

PFIZER INC  
Form 10-K  
February 29, 2016

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, 2015

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.

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Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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, June 28, 2015, was approximately \$209 billion. This excludes shares of common stock held by directors and executive officers at June 28, 2015. 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 25, 2016 was 6,184,139,991 shares of common stock, all of one class.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2015 Annual Report to Shareholders

Parts I, II and IV

Portions of the Proxy Statement for the 2016 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 2015 Form 10-K (defined below) refer to Pfizer Inc. and its subsidiaries. We also have used several other terms in this 2015 Form 10-K, most of which are explained or defined below:

|                       |   |
|-----------------------|---|
| 2015 Financial Report | Exhibit 13 to this 2015 Form 10-K   |
| 2015 Form 10-K        | Annual Report on Form 10-K for the fiscal year ended December 31, 2015  |
| 2016 Proxy Statement  | Proxy Statement for the 2016 Annual Meeting of Shareholders   |
| ACA                   | U.S. Patient Protection and Affordable Care Act, as amended by the Health Care Reconciliation Act   |
| Allergan              | Allergan plc  |
| Alliance revenues     | Revenues from Alliance agreements under which we co-promote products discovered by other companies  |
| ANDA                  | Abbreviated New Drug Application  |
| 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, Scandinavia, South Korea, Finland and New Zealand   |
| EEA                   | European Economic Area  |
| EFPIA                 | European Federation of Pharmaceutical Industries and Associations   |
| 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  |
| FFDCA                 | U.S. Federal Food, Drug and Cosmetic Act  |
| FDA                   | U.S. Food and Drug Administration   |
| FTC                   | U.S. Federal Trade Commission   |
| GEP                   | Global Established Pharmaceutical segment   |
| GIP                   | Global Innovative Pharmaceutical segment  |
| Hospira               | Hospira, Inc.   |
| IPR&D                 | In-process Research and Development   |
| IRS                   | U.S. Internal Revenue Service   |
| ITRSHRA               | Iran Threat Reduction and Syria Human Rights Act of 2012  |
| I.V.                  | intravenous   |
| LOE                   | Loss of Exclusivity   |
| MCO                   | Managed Care Organization   |
| NDA                   | New Drug Application  |
| NYSE                  | New York Stock Exchange   |
| OTC                   | over-the-counter  |
| PBM                   | Pharmacy Benefit Manager  |
| PGS                   | Pfizer Global Supply  |
| PMDA                  | Pharmaceuticals and Medical Device Agency in Japan  |
| R&D                   | Research and Development  |
| SEC                   | U.S. Securities and Exchange Commission   |

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|           |  |
|-----------|--|
| U.S.      | United States  |
| VOC       | Global Vaccines, Oncology and Consumer Healthcare segment                            |
| WRD       | Worldwide Research and Development   |
| WTO-TRIPS | World Trade Organization Agreement on Trade Related Aspects of Intellectual Property |

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, vaccines and medical devices, 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 by other companies. 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.

On November 23, 2015, we announced that we have entered into a definitive merger agreement with Allergan, a global pharmaceutical company incorporated in Ireland, under which we have agreed to combine with Allergan in a stock transaction valued at \$363.63 per Allergan share, for a total enterprise value of approximately \$160 billion, based on the closing price of Pfizer common stock of \$32.18 on November 20, 2015 (the last trading day prior to the announcement) and certain other assumptions. Allergan shareholders will receive 11.3 shares of the combined company for each of their Allergan shares by virtue of a share split, and Pfizer shareholders will have the option of receiving one share of the combined company for each of their Pfizer shares or receiving cash instead of shares of the combined company for some or all of their Pfizer shares, provided that the aggregate amount of cash to be paid in the merger will not be less than \$6 billion or greater than \$12 billion. In the event that elections to receive cash and shares in the merger would otherwise result in an aggregate of less than \$6 billion or greater than \$12 billion of cash being paid out in the merger, then the share elections and cash elections will be subject to proration. The completion of the transaction, which is expected in the second half of 2016, is subject to certain conditions, including receipt of regulatory approval in certain jurisdictions, including the U.S. and EU, the receipt of necessary approvals from both Pfizer and Allergan shareholders, and the completion of Allergan's pending divestiture of its generics business to Teva Pharmaceuticals Industries Ltd. Subject to the terms and conditions of the merger agreement, the businesses of Pfizer and Allergan will be combined under a single company and Pfizer would become a wholly-owned subsidiary of Allergan, which is organized under the laws of Ireland and which, subject to the approval by Allergan shareholders, will be renamed "Pfizer plc." For further discussion on the pending Allergan combination, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business section in our 2015 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). Hospira is now a subsidiary of Pfizer. 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, Licensing Agreements, Collaborative Arrangements, Divestitures, Equity-Method Investments and Cost-Method Investment: Acquisitions in our 2015 Financial Report.

