each additional indication must be balanced against the time and resources required to demonstrate benefit, the increased complexity of development and manufacturing and the potential delays to approval of the lead indication. We try to plan clinical trials prudently and to reasonably anticipate and address challenges, but there is no guarantee that an optimal balance between trial conduct, speed and desired outcome will be achieved each time. The degree to which such potential challenges are foreseen and adequately addressed could affect our future results.

INTERNATIONAL OPERATIONS

Our international operations could be affected by currency fluctuations, capital and exchange controls, economic conditions, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to our products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could adversely affect our business.

Many emerging markets have experienced growth rates in excess of developed markets, leading to an increased contribution to the industry’s global performance. As a result, we have been employing strategies to grow in emerging markets. However, our strategies in emerging markets may not be successful and these countries may not continue to sustain these growth rates. For example, even though China is growing faster than most emerging markets, we face certain challenges in China due to government imposed pricing controls affecting certain Pfizer medicines. In addition, some emerging market countries may be particularly vulnerable to periods of financial or political instability or significant currency fluctuations or may have limited resources for healthcare spending. Even though we constantly monitor the evolving emerging markets for any unanticipated risk to Pfizer, certain financial or political events in such markets, as discussed above, can adversely affect our results.

SPECIALTY PHARMACEUTICALS

Specialty pharmaceuticals are medicines that treat rare or life-threatening conditions that typically have smaller patient populations. The growing availability and use of innovative specialty pharmaceuticals, combined with their relative higher cost as compared to other types of pharmaceutical products, has generated payer interest in developing cost-containment strategies targeted to this sector. The impact of payers’ efforts to control access to and pricing of specialty pharmaceuticals is increasing. For Pfizer to date, a number of factors create a more challenging paradigm given our growing specialty business portfolio. These include formulary restrictions and increasing use of utilization management tools such as step edits, which can lead to higher negotiated rebates or discounts to health plans and PBMs in the U.S., as well as the increasing use of health technology assessments in markets around the world.

CONSUMER HEALTHCARE

The Consumer Healthcare business may be impacted by economic volatility, the timing and severity of the cough, cold and flu season, generic or store brand competition affecting consumer spending patterns and market share gains of competitors' branded products or generic store brands. In addition, regulatory and legislative outcomes regarding the safety, efficacy or unintended uses of specific ingredients in our Consumer Healthcare products may require withdrawal, reformulation and/or relabeling of certain products (e.g., cough/cold products). See Consumer Healthcare Joint Venture with GSK and The Global Economic Environment risk factors below.

PRODUCT MANUFACTURING, SALES AND MARKETING RISKS

Difficulties or delays in product manufacturing, sales or marketing could affect future results through regulatory actions, shut-downs, work stoppages or strikes, approval delays, withdrawals, recalls, penalties, supply disruptions or shortages, reputational harm, product liability, unanticipated costs or otherwise. Examples of such difficulties or delays include, but are not limited to, the inability to increase production capacity commensurate with demand; the failure to predict market demand for, or to gain market acceptance of, approved products; the possibility that the supply of incoming materials may be delayed or become unavailable and that the quality of incoming materials may be substandard and not detected; the possibility that we may fail to maintain appropriate quality standards throughout the internal and external supply network and/or comply with cGMPs and

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other applicable regulations such as serialization (which allows for track and trace of products in the supply chain to enhance patient safety); risks to supply chain continuity and commercial operations as a result of natural (including hurricanes, earthquakes and floods) or man-made disasters (including arson or terrorist attacks) at our facilities or at a supplier or vendor, including those that may be related to climate change; or failure to maintain the integrity of our supply chains against intentional and criminal acts such as economic adulteration, product diversion, product theft, counterfeit goods and cyberattacks.

Regulatory agencies periodically inspect our drug manufacturing facilities to evaluate compliance with applicable cGMP requirements. Failure to comply with these requirements may subject us to possible legal or regulatory actions, such as warning letters, suspension of manufacturing, seizure of product, injunctions, debarment, voluntary recall of a product or failure to secure product approvals, any of which could have a material adverse effect on our business, financial condition and results of operations. In February 2017, for example, we received a warning letter from the FDA communicating the FDA's view that certain violations of cGMP regulations exist at Hospira's manufacturing facility in McPherson, Kansas. We are undertaking corrective actions to address the concerns raised by the FDA. In January 2018, the FDA upgraded the status of Pfizer's McPherson manufacturing facility to VAI based on an October 2017 inspection. The change to VAI status lifted the compliance hold that the FDA placed on approval of pending applications. In June 2018, the FDA informed us that it had completed an evaluation of corrective actions and closed out the February 2017 warning letter issued to our McPherson manufacturing facility after determining that we had addressed the violations contained in the warning letter. In July-August 2018, the FDA conducted a follow-up inspection of our McPherson facility and issued an inspection report noting several findings. Pfizer responded to the FDA's findings, and is in the process of implementing a corrective and preventive action plan to address the FDA's concerns. On the basis of the July-August 2018 FDA inspection, the FDA changed the inspection classification status of the McPherson site to Official Action Indicated (OAI). Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections. Communication with the FDA on the status of the McPherson site is ongoing. As a result of this status, the FDA has refused, and may continue to refuse, to grant premarket approval of applications and/or the FDA may refuse to grant export certificates related to products manufactured at our McPherson site until the site status is upgraded, which will require a successful re-inspection by the FDA. The product shortages we have been experiencing within our portfolio are primarily for products from the legacy Hospira portfolio and are largely driven by capacity constraints, technical issues and supplier quality concerns. We continue to remediate issues at legacy Hospira facilities manufacturing sterile injectables. Any continuing product shortage interruption at these manufacturing facilities could negatively impact our financial results, specifically in our Sterile Injectable Pharmaceuticals portfolio.

In addition, in September 2017, Meridian Medical Technologies, Inc., a subsidiary of Pfizer Inc., received a warning letter from the FDA asserting the FDA's view that certain violations of cGMP and Quality System Regulations exist at Meridian's manufacturing sites in St. Louis, Missouri. Meridian responded to the warning letter and committed to making improvements across the sites. We are undertaking corrective actions to address the concerns raised by the FDA, and communication with the FDA is ongoing. Until the corrective actions are implemented and confirmed by the FDA following a re-inspection, the FDA may refuse to grant premarket approval of applications and/or the FDA may refuse to grant export certificates related to products manufactured at our St. Louis sites.

OUTSOURCING

We outsource certain services to other parties, including transaction processing, accounting, information technology, manufacturing, clinical trial recruitment and execution, clinical lab services, non-clinical research, safety services, integrated facilities management and other areas. Outsourcing of services to third parties could expose us to suboptimal quality of service delivery or deliverables and potentially result in repercussions such as missed deadlines or other timeliness issues, erroneous data, supply disruptions, non-compliance (including with applicable legal or regulatory requirements and industry standards) and/or reputational harm, with potential negative effects on our

results.

COLLABORATIONS AND OTHER RELATIONSHIPS WITH THIRD PARTIES

We depend on third-party collaborators, service providers, and others in the research, development, manufacturing and commercialization of our products and product candidates and also enter into joint ventures and other business development transactions in connection with our business. To achieve expected longer term benefits, we may make substantial upfront payments in such transactions, which may negatively impact our reported earnings. We rely heavily on these parties for multiple aspects of our drug development, manufacturing and commercialization activities, but we do not control many aspects of those activities. Third parties may not complete activities on schedule or in accordance with our expectations. Failure by one or more of these third parties to meet their contractual or other obligations to Pfizer; failure of one or more of these parties to comply with applicable laws or regulations; or any disruption in the relationships between Pfizer and one or more of these third parties, could delay or prevent the development, approval, manufacturing or commercialization of our products and product candidates and could also result in non-compliance or reputational harm, all with potential negative implications for our product pipeline and business.

BIOPHARMACEUTICAL WHOLESALERS

In 2018, our largest biopharmaceutical wholesaler accounted for approximately 15% of our total revenues (and approximately 31% of our total U.S. revenues), and our top three biopharmaceutical wholesalers accounted for approximately 37% of our total

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revenues (and approximately 76% of our total U.S. revenues). If one of our significant biopharmaceutical wholesalers should encounter financial or other difficulties, such wholesaler might decrease the amount of business that it does with us, and we might be unable to collect all the amounts that the wholesaler owes us on a timely basis or at all, which could negatively impact our results of operations. In addition, we expect that consolidation and integration of pharmacy chains and wholesalers will increase competitive and pricing pressures on pharmaceutical manufacturers, including us.

BUSINESS DEVELOPMENT ACTIVITIES

We expect to continue to enhance our in-line products and product pipeline through various forms of business development, which can include alliances, licenses, joint ventures, collaborations, equity- or debt-based investments, dispositions, divestments, mergers and acquisitions. However, these enhancement plans are subject to the availability and cost of appropriate opportunities, competition from other pharmaceutical companies that are seeking similar opportunities and our ability to successfully identify, structure and execute transactions, including the ability to satisfy the conditions to closing of announced transactions in the anticipated timeframes or at all, and successfully integrate acquisitions. Pursuing these opportunities may require us to obtain additional equity or debt financing, and could result in increased leverage and/or a downgrade of our credit ratings. Where we acquire debt or equity securities as all or part of the consideration for business development activities, such as in connection with our contribution agreement entered into with Allogene Therapeutics, Inc., the value of those securities will fluctuate, and may depreciate in value. We may not control the company in which we acquire securities, such as in connection with a divestiture or collaborative arrangement, and as a result, we will have limited ability to determine its management, operational decisions and policies. Further, while we seek to mitigate risks and liabilities of such transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Legal proceedings or regulatory issues often arise as a result of activities that occurred at acquired companies, their partners and other third parties. In 2016, for example, we paid $784.6 million to resolve allegations related to Wyeth’s reporting of prices to the government with respect to Protonix for activities that occurred prior to our acquisition of Wyeth. For these and other reasons, we may not realize the anticipated benefits of such transactions, and expected synergies and accretion may not be realized within the expected timeframes, or at all.

