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PFIZER INC
Form 10-K
February 23, 2017
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark
One)

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

For the fiscal year ended December 31, 2016

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

10017-5755

(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 |
|-------------------------------|-------------------------|

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 No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232-405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) Yes No

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

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

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

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

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 3, 2016, was approximately \$216 billion. This excludes shares of common stock held by directors and executive officers at July 3, 2016. 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 21, 2017 was 5,951,872,174 shares of common stock, all of one class.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2016 Annual Report to Shareholders

Parts I, II and IV

Portions of the Proxy Statement for the 2017 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 2016 Form 10-K (defined below) refer to Pfizer Inc. and its subsidiaries. We also have used several other terms in this 2016 Form 10-K, most of which are explained or defined below.

| | |
|-----------------------|---|
| 2016 Financial Report | Exhibit 13 to this 2016 Form 10-K |
| 2016 Form 10-K | This Annual Report on Form 10-K for the fiscal year ended December 31, 2016 |
| 2017 Proxy Statement | Proxy Statement for the 2017 Annual Meeting of Shareholders |
| ACA | U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act |
| 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 US, Inc. |
| BLA | Biologics License Application |
| BMS | Bristol-Myers Squibb Company |
| cGMPs | current Good Manufacturing Practices |
| CFDA | China Food and Drug Administration |
| DEA | U.S. Drug Enforcement Agency |
| Developed Markets | U.S., Western Europe, Japan, Canada, Australia, Scandinavian countries, South Korea, 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, Africa, Eastern Europe, Central Europe, the Middle East 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 |
| HIS | Hospira Infusion Systems |
| Hospira | Hospira, Inc. |
| ICU Medical | ICU Medical, Inc. |
| IH | Innovative Health |
| IPR&D | In-process Research and Development |
| LOE | Loss of Exclusivity |
| MCO | Managed Care Organization |
| Medivation | Medivation, Inc. |
| NDA | New Drug Application |
| NYSE | New York Stock Exchange |
| OTC | over-the-counter |
| PBM | Pharmacy Benefit Manager |
| PMDA | Pharmaceuticals and Medical Device Agency in Japan |
| R&D | Research and Development |
| SEC | U.S. Securities and Exchange Commission |

| | |
|------|------------------------------------|
| U.K. | United Kingdom |
| U.S. | United States |
| WRD | Worldwide Research and Development |

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Pfizer at a Glance Working together for a healthier world
~\$52.8 Billion in Revenues in 2016

8 Products with Direct Product Sales of Greater than \$1 Billion and IH Alliance Revenues of Greater than \$1 Billion in 2016

2 Distinct Business Segments - Pfizer Innovative Health (~\$29.2 Billion 2016 Revenues) / Pfizer Essential Health (~\$23.6 Billion 2016 Revenues)

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

5 Pfizer Essential Health Product Categories - Global Brands (Legacy Established Products & Peri-LOE Products), Sterile Injectable Pharmaceuticals, Infusion Systems (through February 2, 2017), Biosimilars and Pfizer CentreOne

>125 Countries Where We Sell Our Products

96 Projects in Clinical Research & Development⁽¹⁾

~\$7.9 Billion 2016 R&D Expense

63 Manufacturing Sites Worldwide Operated by PGS⁽²⁾

~96,500 Employees Globally⁽²⁾

⁽¹⁾ As of January 31, 2017

⁽²⁾ As of December 31, 2016

This summary does not include information that will be incorporated by reference into Part III of this 2016 Form 10-K from our 2017 Proxy Statement.

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PART I

ITEM 1. BUSINESS

GENERAL

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 of innovating to bring therapies to patients that extend and significantly improve their 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.

On February 3, 2017, we completed the sale of our global infusion therapy 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 includes IV pumps, solutions and devices. Under the terms of the agreement, we received 3.2 million newly issued shares of ICU Medical common stock, which we valued at approximately \$430 million (based upon the closing price of ICU Medical common stock on the closing date less a discount for lack of marketability), a promissory note from ICU Medical in the amount of \$75 million and net cash of approximately \$200 million before customary adjustments for net working capital. In addition, we are entitled to receive a contingent amount of up to an additional \$225 million in cash based on ICU Medical's achievement of certain cumulative performance targets for the combined company through December 31, 2019. After receipt of the ICU Medical shares, we own approximately 16.4% of ICU Medical as of the closing date. We have agreed to certain restrictions on transfer of our ICU Medical shares for 18 months. For additional information, see Notes to Consolidated Financial Statements—Note 2B. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Assets and Liabilities Held for Sale in our 2016 Financial Report.

On December 22, 2016, which falls in the first fiscal quarter of 2017 for our international operations, we acquired the development and commercialization rights to AstraZeneca's small molecule anti-infectives business, primarily outside

the U.S., including the commercialization and development rights to the newly approved EU drug Zavicefta™ (ceftazidime-avibactam), the marketed agents Merrem™/Meronem™ (meropenem) and Zinforo™ (ceftaroline fosamil), and the clinical development assets aztreonam-avibactam and ceftaroline fosamil-avibactam. Under the terms of the agreement, we made an upfront payment of approximately \$550 million to AstraZeneca upon the close of the transaction and will make a deferred payment of \$175 million in January 2019. In addition, AstraZeneca is eligible to receive up to \$250 million in milestone payments, up to \$600 million in sales-related payments, as well as tiered royalties on sales of Zavicefta™ and aztreonam-avibactam in certain markets.

On September 28, 2016, we acquired Medivation for approximately \$14.3 billion in cash (\$13.9 billion, net of cash acquired). Medivation is now a wholly-owned subsidiary of Pfizer. Medivation is a biopharmaceutical company focused on developing and commercializing small molecules for oncology. Medivation's portfolio includes Xtandi (enzalutamide), an androgen receptor inhibitor that blocks multiple steps in the androgen receptor signaling pathway within tumor cells, and two development-stage oncology assets. Xtandi is being developed and commercialized through a collaboration between Pfizer and Astellas. Astellas has exclusive commercialization rights for Xtandi outside the U.S. For additional information, see the Notes to Consolidated Financial Statements—Note 2A. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Acquisitions in our 2016 Financial Report.

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 now a wholly-owned subsidiary of Pfizer. Anacor is a biopharmaceutical company focused on novel small-molecule therapeutics derived from its boron chemistry platform. Anacor's crisaborole, a non-steroidal topical PDE-4 inhibitor with anti-inflammatory properties, was approved by the FDA on December 14, 2016 under the trade name, Eucrisa. For additional information, see the Notes to Consolidated Financial Statements—Note 2A. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Acquisitions in our 2016 Financial Report.

On September 3, 2015, we acquired Hospira, a leading provider of sterile injectable drugs and infusion technologies as well as a provider of biosimilars, for approximately \$16.1 billion in cash (\$15.7 billion, net of cash acquired). The combination of local Pfizer and Hospira entities may be pending in various jurisdictions and integration is subject to completion of various local legal and regulatory steps. For additional information, see the Notes to Consolidated Financial Statements—Note 2A. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Acquisitions in our 2016 Financial Report.

For a further discussion of our strategy and our business development initiatives, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Our Business Development Initiatives section in our 2016 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 regulates the scientific evaluation, supervision and safety monitoring of our products, and employs a centralized procedure for approval of drugs for the EU and the European Economic Area countries. 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, such as the FDA or EMA, before they begin to conduct their application review process and/or issue their final approval. For additional information, see the Government Regulation and Price Constraints section below.

Note: Some amounts in this 2016 Form 10-K may not add due to rounding. All percentages have been calculated using unrounded amounts.

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AVAILABLE INFORMATION AND PFIZER WEBSITE

Our website is located at www.pfizer.com. This 2016 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 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 such material with, or furnish it to, the SEC.

Throughout this 2016 Form 10-K, we “incorporate by reference” certain information from other documents filed or to be filed with the SEC, including our 2017 Proxy Statement and the 2016 Financial Report, portions of which are filed as Exhibit 13 to this 2016 Form 10-K, and which also will be contained in Appendix A to our 2017 Proxy Statement. The SEC allows us to disclose important information by referring to it in that manner. Please refer to such information. Our 2016 Annual Report to Shareholders consists of the 2016 Financial Report and the Corporate and Shareholder Information attached to the 2017 Proxy Statement. Our 2016 Financial Report will be available on our website on or about February 23, 2017. Our 2017 Proxy Statement will be available on our website on or about March 16, 2017.