COUNTERFEIT PRODUCTS

A counterfeit medicine is one that has been deliberately and fraudulently mislabeled as to its identity and source. A counterfeit Pfizer medicine, therefore, is one manufactured by someone other than Pfizer, but which appears to be the same as an authentic Pfizer medicine. The prevalence of counterfeit medicines is a significant and growing industry-wide issue due to a variety of factors, including, but not limited to, the following: the widespread use of the Internet, which has greatly facilitated the ease by which counterfeit medicines can be advertised, purchased and delivered to individual patients; the availability of sophisticated technology that makes it easier for counterfeiters to make counterfeit medicines; the growing involvement in the medicine supply chain of under-regulated wholesalers and repackagers; the lack of adequate inspection at certain international postal facilities as counterfeit medicines are increasingly delivered direct to customers in small parcel packages; the tendency to misuse and abuse medicines; and the relatively modest risk of penalties faced by counterfeiters compared to the large profits that can be earned by them from the sale of counterfeit medicines. Further, laws against pharmaceutical counterfeiting vary greatly from country to country, and the enforcement of existing law varies greatly from jurisdiction to jurisdiction. For example, in some countries, pharmaceutical counterfeiting is not a crime; in others, it may result in only minimal sanctions. In addition, those involved in the distribution of counterfeit medicines use complex transport routes in order to evade customs controls by disguising the true source of their products.

Pfizer's global reputation makes its medicines prime targets for counterfeiting organizations. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured—often in unregulated, unlicensed, uninspected and unsanitary sites—as well as the lack of regulation of their contents. Failure to mitigate the threat of counterfeit medicines, which is exacerbated by the complexity of the supply chain, could adversely impact our business, by, among other things, causing the loss of patient confidence in the Pfizer name and in the integrity of our medicines, potentially resulting in lost sales, product recalls, and an increased threat of litigation.

We undertake significant efforts to counteract the threats associated with counterfeit medicines, including, among other things, working with the FDA and other regulatory authorities and multinational coalitions to combat the counterfeiting of medicines and supporting efforts by law enforcement authorities to prosecute counterfeiters; assessing new and existing technologies to seek to make it more difficult for counterfeiters to copy our products and easier for patients and healthcare providers to distinguish authentic from counterfeit medicines; implementing business practices designed to protect patient health; promoting public policies intended to hinder counterfeiting; working diligently to raise public awareness about the dangers of counterfeit medicines; working collaboratively with wholesalers, pharmacies, customs offices, and law enforcement agencies to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and repackagers, and using data analytics and risk assessment tools to better target the factors that give rise to the counterfeiting problem in the first place. However, our efforts and the efforts of others may not be entirely successful, and the presence of counterfeit medicines may continue to increase.

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RISKS RELATED TO GOVERNMENT REGULATION AND LEGAL PROCEEDINGS:

PRICING AND REIMBURSEMENT

U.S. and international governmental regulations that mandate price controls and limitations on patient access to our products or establish prices paid by government entities or programs for our products impact our business, and our future results could be adversely affected by changes in such regulations or policies.

In the U.S., many of our products are subject to increasing pricing pressures. Pharmaceutical product pricing is subject to enhanced government and public scrutiny and calls for reform. Some states have implemented, and other states are considering, pharmaceutical price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. Efforts by government officials or legislators to implement measures to regulate prices or payments for pharmaceutical products, including legislation on drug importation, could adversely affect our business if implemented. See the discussion regarding pricing and reimbursement in the Item 1. Business—Government Regulation and Price Constraints—In the United States—Pricing and Reimbursement section of this 2018 Form 10-K. Private third-party payers, such as health plans, increasingly challenge pharmaceutical product pricing, which could result in lower prices, lower reimbursement rates and a reduction in demand for our products. Pricing pressures for our products may occur as a result of highly competitive insurance markets. Healthcare provider purchasers, directly or through group purchasing organizations, are seeking enhanced discounts or implementing more rigorous bidding or purchasing review processes.

We encounter similar regulatory and legislative issues in most other countries. In certain international markets, such as the different EU Member States, Japan, China, Canada and South Korea, governments have significant power as large single payers to regulate prices, access criteria (e.g., through public or private health technology assessments), or other means of cost control, particularly under recent global financing pressures. As a result, we expect that pressures on the pricing component of operating results will continue.

The adoption of restrictive price controls in new jurisdictions or more restrictive ones in existing jurisdictions, failure to obtain or maintain timely or adequate pricing or favorable formulary placement for our products, or failure to obtain such formulary placement at favorable pricing, could also adversely impact revenue. In our vaccines business, we participate in a tender process in many countries for participation in national immunization programs. Failure to secure participation in national immunization programs or to obtain acceptable pricing in the tender process could adversely affect our business.

U.S. HEALTHCARE REFORM

The U.S. healthcare industry is highly regulated and subject to frequent and substantial changes. For example, the ACA was enacted by Congress in March 2010 and established a major expansion of healthcare coverage, financed in part by a number of new rebates, discounts, and taxes that had a significant effect on our expenses and profitability. See the discussion under the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—Industry-Specific Challenges—Regulatory Environment/Pricing and Access—U.S. Healthcare Legislation section in our 2018 Financial Report and in Item 1. Business—Government Regulation and Price Constraints—In the United States. We face uncertainties due to federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. For example, tax reform legislation enacted at the end of 2017 eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). We anticipate continued Congressional interest in modifying provisions of the ACA, particularly given the recent ruling in Texas v. Azar to invalidate the law as

unconstitutional. At this time, the law remains in effect pending appeals of the decision. Given the outcomes of the 2018 U.S. midterm elections with Democrats taking over the U.S. House of Representatives and Republicans growing their majority in the U.S. Senate, we believe it is unlikely Congress will find bipartisan consensus to advance any significant changes to the ACA until the legal process unfolds. The revenues generated for Pfizer by the health insurance exchanges and Medicaid expansion under the ACA are not material, so the impact of the change in law and similar recent administration actions is expected to be limited. Any future replacement, modification or repeal of the ACA may adversely affect our business and financial results, particularly if the legislation reduces incentives for employer-sponsored insurance coverage, and we cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Other U.S. federal or state legislative or regulatory action and/or policy efforts could adversely affect our business, including, among others, general budget control actions, changes in patent laws, the importation of prescription drugs from outside the U.S. at prices that are regulated by governments of various foreign countries (which is among the U.S. presidential administration's policy proposals), revisions to reimbursement of biopharmaceuticals under government programs (such as the implementation of international reference pricing for Medicare Part B drugs, or changes to protected class criteria for Part D drugs), restrictions on U.S. direct-to-consumer advertising, limitations on interactions with healthcare professionals, or the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on cost differences and minimizes the therapeutic differences among pharmaceutical products and restricts access to innovative medicines.

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U.S. ENTITLEMENT REFORM

In the U.S., government action to reduce federal spending on entitlement programs including Medicare and Medicaid may affect payment for our products or services provided using our products. The Congressional Budget Office routinely releases options for reducing federal spending, and the December 2018 release includes proposals to cap federal Medicaid payments to the states, and to require manufacturers to pay a minimum rebate on drugs covered under Medicare Part D for low-income beneficiaries. Significant Medicare reductions could also result if, for example, Congress proceeds with certain proposals to convert the Medicare fee-for-service program into a premium support program, or Congress chooses to implement the recommendations made annually by the Medicare Payment Advisory Commission, which are primarily intended to extend the fiscal solvency of the Medicare program. These and any other significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented could have an adverse impact on our results of operations.

SUBSTANTIAL REGULATION

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the U.S., principally by the FDA and the DEA, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, corporate integrity or deferred prosecution agreements or exclusion from future participation in government healthcare programs, as well as reputational harm.

DEVELOPMENT, REGULATORY APPROVAL AND MARKETING OF PRODUCTS

Innovation is critical to the success of our company, and drug discovery and development is time-consuming, expensive and unpredictable. The outcome of the lengthy and complex process of identifying new compounds and developing new products is inherently uncertain and involves a high degree of risk and cost. The process from early discovery to design and adequate implementation of clinical trials to regulatory approval can take many years. Drug candidates can and do fail at any stage of the process, including as the result of unfavorable pre-clinical and clinical trial results, or unfavorable new clinical data and further analyses of existing clinical data, including results that may not support further clinical development of the applicable product candidate or indication. We may not be able to meet anticipated pre-clinical or clinical endpoints, commencement and/or completion dates for our pre-clinical or clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates. Similarly, we may not be able to successfully address all of the comments received from regulatory authorities such as the FDA and the EMA, or obtain approval from regulators. Regulatory approval of drug or biologic products depends on myriad factors, including a regulator making a determination as to whether a product's benefits outweigh its known risks and a determination of the product's efficacy. Additionally, clinical trial data are subject to differing interpretations and assessments by regulatory authorities. Even after a drug or biologic is approved, it could be adversely affected by regulatory decisions impacting labeling, manufacturing processes, safety and/or other matters. We may not be able to receive or maintain favorable recommendations by technical or advisory committees, such as the Advisory Committee on Immunization Practices that may impact the use of our vaccines. For example, during the October 2018 ACIP meeting, the U.S. Centers for Disease Control and Prevention presented initial data and indicated formal evaluation of evidence (grading) and a potential vote on the maintenance of the 65 years and older recommendation for Prevnar 13 would likely happen in 2019. A potential adverse change in the ACIP recommendation would negatively impact future Prevnar 13 revenues. For additional information, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Discussion section of our 2018 Financial Report. Further, claims and concerns that may arise regarding the safety and efficacy of in-line products and product candidates can result in a negative impact on product sales, product recalls or withdrawals, and/or consumer fraud, product liability and other litigation and claims. Increasing regulatory scrutiny of drug safety and efficacy, with regulatory authorities increasingly focused on

product safety and the risk/benefit profile of products as they relate to already-approved products, has resulted in a more challenging, expensive and lengthy regulatory approval process due to requests for, among other things, additional or more extensive clinical trials prior to granting approval or increased post-approval requirements. For these and other reasons discussed in Item 1A. Risk Factors, we may not obtain the approvals we expect within the timeframe we anticipate, or at all.