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; as well as Chief Executive Officer and Chief Financial Officer certifications, 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 10017-5755. 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 2016 Form 10-K. Pfizer’s references to the URLs for websites are intended to be inactive textual references only.

TABLE OF CONTENTSCOMMERCIAL OPERATIONS

We manage our commercial operations through two distinct business segments: Pfizer Innovative Health (IH) and Pfizer Essential Health (EH), which was previously known as Established Products. Beginning in the second quarter of 2016, we reorganized our operating segments to reflect that we now manage our innovative pharmaceutical and consumer healthcare operations as one business segment, IH. From the beginning of our fiscal year 2014 until the second quarter of 2016, these operations were managed as two business segments: the Global Innovative Products segment and the Vaccines, Oncology and Consumer Healthcare segment. We have revised prior-period information to reflect the reorganization. The IH and EH operating segments are each led by a single manager. Each operating segment has 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 has a geographic footprint across developed and emerging markets.

Some additional information about our business segments follows:

Pfizer Innovative Health

IH focuses 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 include internal medicine, vaccines, oncology, inflammation & immunology, rare diseases and consumer healthcare.

Pfizer Essential Health

EH includes 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, through February 2, 2017, infusion systems. EH also includes an R&D organization, as well as our contract manufacturing business.

Leading brands include:

- Prevnar 13
- Xeljanz
- Eliquis
- Lyrica (U.S., Japan and certain other markets)
- Enbrel (outside the U.S. and Canada)
- Viagra (U.S. and Canada)
- Ibrance
- Xtandi
- Several OTC consumer products (e.g., Advil and Centrum)

Leading brands include:

- Lipitor
- Premarin family
- Norvasc
- Lyrica (Europe, Russia, Turkey, Israel and Central Asia countries)
- Celebrex
- Pristiq
- Several sterile injectable products

We expect that the IH biopharmaceutical portfolio of innovative, largely patent-protected, in-line and newly launched products will be sustained by ongoing investments to develop promising assets and targeted business development in areas of focus to ensure a pipeline of highly-differentiated product candidates in areas of unmet medical need. The assets managed by IH are science-driven, highly differentiated and generally require a high level of engagement with healthcare providers and consumers.

EH is expected to generate strong consistent cash flow by providing patients around the world with access to effective, lower-cost, high-value treatments. EH leverages our biologic development, regulatory and manufacturing expertise to seek to advance its biosimilar development portfolio. Additionally, EH leverages capabilities in formulation development and manufacturing expertise to help advance its generic sterile injectables portfolio. EH may also engage in targeted business development to further enable its commercial strategies.

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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 Geographic Area in the Analysis of the Consolidated Statements of Income section, and the Analysis of Operating Segment Information section in our 2016 Financial Report, which are incorporated by reference.

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INNOVATIVE HEALTH

We recorded direct product sales of more than \$1 billion for each of six IH products in 2016 (Pevnar 13/Prevenar 13, Lyrica (outside all of Europe, Russia, Turkey, Israel and Central Asia countries), Enbrel (outside the U.S. and Canada), Ibrance, Viagra (U.S. and Canada) and Sutent), and for each of five IH products in 2015 and 2014 (Pevnar 13/Prevenar 13, Lyrica (outside all of Europe, Russia, Turkey, Israel and Central Asia countries), Enbrel (outside the U.S. and Canada), Viagra (U.S. and Canada) and Sutent). We also recorded more than \$1 billion in IH Alliance revenues in 2016 and 2015 (primarily Eliquis). See Item 1A. Risk Factors—Dependence on Key In-Line Products below.

Geographic Revenues for Innovative Health*

*Dev Int'l = Developed Markets except U.S.; Em Mkts = Emerging Markets

For additional information regarding the revenues of our IH business, including revenues of major 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—Major Products and —Revenues—Selected Product Descriptions sections in our 2016 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 2016 Financial Report.

The key therapeutic areas comprising our IH business segment include:

Internal Medicine

For a discussion of certain of our key Internal Medicine products, including Lyrica (outside all of Europe, Russia, Turkey, Israel and Central Asia countries), Viagra (U.S. and Canada), Chantix/Champix and Eliquis (jointly developed and commercialized with BMS), see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2016 Financial Report.

Vaccines

For a discussion of certain of our key Vaccine products, including Pevnar 13/Prevenar 13, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2016 Financial Report.

Oncology

For a discussion of certain of our key Oncology products, including Ibrance, Sutent, Xalkori, Inlyta and Xtandi (jointly developed and commercialized with Astellas), see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2016 Financial Report.

Inflammation and Immunology

For a discussion of certain of our key Inflammation and Immunology products, including Enbrel (outside the U.S. and Canada) and Xeljanz, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2016 Financial Report.

Rare Diseases

For a discussion of certain of our key Rare Diseases products, including BeneFix, Genotropin, and Refacto AF/Xyntha, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions

section in our 2016 Financial Report.

Consumer Healthcare

According to Euromonitor International's retail sales data, in 2016, Pfizer's Consumer Healthcare business was the fourth-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.

Major categories and product lines in our Consumer Healthcare business include:

Dietary Supplements: Centrum brands (including Centrum, Centrum Silver, Centrum Men's and Women's, Centrum MultiGummies, Centrum VitaMints, Centrum Specialist, Centrum Flavor Burst and Centrum Kids), Caltrate and Emergen-C;

Pain Management: Advil brands (including Advil, Advil PM, Advil Liqui-Gels, Advil Film Coated, Advil Menstrual Pain, Children's Advil, Infants' Advil and Advil Migraine) and ThermaCare;

Gastrointestinal: Nexium 24HR/Nexium Control and Preparation H; and

Respiratory and Personal Care: Robitussin, Advil Cold & Sinus, Advil Sinus Congestion & Pain, Dimetapp and ChapStick.

ESSENTIAL HEALTH

We recorded direct product sales of more than \$1 billion for each of two EH products in 2016 (Lipitor and the Premarin family of products), three EH products in 2015 (Lipitor, Lyrica (Europe, Russia, Turkey, Israel and Central Asia) and the Premarin family of products) and six EH products in 2014 (Celebrex, Lipitor, Lyrica (Europe, Russia, Turkey, Israel and Central Asia), Zyvox, Norvasc and the Premarin family of products). See Item 1A. Risk Factors—Dependence on Key In-Line Products below.

Geographic Revenues for Essential Health*

*Dev Int'l = Developed Markets except U.S.; Em Mkts = Emerging Markets

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For additional information regarding the revenues of our EH business, including revenues of major 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—Major Products and —Revenues—Selected Product Descriptions sections in our 2016 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 2016 Financial Report.

The product categories in our EH business segment include:

Global Brands, which includes:

Legacy Established Products: includes products that have lost patent protection (excluding Sterile Injectable Pharmaceuticals and Peri-LOE Products); and

Peri-LOE Products: includes products that have recently lost or are anticipated to soon lose patent protection. These products primarily include Lyrica in certain developed Europe markets, Pristiq globally, Celebrex, Zyvox and Revatio in most developed markets, Vfend and Viagra in certain developed Europe markets and Japan, and Inspira in the EU;

Sterile Injectable Pharmaceuticals: includes generic injectables and proprietary specialty injectables (excluding Peri-LOE Products);

Infusion Systems (through February 2, 2017): includes Medication Management Systems products composed of infusion pumps and related software and services, as well as intravenous infusion products, including large volume intravenous solutions and their associated administration sets;

Biosimilars: includes Inflectra/Remsima (biosimilar infliximab) in the U.S. and certain international markets, Nivestim (biosimilar filgrastim) in certain European, Asian and Africa/Middle East markets and Retacrit (biosimilar epoetin zeta) in certain European and Africa/Middle East markets; and

Pfizer CentreOne: includes (i) revenues from legacy Pfizer's contract manufacturing and active pharmaceutical ingredient sales operation (previously known as Pfizer CentreSource), including revenues related to our manufacturing and supply agreements with Zoetis Inc.; and (ii) revenues from legacy Hospira's One-2-One sterile injectables contract manufacturing operation.

For a discussion of certain of our key EH products, including Lipitor, the Premarin family of products, Norvasc, Lyrica (Europe, Russia, Turkey, Israel and Central Asia), Celebrex, Pristiq, Zyvox and Inflectra, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2016 Financial Report.

ALLIANCE REVENUES

We are party to collaboration and/or co-promotion agreements relating to certain biopharmaceutical products, including Eliquis and Xtandi. Eliquis has been jointly developed and is being commercialized in collaboration with BMS. The two companies share commercialization expenses and profit/losses equally on a global basis. In April 2015, we signed an agreement with BMS to transfer full commercialization rights in certain smaller markets to us, beginning in the third quarter of 2015. Xtandi is being developed and commercialized in 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. Pfizer and Astellas also 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). Collaboration rights for Enbrel (in the U.S. and Canada), Spiriva and Rebif have expired. For additional information, including a description of certain of these collaboration and co-promotion agreements and their expiration dates, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions and the Overview of Our Performance,

Operating Environment, Strategy and Outlook—Our Operating Environment—Industry-Specific Challenges—Intellectual Property Rights and Collaboration/Licensing Rights sections in our 2016 Financial Report and Item 1A. Risk Factors—Dependence on Key In-Line Products below.

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RESEARCH AND DEVELOPMENT

Innovation by our R&D organization is very important to our success. Our goal is to discover, develop and bring to market innovative products that address major unmet medical needs.

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. Our R&D spending is conducted through a number of matrix organizations. Our WRD organization is generally responsible for research projects for our IH business until proof-of-concept is achieved and then for transitioning those projects to the IH segment via the GPD organization, which was formed in early 2016, for possible clinical and commercial development.

The GPD organization is a new, unified center for late-stage development for our innovative products. GPD is expected to enable more efficient and effective development and enhance our ability to accelerate and progress assets through our pipeline. GPD combines certain previously separate development-related functions from the IH business and the WRD organization to achieve a development capability that is expected to deliver high-quality, efficient, and well-executed clinical programs by enabling greater speed, greater cost efficiencies, and reduced complexity across our development portfolio.

The WRD and GPD organizations also have responsibility for certain science-based and other end-to-end platform-services organizations, which provide technical expertise and other services to the various R&D projects, including EH R&D projects. These organizations include science-based functions (which are part of our WRD organization), such as Pharmaceutical Sciences, Medicinal Chemistry, Regulatory and Drug Safety. As a result, within each of these functions, we are able to migrate resources among projects, candidates and/or targets in any therapeutic area and in most phases of development, allowing us to react quickly in response to evolving needs.

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 will deliver value in the near term and over time. For additional information regarding our R&D operations, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Research and Development Operations and Costs and Expenses—Research and Development (R&D) Expenses—Description of Research and Development Operations sections in our 2016 Financial Report.

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 promise, innovating new 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 primarily focuses on:

- Biosimilars;
- Inflammation and Immunology;
- Metabolic Disease and Cardiovascular Risks;
- Neuroscience;
- Oncology;
- Rare Diseases; and
- Vaccines.

We also 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 collaborations and 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 enable us to advance our own products as well as in-licensed or acquired products.

Our R&D Pipeline and Competition

Innovation is critical to the success of our company, and drug discovery and development is time-consuming, expensive and unpredictable. According to the Pharmaceutical Benchmarking Forum, out of 20 compounds entering preclinical development, only one is approved by a regulatory authority in a major market (U.S., the EU or Japan). The process from early discovery or design to development to regulatory approval can take more than ten years. 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.

As of January 31, 2017, 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 2016 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.

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INTERNATIONAL OPERATIONS

We have significant operations outside the U.S. Operations in developed and emerging markets are 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.

We sell our products in over 125 countries. Revenues from operations outside the U.S. of \$26.5 billion accounted for 50% of our total revenues in 2016. Japan is our largest national market 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 2016 Financial Report, and the table captioned Revenues by Segment and Geographic Area in our 2016 Financial Report. Those tables are incorporated by reference.

Revenues by National Market

Our international operations are subject, in varying degrees, to a number of risks inherent in carrying on business in other countries. These include, among other things, currency fluctuations, capital and exchange control regulations, expropriation and other restrictive government actions. See Item 1A. Risk Factors—Risks Affecting 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 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 7E. Financial Instruments: Derivative Financial Instruments and Hedging Activities in our 2016 Financial Report, as well as the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2016 Financial Report. Those sections of our 2016 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, PBMs 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.

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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 Centers for Disease Control and Prevention, wholesalers and individual provider offices. We seek to gain access for our products on healthcare authority and MCO formularies, which are lists of approved medicines available to members of the MCOs. MCOs use various benefit designs, such as tiered co-pays for formulary products, to drive utilization of products in preferred formulary positions. We also work with MCOs to assist them with disease management, patient education and other tools that help their medical treatment routines.

In 2016, our top three biopharmaceutical wholesalers accounted for approximately 39% of our total revenues (and approximately 76% of our total U.S. revenues).

% of 2016 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.

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 Government Regulation and Price Constraints—Intellectual Property below.

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. 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.

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| Drug | U.S. Basic Product Patent Expiration Year | Major EU Basic Product Patent Expiration Year | Japan Basic Product Patent Expiration Year |
|---------------------------|--|--|---|
| Viagra | 2012 ⁽¹⁾ | 2013 | 2013 ⁽¹⁾ |
| Lyrica | 2018 | 2014 ⁽²⁾ | 2022 |
| Chantix | 2020 | 2021 | 2022 |
| Xeljanz | 2020 | N/A ⁽³⁾ | 2025 |
| Sutent | 2021 | 2021 | 2024 |
| Eliquis ⁽⁴⁾ | 2023 | 2026 | 2026 |
| Ibrance | 2023 | 2023 | N/A ⁽⁵⁾ |
| Inlyta | 2025 | 2025 | 2025 |
| Prevnar 13/Prevenar 13 | 2026 | 2026 ⁽⁶⁾ | 2029 |
| Eucrisa | 2026 | N/A ⁽⁷⁾ | N/A ⁽⁷⁾ |
| Xtandi ⁽⁸⁾ | 2027 | * ⁽⁸⁾ | * ⁽⁸⁾ |
| Xalkori | 2029 | 2027 | 2028 |

In addition to the basic product patent covering Viagra, which expired in 2012, Viagra is covered by a U.S. method-of-treatment patent which, including the six-month pediatric exclusivity period associated with Revatio ⁽¹⁾(which has the same active ingredient as Viagra), expires in 2020. However, as a result of a patent litigation settlement, Teva Pharmaceuticals USA, Inc. will be allowed to launch a generic version of Viagra in the U.S. in December 2017, or earlier under certain circumstances. The corresponding method-of-treatment patent covering Viagra in Japan expired in May 2014.

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

⁽³⁾ The Xeljanz marketing authorization application has been filed and is under review in the EU.

⁽⁴⁾ Eliquis was developed and is being commercialized in collaboration with BMS.

⁽⁵⁾ The Ibrance marketing authorization application has been filed and is under review in Japan.

The EU patent that covers the combination of the 13 serotype conjugates of Prevenar 13 has been revoked ⁽⁶⁾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.

⁽⁷⁾ Eucrisa is not approved in the EU and Japan.

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

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 a description of certain of our co-promotion agreements and their expiration dates, and a further discussion of our products experiencing, or expected to experience in 2017, 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 2016 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, Xeljanz and Xtandi. For additional information, see the Notes to Consolidated Financial Statements—Note 17A1. Commitments and Contingencies—Legal Proceedings—Patent Litigation in our 2016 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.

Biotechnology Products

Our biotechnology products, including BeneFIX, ReFacto, Xyntha 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 biotechnology 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, which was approved under the FFDA.

Biosimilars are versions of biologic medicines that have been developed and proven to be similar to the original biologic in terms of safety and efficacy and to have no clinically meaningful differences. 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 in 2010 of the ACA, a framework for such approval exists in the U.S. The regulatory implementation of these ACA provisions is ongoing, and, since 2015, the FDA approved a number of biosimilars, including Inflectra (infliximab-dyyb). Pfizer has exclusive commercialization rights to Inflectra from Celltrion Inc. and Celltrion Healthcare, Co., Ltd. (collectively, Celltrion) in the U.S., Canada and certain other territories. Pfizer also shares Inflectra commercialization rights with Celltrion in Europe. For additional information on Inflectra, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions—Inflectra/Remsima section in our 2016 Financial Report. For additional information on the ACA's approval framework for biosimilars, see Government Regulation and Price Constraints—Biosimilar Regulation below.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In 2013, the EMA approved the first biosimilar of a monoclonal antibody, and in January 2016, the European Commission approved an etanercept biosimilar referencing Pfizer's Enbrel. In Japan, the regulatory authority has granted marketing authorizations for certain biosimilars pursuant to a guideline for biosimilar approvals issued in 2009.