POST-APPROVAL DATA

As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these Phase 4 trials could result in the loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. Regulatory agencies in countries outside the U.S. often have similar authority and may impose comparable requirements. Postmarketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect the availability or commercial potential of our products. Further, the discovery of significant problems with a product similar to one of our products could implicate the entire class of products; and this, in turn, could have an adverse effect on the availability or commercial viability of our product(s) as well as other products in the class.

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INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND GOVERNMENT OFFICIALS

Risks and uncertainties apply if we provide, offer, or promise something of value to a healthcare professional, other healthcare provider and/or government official. Requirements or industry standards in the U.S. and certain jurisdictions abroad that require pharmaceutical manufacturers to track and disclose financial interactions with healthcare professionals and healthcare providers increase government and public scrutiny of such financial interactions. If an interaction is found to be improper, government enforcement actions and penalties could result. These risks may increase as both U.S. and foreign enforcement agencies adopt or increase enforcement efforts in respect of existing and new laws and regulations governing product promotion, marketing, anti-bribery and kickbacks, industry regulations, and codes of conduct.

CHANGES IN LAWS AND ACCOUNTING STANDARDS

Our future results could be adversely affected by changes in interpretations of existing laws and regulations, or changes in laws and regulations, including, among others, changes in accounting standards, taxation requirements (including tax rate changes, new tax laws, changes to existing tax laws and revised tax law and regulatory clarifications and/or interpretations, including changes affecting the taxation by the U.S. of income earned outside the U.S. that may result from pending and possible future proposals, including further clarifications and/or interpretations of the Tax Cuts and Jobs Act), competition laws, privacy laws and environmental laws in the U.S. and other countries. For additional information, see the Provision/(Benefit) for Taxes on Income—Changes in Tax Laws and New Accounting Standards sections, and Notes to Consolidated Financial Statements—Note 1B. Basis of Presentation and Significant Accounting Policies: Adoption of New Accounting Standards in 2018 in our 2018 Financial Report.

LEGAL PROCEEDINGS

We and certain of our subsidiaries are involved in various legal proceedings, including patent litigation, such as claims that our patents are invalid and/or do not cover the product of the generic drug manufacturer or where one or more third parties seeks damages and/or injunctive relief to compensate for alleged infringement of its patents by our commercial or other activities, product liability and other product-related litigation, including personal injury, consumer, off-label promotion, securities, antitrust and breach of contract claims, commercial, environmental, government investigations, employment, tax litigation and other legal proceedings, including various means for resolving asbestos litigation, that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable, and excessive verdicts do occur. Although we believe that our claims and defenses in matters in which we are a defendant are substantial, we could in the future incur judgments, enter into settlements of claims or revise our expectations regarding the outcomes of certain matters, and such developments could have a material adverse effect on our results of operations in the period in which the amounts are accrued and/or our cash flows in the period in which the amounts are paid.

Claims against our patents include challenges to the coverage and/or validity of our patents on various products or processes. Although we believe we have substantial defenses to these challenges with respect to all of our material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection for the product at issue, which could lead to a significant loss of sales of that product and could materially affect future results of operations.

Like other pharmaceutical companies, we are subject to extensive regulation by government agencies in the U.S., other developed markets and multiple emerging markets in which we operate. As a result, we have interactions with government agencies on an ongoing basis. Criminal charges, substantial fines and/or civil penalties, limitations on our ability to conduct business in applicable jurisdictions, corporate integrity or deferred prosecution agreements, as well as reputational harm and increased public interest in the matter could result from government investigations. In

addition, in a qui tam lawsuit in which the government declines to intervene, the relator may still pursue a suit for the recovery of civil damages and penalties on behalf of the government.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation under the FFDCA, the Medicaid Drug Rebate Program, the FCPA and other federal and state statutes, including those discussed elsewhere in this 2018 Form 10-K, as well as anti-kickback and false claims laws, and similar laws in international jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information demands from government authorities, and been subject to claims and other actions related to our business activities brought by governmental authorities, as well as by consumers and private payers. In some instances, we have incurred significant expense, civil payments, fines and other adverse consequences as a result of these claims, actions and inquiries. For example, these claims, actions and inquiries may relate to alleged failures to accurately interpret or identify or prevent non-compliance with the laws and regulations associated with the dissemination of product information (approved and unapproved), potentially resulting in government enforcement and damage to our reputation. This risk may be heightened by digital marketing, including social media, mobile applications and blogger outreach.

In connection with the resolution of a U.S. government investigation concerning independent copay assistance organizations that provide financial assistance to Medicare patients, in May 2018, we entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the U.S. Department of Health and Human Services, which is effective for a period of five

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years. In the CIA, we agreed to implement and/or maintain certain compliance program elements to promote compliance with federal healthcare program requirements. Breaches of the CIA could result in severe sanctions against us.

For additional information, including information regarding certain legal proceedings in which we are involved in, see Notes to Consolidated Financial Statements—Note 17A. Contingencies and Certain Commitments—Legal Proceedings in our 2018 Financial Report.

ENVIRONMENTAL CLAIMS AND PROCEEDINGS

We and certain of our subsidiaries are subject to numerous contingencies arising in the ordinary course of business relating to environmental claims and proceedings. Amounts recorded for legal and environmental contingencies can result from a complex series of judgments about future events and uncertainties and can rely heavily on estimates and assumptions. While we have accrued for worldwide environmental liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts accrued. If we fail to properly manage the safety of our facilities and the environmental risks associated therewith or if we are required to increase our accruals for contingencies for environmental claims and proceedings in the future, it could potentially have an adverse effect on our results of operations.

RISKS RELATED TO INTELLECTUAL PROPERTY:

PATENT PROTECTION

Our long-term success largely depends on our ability to market technologically competitive products. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, trade dress, copyright, trade secret and domain name protection laws, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from launching generic or biosimilar versions of our branded products, using our proprietary technologies or from marketing products that are very similar or identical to ours. Our currently pending or future patent applications may not result in issued patents, or be granted on a timely basis. Similarly, any term extensions that we seek may not be granted on a timely basis, if at all. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinct patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term.

Our ability to enforce our patents also depends on the laws of individual countries and each country’s practice with respect to enforcement of intellectual property rights, and the extent to which certain sovereigns may seek to engage in policies or practices that may weaken its intellectual property framework (e.g., a policy of routine compulsory licensing (or threat of compulsory licensing) of pharmaceutical intellectual property). In countries that provide some form of regulatory exclusivity, mechanisms exist permitting some form of challenge to our patents by competitors or generic drug marketers prior to or immediately following the expiration of such regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as “at risk” launches that challenge our patent rights. Most of the suits involve claims by generic drug manufacturers that patents covering our products, processes or dosage forms are invalid and/or do not cover the product of the generic drug manufacturer. Independent actions have been filed alleging that our assertions of, or attempts to enforce, patent rights with respect to certain products constitute unfair competition and/or violations of antitrust laws. Such claims may also be brought as counterclaims to actions we bring to enforce our patents. We are also party to other patent damages suits in various jurisdictions

pursuant to which generic drug manufacturers, payers, governments or other parties are seeking damages from us for alleged delay of generic entry. We also are often involved in other proceedings, such as inter partes review, post-grant review, re-examination or opposition proceedings, before the U.S. Patent and Trademark Office, the European Patent Office, or other foreign counterparts relating to our intellectual property or the intellectual property rights of others. Also, if one of our patents is found to be invalid by such proceedings, generic or competitive products could be introduced into the market resulting in the erosion of sales of our existing products. For example, several of the patents in our pneumococcal vaccine portfolio were challenged in inter partes review and post-grant review proceedings in the U.S. In June 2018, the Patent Trial and Appeal Board ruled on one patent, holding that one claim was valid and that all other claims were invalid. The party challenging that patent has appealed the decision. Challenges to other patents remain pending before the U.S. Patent and Trademark Office. The invalidation of these patents could potentially allow a competitor pneumococcal vaccine into the marketplace. Further, if we are unable to maintain our existing license agreements or other agreements pursuant to which third parties grant us rights to intellectual property, including because such agreements expire or are terminated, our operating results and financial condition could be materially adversely affected.

Likewise, in the U.S. and other countries, we currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks and trade dress to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, by

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requiring our employees, consultants, other advisors and other third parties to execute proprietary information and confidentiality agreements upon the commencement of their employment, engagement or other relationship. Despite these efforts and precautions, we may be unable to prevent a third party from copying or otherwise obtaining and using our trade secrets or our other intellectual property without authorization, and legal remedies in some countries may not adequately compensate us for the damages caused by such unauthorized use. Further, others may independently and lawfully develop substantially similar or identical products that circumvent our intellectual property by means of alternative designs or processes or otherwise.

THIRD PARTY INTELLECTUAL PROPERTY CLAIMS

A properly functioning intellectual property regime is essential to our business model. We are committed to respecting the valid intellectual property rights of other companies, but the patent granting process is imperfect. Accordingly, the pursuit of valid business opportunities may require us to challenge intellectual property rights held by other companies that we believe were improperly granted. Such challenges may include negotiation and litigation, which may not always be successful.

Part of our business depends upon successfully identifying generic pharmaceutical product and biosimilar opportunities and launching products to take advantage of those opportunities, which may involve litigation, associated costs and time delays, and may ultimately not be successful. These opportunities may arise in situations where patent protection of equivalent branded products has expired, where patents have been declared invalid, or where products do not infringe the patents of others. To achieve a “first-to-market” or early market position for generic pharmaceutical products and biosimilars, we may take action, such as litigation, asserting that our products do not infringe patents of existing products or that those patents are invalid or unenforceable.

Third parties may claim that our products infringe one or more patents owned or controlled by the third party. Claims of intellectual property infringement can be costly and time-consuming to resolve, may delay or prevent product launches, and may result in significant damages. We are involved in patent-related disputes with third parties over our attempts to market generic pharmaceutical products and biosimilars. Once we have final regulatory approval of the related generic pharmaceuticals products or biosimilars, we may decide to commercially market these products even though associated legal proceedings (including any appeals) have not been resolved (i.e., “at-risk” launch). If one of our marketed products is found to infringe valid patent rights of a third party, such third party may be awarded significant damages, or we may be prevented from further sales of that product. Such damages may be enhanced as much as three-fold in the event that we or one of our subsidiaries, like Hospira, is found to have willfully infringed valid patent rights of a third party. Any of these adverse consequences could have a material adverse effect on our profitability and financial condition.

RISK RELATED TO TECHNOLOGY:

INFORMATION TECHNOLOGY AND SECURITY

Significant disruptions of information technology systems or breaches of information security could adversely affect our businesses. We rely to a large extent upon sophisticated information technology systems to operate our businesses. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts

of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. As a global pharmaceutical company, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. While we have invested in the protection of data and information technology, our efforts may not prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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RISKS RELATED TO OUR STRATEGIC TRANSACTIONS:

STRATEGIC ACQUISITIONS

The success of any of our strategic acquisitions will depend, in large part, on our ability to realize anticipated benefits from combining these businesses with Pfizer. We, for example, may fail to achieve cost savings anticipated with certain of these acquisitions, or such cost savings within the expected time frame. Similarly, the accretive impact anticipated from certain of these acquisitions may not be realized or may be delayed. Integration of these businesses may result in the loss of key employees, the disruption of ongoing business, including third-party relationships, or inconsistencies in standards, controls, procedures and policies. We also may fail to generate the revenue growth for the acquired business that we expected at the time of entering into the transaction. Expected revenue from acquired products and product candidates also may be constrained by developments outside of our control. Unsuccessful clinical trials, regulatory hurdles and commercialization challenges may adversely impact revenue and income contribution from products and product candidates, including those acquired in these acquisitions. Hospira, for example, has experienced manufacturing disruptions and substantial regulatory scrutiny due to quality issues. Manufacturing problems, as well as any corrective actions and their operational implementation, could adversely impact the revenue we generate from products acquired from Hospira and result in substantial unanticipated costs. For additional information, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business—Product Manufacturing section in our 2018 Financial Report.

CONSUMER HEALTHCARE JOINT VENTURE WITH GSK

The required shareholder and regulatory approvals may not be obtained or the regulatory approvals may contain materially burdensome conditions that could have an adverse effect on us or the joint venture or the other conditions to the completion of the proposed transaction may not be satisfied in a timely manner or at all.

Completion of the proposed transaction is subject to a number of conditions, including, among others, the approval of GSK's shareholders and the receipt of certain governmental and regulatory approvals, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of all required approvals under the antitrust laws of certain other jurisdictions, including the EU. Although Pfizer and GSK have agreed to do all things necessary under applicable antitrust laws to complete the proposed transaction as promptly as reasonably practicable, there can be no assurance that these approvals will be obtained in a timely manner or at all or that the other conditions to closing will be satisfied. In addition, in connection with obtaining the required regulatory approvals, governmental authorities may impose conditions on the completion of the proposed transaction or require changes to the terms of the proposed transaction. If any such conditions or changes are imposed, they may jeopardize or delay completion of the proposed transaction, reduce or delay the anticipated benefits of the proposed transaction or allow the parties to terminate the stock and asset purchase agreement, which could negatively impact our stock price and our or the joint venture's, as applicable, future business and financial results.

We may fail to realize all of the anticipated benefits of the proposed transaction.

The success of the proposed transaction will depend, in part, on the joint venture's ability to realize the anticipated benefits and cost synergies from the proposed transaction. These anticipated benefits and cost savings may not be realized or may not be realized within the expected time period. The joint venture's integration of Pfizer's and GSK's consumer healthcare businesses may result in material unanticipated problems, costs, expenses, liabilities, competitive responses, and loss of customer and other business relationships. Any material unanticipated issues arising from the integration process could negatively impact our stock price and our or the joint venture's, as applicable, future business and financial results.

Moreover, uncertainty about the effect of the proposed transaction on employees, customers, suppliers, distributors and other business partners may have an adverse effect on us and the joint venture. These uncertainties may impair our and/or the joint venture's ability to attract, retain and motivate key personnel until the transaction is consummated and

for a period of time thereafter, and could cause customers, suppliers, distributors and others who deal with us and/or the joint venture to seek to change or cancel existing business relationships with us and/or the joint venture or fail to renew existing relationships. Employee retention may be challenging during the pendency of the proposed transaction, as certain employees may experience uncertainty about their future roles. If key employees depart because of issues related to the uncertainty and difficulty of integration or a desire not to remain with the combined business, our business and the business of the joint venture following the completion of the transaction could be adversely affected. Following the integration of the combined business, GSK intends to separate the joint venture as an independent company via a demerger of its equity interest to its shareholders and a listing of the combined business on the U.K. equity market. GSK will have the sole right to decide whether and when to initiate a separation and listing for a period of five years from closing of the proposed transaction. GSK may also sell all or part of its stake in the joint venture in a contemporaneous initial public offering. Should a separation and listing occur during the first five years after closing, Pfizer has the option to participate through the distribution of some or all of its equity interest in the joint venture to its shareholders. Following a separation or listing, and subject to customary lock-up or similar restrictions, Pfizer will also have the ability to sell its equity interest in the joint venture through the capital markets. After the fifth anniversary of the closing of the proposed transaction, both GSK and Pfizer will have the right to decide whether and when to initiate a separation and public listing of the joint venture. The planned separation and

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public listing transactions may not be initiated or completed within the expected time periods or at all, and both the timing and success of any separation and public listing transaction, as well as the value generated for Pfizer or its shareholders in any such transaction, will be subject to prevailing market conditions and other factors at the time of such transaction. Although Pfizer is entitled to participate in any separation and listing transaction initiated by GSK during the first five years after closing, it is not required to do so, and any future distribution or sale of Pfizer's equity stake in the joint venture will similarly be subject to prevailing market conditions and other factors at the time of such transaction. Pfizer's ability to complete any such future distribution or sale may also be impacted by the size of Pfizer's retained equity stake at the time. The uncertainty relating to the separation and public listing transactions, their implementation, their timing and their yet to be determined effects on the joint venture's business may subject us and the joint venture to risks and uncertainties that may adversely affect our business and financial results.

The joint venture may be subject to additional risks beyond those associated with Pfizer's consumer healthcare business.

After completion of the transaction, the joint venture will be subject to the risks associated with GSK's consumer healthcare business in addition to the risks associated with Pfizer's consumer healthcare business, and the business, financial condition and results of operations of the joint venture may be affected by factors that are different from or in addition to those currently affecting the independent business, financial condition and results of operations of Pfizer's consumer healthcare business. Many of these factors are outside of our and the joint venture's control, and could materially impact the business, financial condition and results of operations of the joint venture. Moreover, although we will have certain consent, board representation and other governance rights with respect to the joint venture, Pfizer will be a minority owner of the joint venture following the completion of the proposed transaction. As a result, Pfizer will not have control over the joint venture, its management or its policies and we may have business interests, strategies and goals that differ in certain respects from those of GSK or the joint venture.

The market value of our common stock may be adversely affected as a result of expected and unexpected costs associated with the proposed transaction and integration of the businesses.

We have incurred, and expect to incur, transaction- and integration-related costs in connection with the proposed transaction. We expect that a substantial portion of these transaction- and integration-related costs will be comprised of non-recurring fees for professional services to complete the proposed transaction, facilities and systems consolidation costs and employment-related costs, although certain unanticipated costs and expenses may be incurred as well. If the stock and asset purchase agreement is terminated, we would have incurred many of these costs, fees and expenses without realizing the expected benefits of the transaction. These costs, fees and expenses could adversely affect our financial results.

OTHER RISKS:

THE GLOBAL ECONOMIC ENVIRONMENT

Like all businesses of our size, we are exposed to both global and industry-specific economic conditions. Governments, corporations, and insurance companies, which provide insurance benefits to patients, have implemented increases in cost-sharing and restrictions on access to medicines, potentially causing patients to switch to generic or biosimilar products, delay treatments, skip doses or use less effective treatments. Government financing pressures can lead to negative pricing pressure in various markets where governments take an active role in setting prices, access criteria (e.g., through public or private health technology assessments), or other means of cost control. Examples include the different EU Member States, Japan, China, Canada, South Korea and a number of other international markets. The U.S. continues to maintain competitive insurance markets, but has also seen significant increases in patient cost-sharing and growing government influence as government programs continue to grow as a source of coverage.