If competitors are able to obtain marketing approval for biosimilars that reference our biotechnology products, our biotechnology products may become subject to competition from these biosimilars, with attendant competitive pressure, and price reductions could follow. Expiration or successful challenge of applicable patent rights could trigger this competition, assuming any relevant exclusivity period has expired. However, biosimilar manufacturing is complex. At least initially upon approval of a biosimilar competitor, biosimilar competition with respect to biologics may not be as significant as generic competition with respect to small molecule drugs.

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 biosimilar medicines. As such, a better-defined biosimilars approval pathway will assist us in pursuing approval of our own biosimilar products in the U.S. See Item 1A. Risk Factors—Biotechnology Products below.

We may face litigation with respect to the validity and/or scope of patents relating to our biotechnology products. Likewise, as we develop and manufacture biosimilars and seek to launch products, 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, global protection of intellectual property rights has been improving. For additional information, see Government Regulation and Price Constraints—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 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.

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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 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).

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-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 a period of exclusivity as the only generic or biosimilar provider.

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 283 million people in the U.S. now have some form of health insurance coverage. Due to the expansion of health insurance coverage (see 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 have recently introduced additional measures such as new-to-market blocks, exclusion lists, indication-based pricing, and value-based pricing/contracting to improve their

cost containment efforts. We are closely monitoring these new 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. In 2015, the FDA approved the first biosimilar and MCOs are evaluating the appropriate placement of these new agents 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

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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. In 2017, there likely will be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. 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 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 do not generally need to conduct clinical trials and can market a competing version of our product after the expiration or loss of our patent and often charge much less.

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.

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. No serious shortages or delays of raw materials were encountered in 2016, and none are expected in 2017. We have successfully secured the materials necessary to meet our requirements where there have been short-term imbalances between supply and demand, but generally at higher prices than those historically paid.

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. **Commitments and Contingencies—Legal Proceedings** in our 2016 Financial Report. Criminal charges, substantial fines and/or civil penalties, warning letters and product recalls or seizures, 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 post-market regulations by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling and storage of our products, record keeping, advertising and promotion. Our products are also subject to post-market surveillance under the FFDCAs and its implementing regulations with respect to drugs, as well as the Public Health Service Act and its implementing regulations with respect to biologics. The FDA also regulates our Consumer Healthcare products.

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.

Before a new biopharmaceutical product may be marketed in the U.S., the FDA must approve an NDA for a new drug or a BLA for a biologic. The steps required before the FDA will approve an NDA or BLA generally include preclinical studies followed by multiple stages of clinical trials conducted by the study sponsor; sponsor submission of the application to the FDA for review; the FDA's review of the data to assess the drug's safety and effectiveness; and the FDA's inspection of the facilities where the product will be manufactured.

Before a generic drug may be marketed in the U.S., the FDA must approve an ANDA. The ANDA review process typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the referenced drug previously approved through the NDA process. The ANDA process, however, does require the sponsor to conduct one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved referenced brand drug, submission of an application to the FDA for review, and the FDA's inspection of the facilities where the product will be manufactured.

As a condition of product approval, the FDA may require a sponsor to conduct post-marketing clinical studies, known as Phase 4 studies, and surveillance programs to monitor the effect of the approved product. The FDA may limit further marketing of a product based on the results of these post-market studies and programs. Any modifications to a drug or biologic, including new indications or changes to labeling or manufacturing processes or facilities, may require the submission and approval of a new or supplemental NDA or BLA before the modification can be implemented, which may require that we develop additional data or conduct additional preclinical studies and clinical trials. Our ongoing manufacture and distribution of drugs and biologics is subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences associated with the product, and adherence to cGMPs, which regulate all aspects of the manufacturing process. We are also subject to numerous regulatory requirements relating to the advertising and promotion of drugs and biologics, including, but not limited to, standards and regulations for direct-to-consumer advertising. Failure to comply with the applicable regulatory requirements governing the manufacture and marketing of our products may subject us to administrative or judicial sanctions, including warning letters, product recalls or seizures, 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, since 2015, approved a number of biosimilars, including Inflectra. Through those approvals and the issuance of draft and final guidance, the FDA has begun to address open questions about the naming convention for biosimilars and the use of data from a non-U.S.-licensed comparator to demonstrate biosimilarity and/or interchangeability with a U.S.-licensed reference product. Over the next several years, the FDA is expected to issue additional draft and final guidance documents impacting biosimilars.

In 2017, there likely will be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. If the ACA is repealed, substantially modified, or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation.

Sales and Marketing. The marketing practices of U.S. biopharmaceutical companies are generally subject to various federal and state healthcare laws that are intended to prevent fraud and abuse in the healthcare industry and 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 any remuneration to generate business, including the purchase or prescription 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 services to third-party payers (including Medicare and Medicaid) that are false or fraudulent. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to any particular industry practices, including the marketing practices of pharmaceutical companies. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions and/or exclusion from federal health care programs (including Medicare and Medicaid). The federal government and various states have also enacted laws to regulate the sales and marketing practices of pharmaceutical companies. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require disclosure to the federal or state government and 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 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 2016 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 2016 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 in certain states. 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 competitive and pricing pressures on pharmaceutical manufacturers, including us.

Healthcare Reform. The U.S. and state governments continue to propose and pass legislation designed to regulate the healthcare industry. In March 2010, the U.S. Congress enacted the ACA, which included changes that significantly affected the pharmaceutical industries, such as:

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increasing drug rebates paid to state Medicaid programs under the Medicaid Drug Rebate Program for brand name and generic prescription drugs and extending those rebates to Medicaid managed care; requiring pharmaceutical manufacturers to provide discounts on brand name prescription drugs sold to Medicare beneficiaries whose prescription drug costs cause the beneficiaries to be subject to the Medicare Part D coverage gap; and imposing an annual fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid.

The ACA included provisions designed to increase the number of Americans covered by health insurance. Specifically, since 2014, the ACA has required most individuals to maintain health insurance coverage or potentially to pay a penalty for noncompliance and has offered states the option of expanding Medicaid coverage to additional individuals. The implementation of the coverage expansion had a negligible impact on Pfizer's 2016 revenues.

The ACA also establishes an Independent Payment Advisory Board (IPAB) to reduce the per capita rate of growth in Medicare spending by proposing changes to Medicare payments if expenditures exceed certain targets. The threshold for triggering IPAB proposals was not reached in 2016, so no adjustments will be made under the IPAB until 2019 at the earliest. If no IPAB members are nominated, the duties of the IPAB will default to the Secretary of the Department of Health and Human Services.

Additionally, efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products could adversely affect our business if implemented. There has recently been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. 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 continue to work with stakeholders to ensure access to medicines within an efficient and affordable healthcare system.

Adoption of other new legislation at the federal or state level could further affect demand for, or pricing of, our products. In 2017, we may face uncertainties because there likely will be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. There is no assurance that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. We will continue to actively work with law makers and advocate for solutions that effectively improve patient health outcomes and lower costs to the healthcare system.

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 and Pharmacovigilance. 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 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, post-marketing 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. These requirements delay marketing authorization in those countries relative to the U.S. and Europe.

China's regulatory system is unique in many ways, and its drug development and registration requirements are not always consistent with U.S. or other international standards. It is common to see treatments entering the Chinese market two to eight years behind first marketing in the U.S. and Europe, because historically China has only issued import drug licenses to treatments approved by a foreign regulatory authority. In addition, to obtain marketing approvals for new drugs in China, a clinical trial authorization issued by the CFDA is required for the conduct of Phase I to III clinical trials. Foreign applicants of imported drugs, if including China-originated data in their Multi-Regional Clinical Trials and meeting the relevant technical review requirements, may receive case-by-case additional local clinical trial waivers. Oral generics, on the other hand, only need to undergo bioequivalence studies upon a filing for record with the CFDA, while sterile injectable generics may need local confirmatory trials for regulatory approval. A Chinese drug license will only be granted if, following review, the CFDA determines that the clinical data confirm the drug's safety and effectiveness.

In the EU, there is detailed legislation and guidance on pharmacovigilance, which has been 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 direct cost to consumers and regulate pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored healthcare system, particularly under recent global economic pressures. Governments, including the different EU Member States, may use a variety of cost-containment measures for our pharmaceutical products, including price cuts, mandatory rebates, value-based pricing, and international reference pricing (i.e., the practice of many countries linking their regulated medicine prices to those of other countries). This international patchwork of price regulation and differing economic conditions and assessments of value across countries has led to different prices in different countries 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) and the Organization for Economic Co-operation and Development (OECD), are increasing policy pressures and scrutiny of international

pharmaceutical pricing through issuing reports and policy recommendations (e.g., 2016 UN High Level Panel Report on Access to Medicines, and 2017 OECD Report on New Health Technologies—Managing Access, Value and Sustainability). Government adoption of these recommendations may lead to additional pricing pressures.