The global economic environment has not had, nor do we anticipate that it will have, a material impact on our liquidity or capital resources. Due to our significant operating cash flows, financial assets, access to capital markets

and available lines of credit and revolving credit agreements, we continue to believe that we have, and will maintain, the ability to meet our liquidity needs for the foreseeable future. We monitor our liquidity position continuously in the face of evolving economic conditions, but there can be no guarantee that changes in global financial markets and global economic conditions will not affect our liquidity or capital resources or impact our ability to obtain financing in the future.

We continue to monitor credit, capital restrictions and economic situations in volatile regions and markets, especially where the ability to obtain U.S. dollars for local currency is unpredictable and challenging. We cannot predict the likelihood of future changes in these economic conditions, or what impact they may have on our results of operations, financial condition or business.

In addition, given that a significant portion of our business is conducted in the EU, including the U.K., the formal change in the relationship between the U.K. and the EU caused by Brexit may pose certain implications for our research, commercial and general business operations in the U.K. and the EU, including the approval and supply of our products. Details on how Brexit will be executed and the impact on the remaining EU countries will dictate how and whether the broader EU will be impacted

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and what the resulting impact on our business may be. For additional information, see the see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—The Global Economic Environment section in our 2018 Financial Report.

We also continue to monitor the global trade environment and potential trade conflicts and impediments. If trade restrictions or tariffs reduce global economic activity, or if other factors lead to a general economic downturn, potential impacts could include declining sales; increased costs; volatility in foreign exchange rates; a decline in the value of our financial assets and pension plan investments; required increases of our pension funding obligations; increased government cost control efforts; delays or failures in the performance of customers, suppliers, and other third parties on whom we may depend for the performance of our business; and the risk that our allowance for doubtful accounts may not be adequate.

FOREIGN EXCHANGE AND INTEREST RATE RISK

Significant portions of our revenues, costs and expenses, as well as our substantial international net assets, are exposed to changes in foreign exchange rates. 53% of our total 2018 revenues were derived from international operations, including 21% from Europe and 22% from China, Japan and the rest of Asia. As we operate in multiple foreign currencies, including the euro, the Japanese yen, the Chinese renminbi, the U.K. pound, the Canadian dollar and approximately 100 other currencies, changes in those currencies relative to the U.S. dollar will impact our revenues and expenses. If the U.S. dollar were to weaken against another currency, assuming all other variables remained constant, our revenues would increase, having a positive impact on earnings, and our overall expenses would increase, having a negative impact on earnings. Conversely, if the U.S. dollar were to strengthen against another currency, assuming all other variables remained constant, our revenues would decrease, having a negative impact on earnings, and our overall expenses would decrease, having a positive impact on earnings. Therefore, significant changes in foreign exchange rates can impact our results and our financial guidance.

The impact of possible currency devaluations in countries experiencing high inflation rates or significant exchange fluctuations, including Venezuela and Argentina, can impact our results and financial guidance. For additional information about our exposure to foreign currency risk, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Financial Guidance for 2019 and Analysis of Financial Condition, Liquidity and Capital Resources sections in our 2018 Financial Report.

In addition, our interest-bearing investments and borrowings, and our pension benefit obligations, net, and our postretirement benefit obligations, net, are subject to risk from changes in interest rates and foreign exchange rates. These risks related to interest-bearing investments and borrowings and the measures we have taken to help contain them are discussed in the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2018 Financial Report. For additional details, see the Notes to Consolidated Financial Statements—Note 7F. Financial Instruments: Derivative Financial Instruments and Hedging Activities and —Note 11. Pension and Postretirement Benefit Plans and Defined Contribution Plans in our 2018 Financial Report and the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions—Benefit Plans section in our 2018 Financial Report. Those sections of our 2018 Financial Report are incorporated by reference.

From time to time, we issue variable rate debt based on LIBOR, or undertake interest rate swaps that contain a variable element based on LIBOR. There is currently uncertainty around whether LIBOR will continue to exist after 2021. If LIBOR ceases to exist, we may need to amend certain agreements and we cannot predict what alternative index would be negotiated with our counterparties. As a result, our interest expense could increase and our available cash flow for general corporate requirements may be adversely affected. Additionally, uncertainty as to the nature of a potential discontinuance, modification, alternative reference rates or other reforms may materially adversely affect the trading market for securities linked to such benchmarks. For additional information, see Analysis of Financial

Condition, Liquidity and Capital Resources—Selected Measures of Liquidity and Capital Resources—LIBOR.

Notwithstanding our efforts to foresee and mitigate the effects of changes in external fiscal circumstances, we cannot predict with certainty changes in currency and interest rates, inflation or other related factors affecting our businesses.

MARKET FLUCTUATIONS IN OUR EQUITY INVESTMENTS

In the first quarter of 2018, we adopted a new accounting standard whereby certain equity investments are measured at fair value with changes in fair value now recognized in net income. We expect the adoption of this new accounting standard may increase the volatility of our income in future periods due to changes in the fair value of equity investments. For additional information, see Notes to Consolidated Financial Statements—Note 1B. Basis of Presentation and Significant Accounting Policies: Adoption of New Accounting Standards in 2018 and the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management sections in our 2018 Financial Report.

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Our pension benefit obligations and postretirement benefit obligations, net of our plan assets, are subject to volatility from changes in fair value of equity investments and other investment risk. For additional information, see Notes to Consolidated Financial Statements—Note 11. Pension and Postretirement Benefit Plans and Defined Contribution Plans and the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions—Benefit Plans section in our 2018 Financial Report.

COST AND EXPENSE CONTROL/UNUSUAL EVENTS/FAILURE TO REALIZE THE ANTICIPATED BENEFITS OF STRATEGIC INITIATIVES AND ACQUISITIONS

Growth in costs and expenses, changes in product, segment and geographic mix and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product withdrawals, recalls and other unusual events that could result from evolving business strategies, evaluation of asset realization and organizational restructuring could adversely affect future results. Such risks and uncertainties include, in particular, our ability to realize the projected benefits of (i) our cost-reduction and productivity initiatives; (ii) the reorganization of our commercial operations into three businesses effective at the beginning of the company's 2019 fiscal year; (iii) any other corporate strategic initiatives; and (iv) any acquisitions, divestitures or other initiatives, such as our proposed transaction with GSK to combine our respective consumer healthcare businesses into a new consumer healthcare joint venture.

INTANGIBLE ASSETS, GOODWILL AND EQUITY-METHOD INVESTMENTS

Our consolidated balance sheet contains significant amounts of intangible assets, including goodwill. For IPR&D assets, the risk of failure is significant, and there can be no certainty that these assets ultimately will yield successful products. The nature of the biopharmaceutical business is high-risk and requires that we invest in a large number of projects in an effort to achieve a successful portfolio of approved products. Our ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market acceptance. As such, we expect that many of these IPR&D assets will become impaired and be written off at some time in the future. If the associated R&D effort is abandoned, the related IPR&D assets will likely be written-off, and we will record an impairment charge. For goodwill, all reporting units can confront events and circumstances that can lead to a goodwill impairment charge (such as, among other things, unanticipated competition, an adverse action or assessment by a regulator, a significant adverse change in legal matters or in the business climate and/or a failure to replace the contributions of products that lose exclusivity). Any such charge may be significant. Our other intangible assets, including developed technology rights and brands, face similar risks for impairment and charges related to such assets may be significant as well. For additional details, see the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions section in our 2018 Financial Report.

We also regularly review our equity-method investments for impairment. An impairment charge may result from the occurrence of unexpected adverse events or management decisions that impact our estimates of expected cash flows to be generated from these investments. We may recognize impairment charges as a result of a weak economic environment, events related to particular customers or asset types, challenging market conditions or decisions by management.

INTERNAL CONTROL OVER FINANCIAL REPORTING

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could undermine the ability to provide accurate disclosure (including with respect to financial information) on a timely basis, which could cause investors to lose confidence in our disclosures (including with respect to financial information), require significant

resources to remediate the lapse or deficiency, and expose us to legal or regulatory proceedings.

TERRORIST ACTIVITY

Our future results could be adversely affected by changes in business, political and economic conditions, including the cost and availability of insurance, due to the threat of terrorist activity in the U.S. and other parts of the world and related U.S. military action overseas.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2018, we had 498 owned and leased properties, amounting to approximately 53 million square feet.

Pfizer continues to own and lease space around the world for sales and marketing, customer service, regulatory compliance, R&D, manufacturing and distribution, and administrative support functions. In many locations, business lines and operations are co-located to achieve synergy and operational efficiencies.

Pfizer's corporate headquarters are in New York City and Pfizer's properties extend internationally to over 90 countries.

In April 2018, we entered an agreement to lease space at the Spiral, an office building in the Hudson Yards neighborhood of New York City. We will relocate our global headquarters to this property with occupancy expected beginning in 2022. In July 2018, we completed the sale of our current headquarters in New York City. We are in a lease-back arrangement with the buyer while we complete our relocation. We continue to advance our global workplace strategy to provide workplaces that enable collaboration and foster innovation.

We have numerous facilities across the world to support our R&D organizations, with a heavy concentration in North America. In 2019, we will operationalize the new R&D facilities in St. Louis, Missouri and Andover, Massachusetts.

Our PGS division is headquartered in various locations, with leadership teams primarily in New York City, New York and in Peapack, New Jersey. As of December 31, 2018, PGS had responsibility for 58 plants around the world, which manufacture products for our commercial divisions. Locations with major manufacturing facilities include Belgium, China, Germany, India, Ireland, Italy, Japan, Puerto Rico, Singapore and the U.S. Our PGS division's plant network strategy is expected to result in the exit of four of these sites over the next several years. PGS also operates multiple distribution facilities around the world.

In general, we believe that our properties are well-maintained, adequate and suitable for their current requirements and for our operations in the foreseeable future. See the Notes to Consolidated Financial Statements—Note 9. Property, Plant and Equipment in our 2018 Financial Report, which provides amounts invested in land, buildings and equipment and which is incorporated by reference. See also the discussion in the Notes to Consolidated Financial Statements—Note 15. Lease Commitments in our 2018 Financial Report, which is also incorporated by reference.

ITEM 3. LEGAL PROCEEDINGS

Certain legal proceedings in which we are involved are discussed in the Notes to Consolidated Financial Statements—Note 17A. Contingencies and Certain Commitments—Legal Proceedings in our 2018 Financial Report, which is incorporated by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company are set forth in this table. Each holds the office or offices indicated until his or her successor is chosen and qualified at the regular meeting of the Board of Directors to be held on the date of the 2019 Annual Meeting of Shareholders, or until his or her earlier death, resignation or removal. Each of the executive officers is a member of the Pfizer Executive Leadership Team.

Name	Age	Position
Albert Bourla	57	Chief Executive Officer since January 2019. Chief Operating Officer from January 2018 until December 2018; Group President, Pfizer Innovative Health from June 2016 until December 2017; Group President, Global Innovative Pharma Business (responsible for Vaccines, Oncology and Consumer Healthcare since 2014) from February 2016 until June 2016. President and General Manager of Established Products Business Unit from December 2010 until December 2013. Area President Europe, Africa, Asia and Pacific of Pfizer Animal Health from 2009 until November 2010. Area President Europe, Africa and Middle East of Pfizer Animal Health from 2005 until 2009. Our Director since February 2018. Board member of Pharmaceutical Research and Manufacturers of America (PhRMA). Board member of the Pfizer Foundation, which promotes access to quality healthcare. Member of the Board of Directors of the Partnership for New York City and Catalyst, a global non-profit organization accelerating progress for the advancement of women into leadership.
Frank A. D'Amelio	61	Chief Financial Officer, Executive Vice President, Business Operations and Global Supply since November 2018. Executive Vice President, Business Operations and Chief Financial Officer from December 2010 until October 2018. Senior Vice President and Chief Financial Officer from September 2007 until December 2010. Prior to joining Pfizer, he was Senior Executive Vice President of Integration and Chief Administrative Officer of Alcatel-Lucent from November 2006 until August 2007. Prior to the Alcatel-Lucent merger, he was Chief Operating Officer of Lucent and before that Chief Financial Officer of Lucent. Director of Zoetis Inc. and of Humana Inc. and Chair of the Humana Audit Committee. Director of the Independent College Fund of New Jersey.
Mikael Dolsten	60	Chief Scientific Officer, President, Worldwide Research, Development and Medical since January 2019. President of Worldwide Research and Development from December 2010 until December 2018. Senior Vice President; President of Worldwide Research and Development from May 2010 until December 2010. Senior Vice President; President of Pfizer BioTherapeutics Research & Development Group from October 2009 until May 2010. He was Senior Vice President of Wyeth and President, Wyeth Research from June 2008 until October 2009. He was a Private Equity Partner at Orbimed Advisors, LLC from January 2008 until June 2008. Director of Karyopharm Therapeutics Inc. Chairman of the Translational Advisory Board of Apple Tree Partners from 2016 to 2017.
Lidia Fonseca	50	Chief Digital and Technology Officer, Executive Vice President since January 2019. Chief Information Officer and Senior Vice President of Quest Diagnostics Incorporated from 2014 to 2018. Senior Vice President of Laboratory Corporation of America Holdings from 2008 until March 2013. Director of Tegna, Inc.
Michael Goettler	51	Group President, Pfizer Upjohn since January 2019. Executive Vice President from July 2018 until December 2018. Global President of Pfizer Inflammation & Immunology from January 2018 until June 2018. Global President of Pfizer Rare Disease from January 2016 until December 2017.

		Global Commercial Officer, Senior Vice President for Pfizer's Global Innovative Pharma Business from January 2014 until December 2015. Regional President, Europe for Pfizer Specialty Care and the chair of the European Management Team from June 2012 until December 2013. Regional President Asia - Pacific for Specialty Care from October 2009 until June 2012. Member of the board of directors of PSI (Population Services International).
Angela Hwang	53	Group President, Pfizer Biopharmaceuticals Group since January 2019. Group President, Pfizer Essential Health from January 2018 until December 2018. Global President, Pfizer Inflammation and Immunology from January 2016 until December 2017. Regional Head, U.S. Vaccines from January 2014 until December 2015. Vice President, Emerging Markets for the Primary Care business from September 2011 until December 2013. Vice President, U.S. Brands business within Essential Health from October 2009 until August 2011.
Rady A. Johnson	57	Chief Compliance, Quality and Risk Officer, Executive Vice President since January 2019. Executive Vice President, Chief Compliance and Risk Officer from December 2013 until December 2018. Senior Vice President and Associate General Counsel from October 2006 until December 2013.
Douglas M. Lankler	53	General Counsel, Executive Vice President since December 2013. Corporate Secretary from January 2014 until February 2014. Executive Vice President, Chief Compliance and Risk Officer from February 2011 until December 2013. Executive Vice President, Chief Compliance Officer from December 2010 until February 2011. Senior Vice President and Chief Compliance Officer from January 2010 until December 2010. Senior Vice President, Deputy General Counsel and Chief Compliance Officer from August 2009 until January 2010. Senior Vice President, Associate General Counsel and Chief Compliance Officer from October 2006 until August 2009.
Freda C. Lewis-Hall	64	Chief Patient Officer, Executive Vice President since January 2019. Executive Vice President, Chief Medical Officer from December 2010 until December 2018. Senior Vice President, Chief Medical Officer from May 2009 until December 2010. Previously, she was Chief Medical Officer and Executive Vice President, Medicines Development at Vertex Pharmaceuticals from June 2008 until May 2009. Dr. Lewis-Hall was Senior Vice President, U.S. Pharmaceuticals, Medical Affairs for Bristol-Myers Squibb Company from 2003 until May 2008. Director of Tenet Healthcare Corporation from December 2014 to May 2017.
A. Rod MacKenzie	59	Chief Development Officer, Executive Vice President since June 2016. Senior Vice President, Chief Development Officer from March 2016 until June 2016. Group Senior Vice President and Head, Pharma Therapeutics Research and Development from 2010 until March 2016. Senior Vice President, Head of Worldwide Research from 2007 until 2010. Dr. MacKenzie represents Pfizer as a member of the Board of Directors of ViiV Healthcare Limited.
Dawn Rogers	54	Chief Human Resources Officer, Executive Vice President since January 2019. Executive Vice President, Worldwide Human Resources from June 2018 until December 2018. Senior Vice President, Human Resources for the Chief Operating Officer from November 2017 until May 2018. Senior Vice President of Human Resources for Pfizer Essential Health, Global Product Development, and the Legal and Compliance Divisions from 2016 until November 2017. Senior Vice President of Human Resources for the Global Innovative Pharma Business from 2013 until 2016. Senior Vice President of Human Resources for the Primary Care Business Unit from 2011 until 2013. Senior Vice President of Human Resources for Worldwide Research and Development from 2008 until 2011. Vice President of Human Resources for Pfizer's European Commercial Operations from 2006 to 2008.

Sally Susman	57	Chief Corporate Affairs Officer, Executive Vice President since January 2019. Executive Vice President, Corporate Affairs (formerly Policy, External Affairs and Communications) from December 2010 until December 2018. Senior Vice President, Policy, External Affairs and Communications from December 2009 until December 2010. Senior Vice President and Chief Communications Officer from February 2008 until December 2009. Prior to joining Pfizer, Ms. Susman held senior level positions at The Estée Lauder Companies, including Executive Vice President from 2004 to January 2008. Director of WPP plc.
John D. Young	54	Chief Business Officer, Group President since January 2019. Group President, Pfizer Innovative Health from January 2018 until December 2018. Group President, Pfizer Essential Health from June 2016 until December 2017; Group President, Global Established Pharma Business from January 2014 until June 2016. President and General Manager, Pfizer Primary Care from June 2012 until December 2013. Primary Care Business Unit's Regional President for Europe and Canada from 2009 until June 2012. U.K. Country Manager from 2007 until 2009. Director of Johnson Controls International plc.

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PART II

ITEM 5. MARKET FOR THE COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The principal market for our common stock is the NYSE. Our common stock currently trades on the NYSE under the symbol "PFE". As of February 26, 2019, there were 150,398 holders of record of our common stock. Additional information required by this item is incorporated by reference from the Selected Quarterly Financial Data (Unaudited) and Peer Group Performance Graph sections in our 2018 Financial Report.

The following table provides certain information with respect to our purchases of shares of the Company's common stock during the fourth fiscal quarter of 2018:

Issuer Purchases of Equity Securities[a]

Period	Total Number of Shares Purchased[b]	Average Price Paid per Share[b]	Total Number of Shares Purchased as Part of Publicly Announced Plan[a]	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan[a]
October 1, 2018 through October 28, 2018	38,477,427	$ 44.25	38,410,129	$ 7,487,879,989
October 29, 2018 through November 30, 2018	43,812,603	$ 43.50	43,795,856	$ 5,582,880,460
December 1, 2018 through December 31, 2018	32,598,112	$ 43.77	32,559,080	$ 14,157,881,147
Total	114,888,142	$ 43.83	114,765,065	

(a) For additional information, see the Notes to Consolidated Financial Statements—Note 12. Equity in our 2018 Financial Report, which is incorporated by reference.

(b) In addition to the amounts purchased under our share repurchase program, these columns represent (i) 118,667 shares, primarily representing common stock surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of awards under our long-term incentive programs and (ii) the open market purchase by the trustee of 4,410 shares of common stock in connection with the reinvestment of dividends paid on common stock held in trust for employees who were granted performance share awards and who deferred receipt of such awards.