In Japan, the government recently released a basic framework for pharmaceutical pricing that may lead to the adoption of cost effectiveness assessments and pricing reviews. In China, government-set price caps were lifted for the vast majority of drug products on June 1, 2015. However, the government continues to exercise indirect price control by setting reimbursement standards through a negotiation mechanism between drug manufacturers and social insurance administrations. In addition, the CFDA is now asking some companies to enter into pricing commitments as a condition for regulatory approval.

EU Regulatory Changes. The EU adopted a new Clinical Trials Regulation in May 2014, which is expected to come into effect by October 2018. This new 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.

In another effort to increase the public availability of clinical trial results, the EMA adopted a new policy on Publication of Clinical Data for Medicinal Products for Human Use, which became effective January 1, 2015 and is now being actively implemented. Under this policy, the EMA now proactively publishes clinical trial data from application dossiers for new marketing authorizations, including data from trials taking place outside the EU, after the EMA has made a decision on the marketing authorization. The policy includes limited exceptions for commercially confidential information and the exclusion of any protected personal data.

Brexit. In June 2016, the U.K. electorate voted in a referendum to leave the EU, which is commonly referred to as “Brexit”. At present, it is unclear whether the U.K. will remain within, or affiliated to, the EU system of medicines approval and regulation, or separate itself completely. Immediately following Brexit, EU laws are expected to continue to apply until amended or repealed by the U.K. Parliament. It is however probable that the EMA, currently in London, will have to relocate to an EU member state, many of which have already bid to become the new host country. For additional information on Brexit, see the Analysis of Financial Condition, Liquidity and Capital Resources—Global Economic Conditions—U.K. in our 2016 Financial Report.

China Regulatory Changes. In an effort to encourage drug innovation and reduce the existing drug approval backlogs, the CFDA unveiled several reform initiatives for China’s drug approval system. The regulator now divides drugs into new drugs and generics, with the definition for new drugs changed from “drugs never marketed in China” to “drugs that are neither marketed in or outside China.” This change in definition creates more incentives for China’s domestic drug manufacturers than for multinational firms, because imported drugs first marketed outside China are no longer considered new drugs. Furthermore, the revised rules do not clarify whether foreign regulatory approval is still required for imported drug final approval in China. Another major initiative is the piloting of the “marketing authorization holder” system in ten provinces in China, where the market authorization/drug license holders are no longer required to be the actual manufacturers. The “marketing authorization holder” system will allow for more flexibilities in contract manufacturing arrangements and asset transfers, but it is not applicable to imported drugs.

A number of other policy changes are expected to be able to streamline and accelerate domestic and imported drug approvals in China. These changes include introducing an umbrella clinical trial authorization for all three phases of registration studies (instead of the original phase-by-phase approvals), implementing a filing/recordation system for bioequivalence studies on generics (instead of the original review and approval system), and admitting more types of drugs as innovative drugs eligible for the fast track/green channel approval pathway.

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, in 2013, the EFPIA released its disclosure code of transfers of value to healthcare professionals and organizations. The code requires all members of EFPIA, including Pfizer, to disclose transfers of

value to healthcare professionals and healthcare organizations beginning in 2016, covering the relevant transfers in 2015.

Intellectual Property. The World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (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, a number of 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 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. There is considerable political and economic pressure to weaken existing 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.

Canada's intellectual property regime for drugs provides some level of patent protection and data exclusivity (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, Canadian authorities reluctantly agreed to introduce a right of appeal, a form of patent term restoration and to elevate the current data protection to a treaty obligation, further aligning its intellectual property regime to the EU.

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 2016. 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.

In India, policies favoring compulsory licensing of patents, the increasing 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.

In South Korea, the laws and regulations for the patent-regulatory approval linkage system was implemented as part of the U.S.-Korea Free Trade Agreement in 2012. The Korean patent-regulatory approval linkage system includes biologics.

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. Commitments and Contingencies—Legal Proceedings—Commercial and Other Matters in our 2016 Financial Report. As a result, we incurred capital and operational expenditures in 2016 for environmental compliance purposes and for the clean-up of certain past industrial activity as follows:

- environment-related capital expenditures— \$27 million; and
- other environment-related expenses— \$126 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. 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 these potential 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 2016 Financial Report, is incorporated by reference.

EMPLOYEES

In our innovation-intensive business, our employees are vital to our success. We believe we have good relationships with our employees. As of December 31, 2016, we employed approximately 96,500 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 2016, 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 2016 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 2016 Form 10-K and in our 2016 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,” “target,” “forecast,” “aim” and other words and terms of similar meaning or by using future dates in connection with any discussion of, among other things, our anticipated future operating and financial performance, business plans and prospects, in-line products and product candidates, strategic reviews, capital allocation, business-development plans, and plans relating to share repurchases and dividends. In particular, these include statements relating to future actions, business plans and prospects, our acquisitions of Hospira, Anacor, Medivation and AstraZeneca’s small molecule anti-infectives business, the disposition of the Hospira Infusion Systems net assets, prospective products or product approvals, 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 financial guidance set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Financial Guidance for 2017 section in our 2016 Financial Report; the anticipated costs and cost savings, including from our acquisition of Hospira and our cost-reduction/productivity initiatives, set forth in the Costs and Expenses—Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives section in our 2016 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 2016 Financial Report; and the contributions that we expect to make from our general assets to the Company’s pension and postretirement plans during 2017 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 2016 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 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

Consolidation among MCOs has increased the negotiating power of MCOs and other private insurers. Private third-party insurers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain or maintain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. This cost shifting has given consumers greater control of 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. MCOs have recently introduced 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 health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater

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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.

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, Xeljanz and Xtandi. Our licensing and collaboration partners also face challenges by generic drug manufacturers to patents covering several of their products that may impact our licenses or co-promotion rights to such products. 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 which 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 branded products from competitors, as well as other generic and biosimilar manufacturers. The ability to launch a generic or biosimilar pharmaceutical product at or before anticipated generic or biosimilar market formation is important to that product’s profitability. Prices for products typically decline, sometimes dramatically, following generic market formation, 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.

DEPENDENCE ON KEY IN-LINE PRODUCTS

We recorded direct product revenues of more than \$1 billion for each of eight biopharmaceutical products: Prevnar 13/Prevenar 13, Lyrica, Enbrel, Ibrance, Lipitor, Viagra, Sutent and the Premarin family of products, as well as more than \$1 billion in Alliance revenues (primarily Eliquis) in 2016. Those products and Alliance revenues accounted for 43% of our total revenues in 2016. 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 or, if a new, more effective treatment should be introduced, the adverse impact on our revenues could be significant. Patents covering several of our best-selling medicines have recently expired or will expire in the next 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, pursuant to terms of a settlement agreement, certain formulations of Zyvox became subject to generic competition in the U.S. in January 2015. 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 2016 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. For additional information on recent losses of collaborations rights, 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 of Collaboration Rights section in our 2016 Financial Report.

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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 in order to deliver a robust pipeline could adversely impact the productivity of our pipeline. Further, even if the areas with the greatest market attractiveness are identified, the science may not work 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 will deliver value in the near term and over time. There can be no assurance that these strategies will deliver the desired result, which could affect profitability in the future.

BIOTECHNOLOGY PRODUCTS

Abbreviated legal pathways for the approval of biosimilars exist in certain 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 biotechnology products, our biotechnology products may become subject to competition from these biosimilars, with attendant competitive pressure, and price reductions could follow. The expiration or successful challenge of applicable patent rights could trigger this competition, assuming any relevant exclusivity period has expired. We may face litigation with respect to the validity and/or scope of patents relating to our biotechnology products.

We are developing biosimilar medicines. The evolving pathway for registration and approval of biosimilar products by the FDA and regulatory authorities in certain other countries could diminish the value of our investments in biosimilars. Other risks related to our development of biosimilars include the potential for steeper than anticipated price erosion due to increased competitive intensity, 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 prescriptions of biosimilars due to potential concerns over comparability with innovator medicines.

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 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 addressed could affect our future results.