On February 7, 2019, we entered into an accelerated share repurchase agreement with Goldman, Sachs & Co. LLC. This agreement was entered into pursuant to our previously announced share repurchase authorization. For additional information, see the Notes to Consolidated Financial Statements—Note 19. Subsequent Event in our 2018 Financial Report, which is incorporated by reference.

ITEM 6. SELECTED FINANCIAL DATA

Information required by this item is incorporated by reference from the discussion under the heading Financial Summary in our 2018 Financial Report.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Information required by this item is incorporated by reference from the discussion under the heading Financial Review in our 2018 Financial Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information required by this item is incorporated by reference from the discussion under the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2018 Financial Report.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Information required by this item is incorporated by reference from the Report of Independent Registered Public Accounting Firm on the Consolidated Financial Statements in our 2018 Financial Report and from the consolidated financial statements, related notes and supplementary data in our 2018 Financial Report.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls

As of the end of the period covered by this 2018 Form 10-K, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the SEC.

Internal Control over Financial Reporting

Management's report on the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), and the related report of our independent registered public accounting firm, are included in our 2018 Financial Report under the headings Management's Report on Internal Control Over Financial Reporting and Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting, respectively, and are incorporated by reference.

Changes in Internal Controls

During our most recent fiscal quarter, there has not been any change in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the discussion under the heading Item 1—Election of Directors in our 2019 Proxy Statement. Information about compliance with Section 16(a) of the Exchange Act is incorporated by reference from the discussion under the heading Securities Ownership—Section 16(a) Beneficial Ownership Reporting Compliance in our 2019 Proxy Statement. Information about the Pfizer Policies on Business Conduct governing our employees, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer, and the Code of Business Conduct and Ethics for Members of the Board of Directors, is incorporated by reference from the discussions under the headings Governance—Pfizer Policies on Business Conduct and —Code of Conduct for Directors in our 2019 Proxy Statement. Information regarding the procedures by which our shareholders may recommend nominees to our Board of Directors is incorporated by reference from the discussion under the headings Item 1—Election of Directors—Criteria for Board Membership and Submitting Proxy Proposals and Director Nominations for the 2020 Annual Meeting in our 2019 Proxy Statement. Information about our Audit Committee, including the members of the Committee, and our Audit Committee financial experts, is incorporated by reference from the discussion under the heading Governance—Board Information—Board and Committee Information—Board Committees—The Audit Committee in our 2019 Proxy Statement. The balance of the information required by this item is contained in the discussion entitled Executive Officers of the Company in Part I of this 2018 Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information about Director and executive compensation is incorporated by reference from the discussion under the headings Non-Employee Director Compensation; Executive Compensation; and Governance—Board Information—Board and Committee Information—Board Committees—The Compensation Committee—Compensation Committee Interlocks and Insider Participation in our 2019 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this item is incorporated by reference from the discussion under the headings Executive Compensation—Compensation Tables—Equity Compensation Plan Information and Securities Ownership in our 2019 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information about certain relationships and transactions with related parties is incorporated by reference from the discussion under the headings Related Person Transactions and Indemnification—Transactions with Related Persons in our 2019 Proxy Statement. Information about director independence is incorporated by reference from the discussion under the heading Governance—Other Governance Practices and Policies—Director Independence in our 2019 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accounting firm in 2018 and 2017 is incorporated by reference from the discussion under the heading Item 2—Ratification of Selection of Independent Registered Public Accounting Firm—Audit and Non-Audit Fees in our 2019 Proxy Statement. Our Audit Committee’s policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated by reference from the discussion under the heading Item 2—Ratification of Selection of

Independent Registered Public Accounting Firm—Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm in our 2019 Proxy Statement.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

15(a)(1) Financial Statements. The following consolidated financial statements, related notes, report of independent registered public accounting firm and supplementary data from our 2018 Financial Report are incorporated by reference into Item 8 of Part II of this 2018 Form 10-K:

- Report of Independent Registered Public Accounting Firm on the Consolidated Financial Statements
- Consolidated Statements of Income
- Consolidated Statements of Comprehensive Income
- Consolidated Balance Sheets
- Consolidated Statements of Equity
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements
- Selected Quarterly Financial Data (Unaudited)

15(a)(2) Financial Statement Schedules. Schedules are omitted because they are not required or because the information is provided elsewhere in the financial statements. The financial statements of unconsolidated subsidiaries are omitted because, considered in the aggregate, they would not constitute a significant subsidiary.

15(a)(3) Exhibits. These exhibits are available upon request. Requests should be directed to our Corporate Secretary, Pfizer Inc., 235 East 42nd Street, New York, New York 10017. The exhibit numbers preceded by an asterisk (*) indicate exhibits filed with this 2018 Form 10-K. All other exhibit numbers indicate exhibits filed by incorporation by reference. Exhibit numbers 10.1 through 10.33 are management contracts or compensatory plans or arrangements.

2.1	Agreement and Plan of Merger, dated as of August 20, 2016, among Pfizer Inc., Montreal, Inc. and Medivation, Inc. is incorporated by reference from our Current Report on Form 8-K filed on August 22, 2016 (File No. 001-03619). (Pursuant to Item 601(b)(2) of Regulation S-K, the registrant hereby agrees to supplementally furnish to the Securities and Exchange Commission upon request any omitted schedule or exhibit to the Merger Agreement.)
*2.2	Stock and Asset Purchase Agreement, dated December 19, 2018, by and among Pfizer Inc., GlaxoSmithKline plc and GlaxoSmithKline Consumer Healthcare Holdings Limited. (Pursuant to Item 601(b)(2) of Regulation S-K, the registrant hereby agrees to supplementally furnish to the Securities and Exchange Commission upon request any omitted schedule or exhibit to the Stock and Asset Purchase Agreement.)[1]
3.1	Our Restated Certificate of Incorporation dated April 12, 2004, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended March 28, 2004 (File No. 001-03619).
3.2	Amendment dated May 1, 2006 to Restated Certificate of Incorporation dated April 12, 2004, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended July 2, 2006 (File No. 001-03619).
3.3	Our By-laws, as amended December 18, 2017, are incorporated by reference from our Current Report on Form 8-K filed on December 21, 2017 (File No. 001-03619).
4.1	Indenture, dated as of January 30, 2001, between us and The Chase Manhattan Bank, is incorporated by reference from our Current Report on Form 8-K filed on January 30, 2001 (File No. 001-03619).
4.2	First Supplemental Indenture, dated as of March 24, 2009, between us and The Bank of New York Mellon (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank)), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended June 28, 2009 (File No. 001-03619).

4.3	Second Supplemental Indenture, dated as of June 2, 2009, between us and The Bank of New York Mellon (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank)), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K filed on June 3, 2009 (File No. 001-03619).
4.4	Third Supplemental Indenture, dated as of June 3, 2013, between us and The Bank of New York Mellon (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank)), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K filed on June 3, 2013 (File No. 001-03619).

[1] Application has been made to the Securities and Exchange Commission for confidential treatment of certain portions of this exhibit. Omitted material for which confidential treatment has been requested has been separately filed with the Securities and Exchange Commission.

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4.5	Fourth Supplemental Indenture, dated as of May 15, 2014, between us and The Bank of New York Mellon (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank)), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on May 15, 2014 (File No. 001-03619).
4.6	Fifth Supplemental Indenture, dated as of October 5, 2015, between us and The Bank of New York Mellon (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank)), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on October 6, 2015 (File No. 001-03619).
4.7	Sixth Supplemental Indenture, dated as of June 3, 2016, between us and The Bank of New York Mellon (formerly The Bank of New York (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank (National Association)))), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on June 3, 2016 (File No. 001-03619).
4.8	Seventh Supplemental Indenture, dated as of November 21, 2016, between us and The Bank of New York Mellon (formerly The Bank of New York (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank (National Association)))), as trustee, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on November 21, 2016 (File No. 001-03619).
4.9	Eighth Supplemental Indenture, dated as of March 17, 2017, among us, The Bank of New York Mellon (formerly The Bank of New York (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank (successor to the Chase Manhattan Bank (National Association)))), as trustee, and The Bank of New York Mellon, London Branch, as paying agent, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on March 17, 2017 (File No. 001-03619).
4.10	Ninth Supplemental Indenture, dated as of March 6, 2017, among us, The Bank of New York Mellon (formerly The Bank of New York (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank (National Association)))), as trustee, and The Bank of New York Mellon, London Branch, as paying agent and calculation agent, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on March 6, 2017 (File No. 001-03619).
4.11	Tenth Supplemental Indenture, dated as of December 19, 2017, among us, The Bank of New York Mellon (formerly The Bank of New York (successor to JPMorgan Chase Bank, N.A. (formerly JPMorgan Chase Bank, formerly The Chase Manhattan Bank (National Association)))), as trustee, and The Bank of New York Mellon, London Branch, as paying agent, to Indenture dated as of January 30, 2001, is incorporated by reference from our Current Report on Form 8-K report filed on December 19, 2017 (File No. 001-03619).
4.12	Indenture, dated as of April 10, 1992, between Wyeth (formerly American Home Products Corporation) and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, N.A.), as trustee, is incorporated by reference from Wyeth's Registration Statement on Form S-3 (File No. 33-57339), filed on January 18, 1995.

4.13	Supplemental Indenture, dated as of October 13, 1992, between Wyeth and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, N.A.), as trustee, is incorporated by reference from Wyeth's Registration Statement on Form S-3 (File No. 33-57339), filed on January 18, 1995.
4.14	Fifth Supplemental Indenture, dated as of December 16, 2003, between Wyeth and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, N.A.), as trustee, is incorporated by reference from Wyeth's 2003 Annual Report on Form 10-K (File No. 001-01225).
4.15	Sixth Supplemental Indenture, dated as of November 14, 2005, between Wyeth and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, N.A.), as trustee, is incorporated by reference from Wyeth's Current Report on Form 8-K filed on November 15, 2005 (File No. 001-01225).
4.16	Seventh Supplemental Indenture, dated as of March 27, 2007, between Wyeth and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, N.A.), as trustee, is incorporated by reference from Wyeth's Current Report on Form 8-K filed on March 28, 2007 (File No. 001-01225).
4.17	Eighth Supplemental Indenture, dated as of October 30, 2009, between Wyeth, us and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, formerly The Chase Manhattan Bank), as trustee, to Indenture dated as of April 10, 1992 (as amended on October 13, 1992), is incorporated by reference from our Current Report on Form 8-K filed on November 3, 2009 (File No. 001-03619).
4.18	Indenture, dated as of September 7, 2018, between us and The Bank of New York Mellon, as trustee, is incorporated by reference from our Current Report on Form 8-K filed on September 7, 2018 (File No. 001-03619).
4.19	First Supplemental Indenture, dated as of September 7, 2018, between us and The Bank of New York Mellon, as trustee, is incorporated by reference from our Current Report on Form 8-K filed on September 7, 2018 (File No. 001-03619).
4.20	Except as set forth in Exhibits 4.1-19 above, the instruments defining the rights of holders of long-term debt securities of the Company and its subsidiaries have been omitted.[2]

[2] We agree to furnish to the Securities and Exchange Commission, upon request, a copy of each instrument with respect to issuances of long-term debt of the Company and its subsidiaries.

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10.1	2001 Stock and Incentive Plan is incorporated by reference from our Proxy Statement for the 2001 Annual Meeting of Shareholders (File No. 001-03619).
10.2	Pfizer Inc. 2004 Stock Plan, as Amended and Restated is incorporated by reference from our 2011 Annual Report on Form 10-K (File No. 001-03619).
10.3	Pfizer Inc. 2014 Stock Plan is incorporated by reference from our Proxy Statement for the 2014 Annual Meeting of Shareholders (File No. 001-03619).
10.4	Form of Acknowledgment and Consent and Summary of Key Terms for Stock Option Grants, RSUs and TSRUs is incorporated by reference from our 2017 Annual Report on Form 10-K (File No. 001-03619).
10.5	Form of Executive Grant Letter is incorporated by reference from our 2015 Annual Report on Form 10-K (File No. 001-03619).
10.6	Pfizer Consolidated Supplemental Pension Plan for United States and Puerto Rico Employees is incorporated by reference from our 2017 Annual Report on Form 10-K (File No. 001-03619).
*10.7	Amendment No. 1 to the Pfizer Consolidated Supplemental Pension Plan for United States and Puerto Rico Employees.
10.8	Pfizer Supplemental Savings Plan is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended April 3, 2016 (File No. 001-03619).
10.9	Amendment No. 1 to the Pfizer Supplemental Savings Plan (Amended and Restated as of January 1, 2016), is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended October 1, 2017 (File No. 001-03619).
10.10	Amendment No. 2 to the Pfizer Supplemental Savings Plan is incorporated by reference from our 2017 Annual Report on Form 10-K (File No. 001-03619).
10.11	Amendment No. 3 to the Pfizer Supplemental Savings Plan is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended September 30, 2018 (File No. 001-03619).
*10.12	Amendment No. 4 to the Pfizer Supplemental Savings Plan.
*10.13	Amendment No. 5 to the Pfizer Supplemental Savings Plan.
10.14	Pfizer Inc. Global Performance Plan is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended October 1, 2017 (File No. 001-03619).
10.15	Executive Annual Incentive Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
10.16	Amended and Restated Deferred Compensation Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
10.17	Amendment to Amended and Restated Deferred Compensation Plan, dated June 20, 2013, is incorporated by reference from our 2013 Annual Report on Form 10-K (File No. 001-03619).

10.18	Amendment No. 2 to Amended and Restated Deferred Compensation Plan, dated April 27, 2016, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended July 3, 2016 (File No. 001-03619).
10.19	Wyeth 2005 (409A) Deferred Compensation Plan (frozen as of January 2012), together with all material Amendments, is incorporated by reference from our 2013 Annual Report on Form 10-K (File No. 001-03619).
10.20	Amended and Restated Wyeth Supplemental Employee Savings Plan (effective as of January 1, 2005 and frozen as of January 2012), together with all material Amendments is incorporated by reference from our 2011 Annual Report on Form 10-K (File No. 001-03619).
10.21	Amendment to Amended and Restated Wyeth Supplemental Employee Savings Plan, dated June 20, 2013, is incorporated by reference from our 2013 Annual Report on Form 10-K (File No. 001-03619).
10.22	The form of Indemnification Agreement with each of our non-employee Directors is incorporated by reference from our 1996 Annual Report on Form 10-K (File No. 001-03619).
10.23	The form of Indemnification Agreement with each of the Named Executive Officers identified in our 2018 Proxy Statement is incorporated by reference from our 1997 Annual Report on Form 10-K (File No. 001-03619).
10.24	Letter to Frank A. D'Amelio regarding replacement pension benefit dated August 22, 2007 is incorporated by reference from our Current Report on Form 8-K filed on August 22, 2007 (File No. 001-03619).
10.25	Pfizer Inc. Executive Severance Plan is incorporated by referenced from our Current Report on Form 8-K filed on February 20, 2009 (File No. 001-03619).
*10.26	Amendment No. 1 to Pfizer Inc. Executive Severance Plan.

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10.27	Annual Retainer Unit Award Plan (for Non-Employee Directors) (frozen as of March 1, 2006) as amended, is incorporated by reference from our 2008 Annual Report on Form 10-K (File No. 001-03619).
10.28	Nonfunded Deferred Compensation and Unit Award Plan for Non-Employee Directors, as amended, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended September 28, 2014 (File No. 001-03619).
10.29	Form of Special Award Letter Agreement is incorporated by reference from our Current Report on Form 8-K filed on October 28, 2009 (File No. 001-03619).
10.30	Offer Letter to G. Mikael Dolsten, dated April 6, 2009, is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended April 3, 2011 (File No. 001-03619).
10.31	Form of Special Performance-Based Incentive Award Letter is incorporated by reference from our 2017 Annual Report on Form 10-K (File No. 001-03619).
10.32	Form of Special Performance-Based Incentive Grant Letter is incorporated by reference from our 2017 Annual Report on Form 10-K (File No. 001-03619).
*10.33	Time Sharing Agreement, dated December 17, 2018, by and between Pfizer Inc. and Ian C. Read.
*13	Portions of the 2018 Financial Report, which, except for those sections incorporated by reference, are furnished solely for the information of the SEC and are not to be deemed “filed.”
*21	Subsidiaries of the Company.
*23	Consent of Independent Registered Public Accounting Firm.
*24	Power of Attorney (included as part of signature page).
*31.1	Certification by the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*101.INS	XBRL Instance Document
*101.SCH	XBRL Taxonomy Extension Schema
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase
*101.LAB	XBRL Taxonomy Extension Label Linkbase
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase

*101.DEF XBRL Taxonomy Extension Definition Document

ITEM 16. FORM 10-K SUMMARY

A Form 10-K summary is provided at the beginning of this 2018 Form 10-K, with hyperlinked cross-references. This allows users to easily locate the corresponding items in this 2018 Form 10-K, where the disclosure is fully presented. The summary does not include certain Part III information that is incorporated by reference from our 2019 Proxy Statement.

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SIGNATURES

Under the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report was signed on behalf of the Registrant by the authorized person named below.

Pfizer Inc.

Dated: February 28, 2019 By: /S/ MARGARET M. MADDEN
Margaret M. Madden
Senior Vice President and Corporate Secretary
Chief Governance Counsel

We, the undersigned directors and officers of Pfizer Inc., hereby severally constitute Douglas M. Lankler and Margaret M. Madden, and each of them singly, our true and lawful attorneys with full power to them and each of them to sign for us, in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Under the requirements of the Securities Exchange Act of 1934, this report was signed by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Signature	Title	Date
/S/ ALBERT BOURLA Albert Bourla	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2019
/S/ FRANK A. D'AMELIO Frank A. D'Amelio	Chief Financial Officer, Executive Vice President, Business Operations and Global Supply (Principal Financial Officer)	February 26, 2019
/S/ LORETTA V. CANGIALOSI Loretta V. Cangialosi	Senior Vice President—Controller (Principal Accounting Officer)	February 26, 2019
/S/ IAN C. READ Ian C. Read	Executive Chairman of the Board	February 28, 2019
/S/ DENNIS A. AUSIELLO Dennis A. Ausiello	Director	February 26, 2019
/S/ RONALD E. BLAYLOCK Ronald E. Blaylock	Director	February 27, 2019
/S/ W. DON CORNWELL W. Don Cornwell	Director	February 26, 2019
	Director	

/S/ JOSEPH J. ECHEVARRIA Joseph J. Echevarria		February 26, 2019
/S/ HELEN H. HOBBS Helen H. Hobbs	Director	February 28, 2019

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Signature	Title	Date
/S/ JAMES M. KILTS James M. Kilts	Director	February 26, 2019
/S/ DAN R. LITTMAN Dan R. Littman	Director	February 26, 2019
/S/ SHANTANU NARAYEN Shantanu Narayen	Director	February 26, 2019
/S/ SUZANNE NORA JOHNSON Suzanne Nora Johnson	Director	February 26, 2019
/S/ JAMES C. SMITH James C. Smith	Director	February 26, 2019