RISKS AFFECTING INTERNATIONAL OPERATIONS

Our international operations could be affected by currency fluctuations, capital and exchange controls, 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, including the full integration of emerging markets into each of our two distinct operating segments: IH and EH. However, there is no assurance that our strategies in emerging markets will be successful or that these countries will continue to sustain these growth rates. 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

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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. While the impact of payers' efforts to control access to and pricing of specialty pharmaceuticals has had limited impact on Pfizer to date, a number of factors may lead to a more significant adverse business impact in the future given our growing specialty business portfolio. These include the increasing use of health technology assessments in markets around the world, U.S. PBMs seeking to negotiate greater discounts, deteriorating finances of certain governments, the uptake of biosimilars as they become available and efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products.

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 The Global Economic Environment risk factor below.

PRODUCT MANUFACTURING AND MARKETING RISKS

Difficulties or delays in product manufacturing or marketing could affect future results through regulatory actions, shut-downs, 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 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 as a result of natural or man-made disasters 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, and counterfeit goods.

Regulatory agencies periodically inspect our drug manufacturing facilities to ensure 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 or voluntary recall of a product, any of which could have a material adverse effect on our business, financial condition and results of operations. In February 2017, we received a warning letter from the FDA communicating FDA's view that certain violations of cGMP regulations exist at Hospira's manufacturing facility in McPherson, Kansas. Hospira is undertaking corrective actions to address the concerns raised by the FDA. Communication with the FDA is ongoing. Until the violations are corrected, the FDA may refuse to grant premarket approval applications and/or the FDA may refuse to grant export certificates related to products manufactured at McPherson, Kansas.

OUTSOURCING AND ENTERPRISE RESOURCE PLANNING

We outsource certain services to third parties in areas including transaction processing, accounting, information technology, manufacturing, clinical trial execution, clinical lab services, non-clinical research, safety services, integrated facilities management and other areas. For example, in 2016, we placed the majority of our clinical trial execution services with four strategic Clinical Research Organizations (CROs). Service performance issues with these CROs may adversely impact the progression of our clinical trial programs. Outsourcing of services to third parties could expose us to sub-optimal quality of service delivery or deliverables, which may result in repercussions such as missed deadlines or other timeliness issues, erroneous data, supply disruptions, non-compliance (including with applicable legal requirements and industry standards) or reputational harm, with potential negative implications for our results.

We continue to pursue a multi-year initiative to outsource some transaction-processing activities within certain accounting processes and are migrating to a consistent enterprise resource planning system across the organization. These are enhancements of ongoing activities to support the growth of our financial shared service capabilities and standardize our financial systems. If any difficulties in the migration to or in the operation of our enterprise resource planning system were to occur, they could adversely affect our operations, including, among other ways, through a failure to meet demand for our products, or adversely affect our ability to meet our financial reporting obligations.

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COLLABORATIONS AND OTHER RELATIONSHIPS WITH THIRD PARTIES

We depend on third-party collaborators, service providers, and others in the development 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 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, regulatory or other obligations to Pfizer, or any disruption in the relationships between Pfizer and these third parties, could delay or prevent the development, approval 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.

DIFFICULTIES OF OUR BIOPHARMACEUTICAL WHOLESALERS

In 2016, our largest biopharmaceutical wholesaler accounted for approximately 16% of our total revenues (and approximately 31% of our total U.S. revenues), and our top three biopharmaceutical wholesalers accounted for approximately 39% of our total 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.

BUSINESS DEVELOPMENT ACTIVITIES

We expect to continue to enhance our in-line products and product pipeline through collaborations, alliances, licenses, joint ventures, equity- or debt-based investments, 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 timeframe or at all, and integrate acquisitions. 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. Additionally, we may not realize the anticipated benefits of such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame.

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; and the relatively modest risk of penalties faced by counterfeiters. 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; and 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. No

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assurance can be given, however, that our efforts and the efforts of others will be entirely successful, and the presence of counterfeit medicines may continue to increase.

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. Additionally, efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products could adversely affect our business if implemented. 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 Europe, Japan, China, Canada and South Korea, 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, 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 timely or adequate government-approved pricing or formulary placement where required for our products or obtaining such pricing or placement at unfavorable 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/HEALTHCARE LEGISLATION

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 health care 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 2016 Financial Report and in Item 1. Business under the caption Government Regulation and Price Constraints—In the United States. In 2017, we may face uncertainties because there likely will be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. Although the revenues generated for Pfizer by the Medicaid expansion and health insurance exchanges under the ACA have been exceeded by the new rebates, discounts, and taxes, there is no assurance that repeal or replacement of the ACA will not adversely affect our business and financial results, particularly if replacement legislation reduces

incentives for employer-sponsored insurance coverage, and we cannot predict how 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, 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), 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.

U.S. DEFICIT-REDUCTION ACTIONS

In the U.S., government actions to reduce the national deficit may affect payment by government programs for our products or services provided using our products. The Congressional Budget Office routinely releases options for reducing the federal deficit, and the December 2016 release includes proposals to cap Medicaid grants to the states, and to require manufacturers to pay a minimum rebate on drugs covered under part D of Medicare for low-income beneficiaries. Significant Medicare reductions could also result if Congress proceeds with certain proposals to convert the Medicare fee-for-service program into a premium support program, or it 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

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programs that may be implemented, and/or any significant additional taxes or fees that may be imposed on us, as part of any broad deficit-reduction effort 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, or exclusion from future participation in government healthcare programs.

DEVELOPMENT, REGULATORY APPROVAL AND MARKETING OF PRODUCTS

Innovation is critical to the success of our company. 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. Drug discovery and development is time-consuming, expensive and unpredictable. The process from early discovery or design to development 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, including unfavorable new clinical data and additional analyses of existing clinical data. There can be no assurance regarding our ability to meet anticipated pre-clinical and clinical trial commencement and completion dates, regulatory submission and approval dates, and launch dates for product candidates, or as to whether or when we will receive regulatory approval for new products or for new indications or dosage forms for existing products, which will depend on the assessment by regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted. Decisions by regulatory authorities regarding labeling, ingredients and other matters could adversely affect the availability or commercial potential of our products. There is no assurance that we will be able to address the comments in complete response letters received by us with respect to certain of our drug applications to the satisfaction of the FDA, that any of our late stage pipeline products will receive regulatory approval and/or be commercially successful or that recently approved products will be approved in other markets and/or be commercially successful. There is also a risk that we may not adequately address existing regulatory agency findings concerning the adequacy of our regulatory compliance processes and systems or implement sustainable processes and procedures to maintain regulatory compliance and to address future regulatory agency findings, should they occur. In addition, there are risks associated with interim data, including the risk that final results of studies for which interim data have been provided and/or additional clinical trials may be different from (including less favorable than) the interim data results and may not support further clinical development of the applicable product candidate or indication.

There are many considerations that can affect the marketing of our products around the world. Regulatory delays, the inability to successfully complete or adequately design and implement clinical trials within the anticipated quality, time and cost guidelines or in compliance with applicable regulatory expectations, claims and concerns about safety and efficacy, new discoveries, patent disputes and claims about adverse side effects are a few of the factors that can adversely affect our business. Further, claims and concerns about safety and efficacy 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 clinical trials prior to granting approval or increased post-approval requirements, such as risk evaluation and mitigation strategies.

In addition, failure to put in place adequate controls and/or resources for effective collection, reporting and management of adverse events from clinical trials and post-marketing surveillance, in compliance with current and evolving regulatory requirements could result in risks to patient safety, regulatory actions and risks to product sales.

The FDA, along with other regulatory agencies around the world, has been experiencing a backlog of generic drug applications, which has delayed approvals of new generic products. These delays have become longer, and while the FDA has stated that it 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.

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. Post-marketing 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 that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on the availability or commercial potential of the affected products. Accordingly, new data about our products, or products similar to our products, could negatively impact demand for our products due to real or

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perceived side effects or uncertainty regarding efficacy and, in some cases, could result in updated labeling, restrictions on use, product withdrawal or recall.

INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND GOVERNMENT OFFICIALS

Risks and uncertainties apply if we provide something of value to a healthcare professional and/or government official. If the interaction is found to be improper, government enforcement actions and penalties could result. These risks may increase as non-U.S. jurisdictions adopt or increase enforcement efforts of new anti-bribery laws and regulations.

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 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), competition laws, privacy laws and environmental laws in the U.S. and other countries. For additional information, see the Provision for Taxes on Income—Changes in Tax Law 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 our 2016 Financial Report.

LEGAL PROCEEDINGS

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, antitrust, environmental, employment and tax litigations and claims, government investigations and other legal proceedings 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 we have substantial defenses in these matters, 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 investigations and 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, and substantial fines and/or civil penalties, as well as limitations on our ability to conduct business in applicable jurisdictions, could result from government investigations.

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 2016 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.

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 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.

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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 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 a policy of routine compulsory licensing of pharmaceutical intellectual property as a result of local political pressure or in the case of national emergencies. 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 to challenge our patent rights. Most of the suits by generic drug manufacturers involve claims that patents covering our products, processes or dosage forms are invalid and/or do not cover the product of the generic drug manufacturer. Also, counterclaims, as well as various 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. 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. 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 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 be successful.

Part of our EH 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

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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 those proceedings ultimately determine that our products infringe the patent rights of third parties, we may face patent infringement damages, including the possibility of owing the third party a reasonable royalty or the lost profits from the sale of the branded product. Remedies also may include or consist of an injunction preventing us from further manufacture or sales of the affected product during the term of one or more of the valid, infringed patents. 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, there can be no assurance that our efforts will 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.

RISKS RELATED TO OUR STRATEGIC TRANSACTIONS:

STRATEGIC ACQUISITIONS

The success of our acquisitions of Hospira, Anacor, Medivation and AstraZeneca’s small molecule anti-infectives business 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 the acquisition of Hospira, or such cost savings within the expected time frame. Similarly, the accretive impact anticipated from the acquisitions of Hospira, Anacor and Medivation 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 regularly adversely impact revenue and income contribution from products and product candidates, including those acquired in these acquisitions. Hospira, for example, has

experienced manufacturing disruptions, device remediations and substantial regulatory scrutiny due to quality issues, including receiving a warning letter from the FDA in February 2017 communicating FDA's view that certain violations of cGMP regulations exist at Hospira's manufacturing facility in McPherson, Kansas. 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.

OTHER RISKS:

THE GLOBAL ECONOMIC ENVIRONMENT

Like all businesses, 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 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 Europe, 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

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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 to our research, commercial and general business operations in the U.K. and the EU. 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 and what the resulting impact on our business may be, especially in EU nations with weaker economic conditions such as Greece. For additional information, see the Analysis of Financial Condition, Liquidity and Capital Resources—Global Economic Conditions—U.K. section in our 2016 Financial Report.

We also continue to monitor the global trade environment and potential trade conflicts. If trade restrictions 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 and earnings, as well as our substantial international net assets, are exposed to changes in foreign exchange rates. 50% of our total 2016 revenues were derived from international operations, including 21% from Europe and 20% from 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, including those changes resulting from the volatility following the U.K. referendum in which voters approved Brexit, can impact our results and our financial guidance.

The impact of possible currency devaluations in countries experiencing high inflation rates or significant exchange fluctuations 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 2017 and Analysis of Financial Condition, Liquidity and Capital Resources sections in our 2016 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 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 2016 Financial Report. For additional details, see the Notes to Consolidated Financial Statements—Note 7E. Financial Instruments: Derivative Financial Instruments and Hedging Activities and —Note 11. Pension and Postretirement Benefit Plans and Defined Contribution Plans in our 2016 Financial Report and the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions—Benefit Plans section in our 2016 Financial Report. Those sections of our 2016 Financial Report are incorporated by reference.

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.

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COST AND EXPENSE CONTROL/UNUSUAL EVENTS/FAILURE TO REALIZE THE ANTICIPATED BENEFITS OF STRATEGIC INITIATIVES AND ACQUISITIONS/INTANGIBLE ASSETS, GOODWILL AND EQUITY-METHOD INVESTMENTS

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) our internal separation of our commercial operations into our current operating structure; (iii) any other corporate strategic initiatives; and (iv) any acquisitions, divestitures or other initiatives, such as our acquisitions of Hospira, Anacor, Medivation and AstraZeneca's small molecule anti-infectives business.

In addition, 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. 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 2016 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

In 2016, we continued to consolidate operations to achieve efficiencies and dispose of excess space. As of December 31, 2016, we had 567 owned and leased properties, amounting to approximately 57 million square feet.

In 2016, we reduced the number of properties in our portfolio by 28 sites and 2.3 million square feet with the disposal of surplus real property assets and with reductions of operating space in all regions. These reductions include partial offsets due to acquisitions of Anacor, Bamboo Therapeutics Inc., substantially all of the assets of BIND Therapeutics, Inc. and Medivation.

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.

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

In 2017, we intend to progress our plans to relocate from our current New York City corporate headquarters to a more modern facility in Manhattan. In addition, we plan continued execution on consolidating properties related to Hospira and other acquired companies. We also plan to further expand 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 2017, we will continue to consolidate our R&D operations in Cambridge, Massachusetts into the Kendall Square neighborhood, and continue to advance our operations in St. Louis, Missouri and Andover, Massachusetts.

Our Pfizer Global Supply (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, 2016, PGS operated 63 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 eight 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 2016 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 2016 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. Commitments and Contingencies—Legal Proceedings in our 2016 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 2017 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 |
|-------------------|-----|---|
| Ian C. Read | 63 | Chairman of the Board and Chief Executive Officer of Pfizer since December 2011. President and Chief Executive Officer from December 2010. Previously, he served as Senior Vice President and Group President of the Worldwide Biopharmaceutical Businesses, which he led from 2006 through December 2010. In that role, he oversaw five global business units—Primary Care, Specialty Care, Oncology, Established Products and Emerging Markets. Mr. Read began his career with Pfizer in 1978 as an operational auditor. He worked in Latin America through 1995, holding positions including Chief Financial Officer, Pfizer Mexico, and Country Manager, Pfizer Brazil. In 1996, he was appointed President of Pfizer’s International Pharmaceuticals Group, with responsibility for Latin America and Canada. He became Executive Vice President, Europe, in 2000, was named a Corporate Vice President in 2001, and assumed responsibility for Canada, in addition to Europe, in 2002. Mr. Read later became accountable for operations in both the Africa/Middle East region and Latin America as well. Director of Kimberly-Clark Corporation. Mr. Read serves on the Boards of Pharmaceutical Research and Manufacturers of America (PhRMA) and the Partnership of New York City. Member of the U.S.-China Business Council. Our Director since December 2010. |
| Albert Bourla | 55 | Group President, Pfizer Innovative Health since June 2016; Group President, Global Innovative Pharma Business from February 2016 until June 2016 and Group President, Vaccines, Oncology and Consumer Healthcare since January 2014. 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. |
| Frank A. D’Amelio | 59 | Executive Vice President, Business Operations and Chief Financial Officer since December 2010. 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. He is a Director of the Independent College Fund of New Jersey. |
| Mikael Dolsten | 58 | President of Worldwide Research and Development since December 2010. 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. |

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| | | |
|------------------------|----|--|
| Charles H. Hill III | 61 | Executive Vice President, Worldwide Human Resources since December 2010. Senior Vice President, Human Resources for Worldwide Biopharmaceuticals Businesses from 2008 through December 2010. Vice President, Human Resources, Worldwide Pharmaceutical Operations from 2004 through 2008. Director of Zoetis Inc. from July 2012 until June 2013. |
| Rady A. Johnson | 55 | Executive Vice President, Chief Compliance and Risk Officer since December 2013. Senior Vice President and Associate General Counsel from October 2006 until December 2013. |
| Douglas M. Lankler | 51 | Executive Vice President and General Counsel 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 | 61 | Executive Vice President, Chief Medical Officer since December 2010. 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. |
| Kirsten Lund-Jurgensen | 57 | Executive Vice President, President, Pfizer Global Supply since December 2016. Vice President, Innovative Health Product Portfolio Management and Consumer Operations from August 2015 until December 2016. Vice President, Vaccines, Oncology, Consumer Product Portfolio Management and Consumer Operations from January 2014 until August 2015. Vice President, Product Portfolio Management for Primary Care, Established Products and Oncology from December 2012 until December 2013. Vice President of the Primary Care and Oncology Operating Unit (Manufacturing Sites in Europe, Singapore, Canada) from October 2009 until November 2012. Vice President of the Patented Products Operating Unit (Manufacturing Sites in Europe, Singapore) from May 2008 until October 2009. |
| Alexander R. MacKenzie | 57 | Executive Vice President, Chief Development Officer 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. |
| Laurie J. Olson | 53 | Executive Vice President, Strategy, Portfolio and Commercial Operations since July 2012. Senior Vice President - Strategy and Portfolio Management from 2011 until July 2012. Senior Vice President - Portfolio Management and Analytics from 2008 until 2010. Since joining Pfizer in 1987 as an Analyst in the Company's marketing research organization, Ms. Olson has served in a variety of marketing leadership positions with increasing responsibility in both the Company's U.S. and global commercial organizations. |
| Sally Susman | 55 | Executive Vice President, Corporate Affairs (formerly Policy, External Affairs and Communications) since December 2010. Senior Vice President, Policy, External Affairs and Communications from December 2009 until December 2010. Senior Vice President and Chief |

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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 52 Group President, Pfizer Essential Health since June 2016; 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.

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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. The stock currently trades on the NYSE under the symbol "PFE". As of February 21, 2017, there were 166,694 holders of record of our common stock. Additional information required by this item is incorporated by reference from the Quarterly Consolidated Financial Data (Unaudited) and Peer Group Performance Graph sections in our 2016 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 2016:

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 3, 2016 through October 30, 2016 | 33,946 | \$ 33.64 | — | \$ 11,355,862,076 |
| October 31, 2016 through November 30, 2016 | 14,578 | \$ 31.57 | — | \$ 11,355,862,076 |
| December 1, 2016 through December 31, 2016 | 25,816 | \$ 32.28 | — | \$ 11,355,862,076 |
| Total | 74,340 | \$ 32.76 | — | |

On October 23, 2014, we announced that the Board of Directors had authorized an \$11 billion share-purchase plan (the October 2014 Stock Purchase Plan), and share purchases commenced thereunder in January 2015. In December 2015, the Board of Directors authorized a new \$11 billion share repurchase program to be utilized over time. On March 8, 2016, we entered into an accelerated share repurchase agreement with Goldman, Sachs & Co. (GS&Co.) to repurchase \$5 billion of our common stock. Pursuant to the terms of the agreement, on March 10, 2016, we paid \$5 billion to GS&Co. and received an initial delivery of approximately 136 million shares of our common stock from GS&Co. based on a price of \$29.36 per share, which represented, based on the closing share price of our common stock on the NYSE on March 8, 2016, approximately 80% of the notional amount of the accelerated share repurchase agreement. On June 20, 2016, the accelerated share repurchase agreement with GS&Co. was completed, which, per the terms of the agreement, resulted in GS&Co. owing us a certain number of shares of Pfizer common stock. Pursuant to the agreement's settlement terms, we received an additional 18 million shares of our common stock from GS&Co. on June 20, 2016. The average price paid for all of the shares delivered under the accelerated share repurchase agreement was \$32.38 per share. The common stock received is included in Treasury stock. This agreement was entered into pursuant to our previously announced share repurchase authorization. At December 31, 2016, our remaining share-purchase authorization was approximately \$11.4 billion at December 31, 2016.

These columns reflect the following transactions during the fourth fiscal quarter of 2016: (i) the surrender to Pfizer of 70,024 shares of common stock to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees; (ii) the surrender to Pfizer of 2,105 shares of common stock to satisfy tax withholding obligations in connection with the vesting of performance share awards issued to employees; (iii) the surrender to Pfizer of 1,669 shares of common stock to pay the exercise price and to satisfy tax withholding obligations in connection with the exercise of employee stock options issued to employees; (iv) the open market purchase by the trustee of 532 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; and (v) the surrender of 10 shares of common stock to satisfy withholding obligations in connection with the settlement of total shareholder return units.

On February 2, 2017, we entered into an accelerated share repurchase agreement with Citibank N.A. This agreement was entered into pursuant to Pfizer's previously announced share repurchase authorization. For additional information, see the Notes to Consolidated Financial Statements—Note 19. Subsequent Events in our 2016 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 2016 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 2016 Financial Report.

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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 2016 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 2016 Financial Report and from the consolidated financial statements, related notes and supplementary data in our 2016 Financial Report.

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 2016 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 2016 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 2017 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 2017 Proxy Statement. Information about the Pfizer Policies on Business Ethics and 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—Other Governance Practices and Policies—Pfizer Policies on Business Ethics and Conduct and —Code of conduct for Directors in our 2017 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 2018 Annual Meeting in our 2017 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 2017 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 2016 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 2017 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 2017 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 2017 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 2017 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 2016 and 2015 is incorporated by reference from the discussion under the heading Item 2—Ratification of Selection of Our Independent Registered Public Accounting Firm—Audit and Non-Audit Fees in our 2017 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 Our 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 2017 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 2016 Financial Report are incorporated by reference into Item 8 of Part II of this 2016 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

Quarterly Consolidated 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 10017-5755. The exhibit numbers preceded by an asterisk (*) indicate exhibits filed with this 2016 Form 10-K. All other exhibit numbers indicate exhibits filed by incorporation by reference. Exhibit numbers 10.1 through 10.24 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.)

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 14, 2015, are incorporated by reference from our Current Report on Form 8-K filed on December 18, 2015 (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).
- 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 Indenture, dated as of April 10, 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.
- 4.10 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.
- 4.11 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).
- 4.12 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).
- 4.13 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).
- 4.14 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).

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- 4.15 Except as set forth in Exhibits 4.1-14 above, the instruments defining the rights of holders of long-term debt securities of the Company and its subsidiaries have been omitted.¹
- 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 Stock Option Grant Notice and Summary of Key Terms.
- 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 Amended and Restated Nonfunded Supplemental Retirement Plan, together with all material Amendments is incorporated by reference from our 2011 Annual Report on Form 10-K (File No. 001-03619).
- 10.7 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).
- 10.8 Pfizer Inc. Global Performance Plan is incorporated by reference from our 2015 Annual Report on Form 10-K (File No. 001-03619).
- 10.9 Executive Annual Incentive Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
- 10.10 Amended and Restated Deferred Compensation Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
- 10.11 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).
- ¹ We agree to furnish to the SEC, upon request, a copy of each instrument with respect to issuances of long-term debt of the Company and its subsidiaries.
- 10.12 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).
- 10.13 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).
- 10.14 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).
- 10.15

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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).

- 10.16 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).
- 10.17 The form of Indemnification Agreement with each of the Named Executive Officers identified in our 2016 Proxy Statement is incorporated by reference from our 1997 Annual Report on Form 10-K (File No. 001-03619).
- 10.18 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).
- 10.19 Executive Severance Plan is incorporated by referenced from our Current Report on Form 8-K filed on February 20, 2009 (File No. 001-03619).
- 10.20 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).
- 10.21 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).
- 10.22 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).
- 10.23 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).
- 10.24 Offer Letter to Geno J. Germano, 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).
- *12 Computation of Ratio of Earnings to Fixed Charges.
- *13 Portions of the 2016 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 KPMG LLP, 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

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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 2016 Form 10-K, with hyperlinked cross-references. This allows users to easily locate the corresponding items in this 2016 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 2017 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 23, 2017 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/ IAN C. READ Ian C. Read | Chairman, Chief Executive Officer and Director (Principal Executive Officer) | February 21, 2017 |
| /S/ FRANK A. D'AMELIO Frank A. D'Amelio | Executive Vice President, Business Operations and Chief Financial Officer (Principal Financial Officer) | February 21, 2017 |
| /S/ LORETTA V. CANGIALOSI Loretta V. Cangialosi | Senior Vice President—Controller (Principal Accounting Officer) | February 21, 2017 |
| /S/ DENNIS A. AUSIELLO Dennis A. Ausiello | Director | February 21, 2017 |
| /S/ W. DON CORNWELL W. Don Cornwell | Director | February 21, 2017 |
| /S/ JOSEPH J. ECHEVARRIA Joseph J. Echevarria | Director | February 21, 2017 |
| /S/ FRANCES D. FERGUSSON Frances D. Fergusson | Director | February 21, 2017 |
| /S/ HELEN H. HOBBS Helen H. Hobbs | Director | February 22, 2017 |

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| Signature | Title | Date |
|--|----------|-------------------|
| /S/ JAMES M. KILTS James M. Kilts | Director | February 21, 2017 |
| /S/ SHANTANU NARAYEN Shantanu Narayen | Director | February 22, 2017 |
| /S/ SUZANNE NORA JOHNSON Suzanne Nora Johnson | Director | February 21, 2017 |
| /S/ STEPHEN W. SANGER Stephen W. Sanger | Director | February 22, 2017 |
| /S/ JAMES C. SMITH James C. Smith | Director | February 21, 2017 |