On June 24, 2013, we completed the full disposition of our Animal Health business. For additional information, see the Notes to Consolidated Financial Statements—Note 2D. Acquisitions, Licensing Agreements, Collaborative Arrangements, Divestitures, Equity-Method Investments and Cost-Method Investment: Divestitures in our 2015 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 and —Our Business Development Initiatives sections in our 2015 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 EEA 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 Government Regulation and Price Constraints below.

Note: Some amounts in this 2015 Form 10-K may not add due to rounding. All percentages have been calculated using unrounded amounts.



AVAILABLE INFORMATION AND PFIZER WEBSITE

Our website is located at [www.pfizer.com](http://www.pfizer.com). This 2015 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 2015 Form 10-K, we “incorporate by reference” certain information from other documents filed or to be filed with the SEC, including our 2016 Proxy Statement and the 2015 Financial Report, portions of which are filed as Exhibit 13 to this 2015 Form 10-K, and which also will be contained in Appendix A to our 2016 Proxy Statement. The SEC allows us to disclose important information by referring to it in that manner. Please refer to such information. Our 2015 Annual Report to Shareholders consists of the 2015 Financial Report and the Corporate and Shareholder Information attached to the 2016 Proxy Statement. Our 2015 Financial Report will be available on our website on or about February 29, 2016. Our 2016 Proxy Statement will be available on our website on or about March 15, 2016.

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 these ethics policies and standards 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 2015 Form 10-K. Pfizer’s references to the URLs for websites are intended to be inactive textual references only.

COMMERCIAL OPERATIONS

We manage our commercial operations through two distinct businesses: an Innovative Products business and an Established Products business. The Innovative Products business is composed of two operating segments, each of which has been led by a single manager in 2015 and 2014—the Global Innovative Pharmaceutical segment and the Global Vaccines, Oncology and Consumer Healthcare segment. Effective February 8, 2016, the Innovative Products business is led by a single manager. The Established Products business consists of the Global Established Pharmaceutical segment, which is also 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 each business and operating segment follows:

## Innovative Products Business

Global Innovative Pharmaceutical segment:

GIP focuses on developing and commercializing novel, value-creating medicines that significantly improve patients' lives. Key therapeutic areas include inflammation/immunology, cardiovascular/metabolic, neuroscience/pain and rare diseases and include leading brands, such as Xeljanz, Eliquis, Lyrica (U.S. and Japan), Enbrel (outside the U.S. and Canada) and Viagra (U.S. and Canada).

Global Vaccines, Oncology and Consumer Healthcare segment:

VOC focuses on the development and commercialization of vaccines and products for oncology and consumer healthcare. Consumer Healthcare manufactures and markets several well-known, over-the-counter (OTC) products. Each of the three businesses in VOC operates as a separate, global business, with distinct specialization in terms of the science and market approach necessary to deliver value to consumers and patients.

## Established Products Business

Global Established Pharmaceutical segment:

GEP 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 infusion systems.

We expect that the GIP and VOC biopharmaceutical portfolios 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 these groups are science-driven, highly differentiated and generally require a high level of engagement with healthcare providers and consumers.

GEP is expected to generate strong consistent cash flow by providing patients around the world with access to effective, lower-cost, high-value treatments. GEP leverages our biologic development, regulatory and manufacturing expertise to seek to advance its biosimilar development portfolio. Additionally, GEP leverages capabilities in formulation development and manufacturing expertise to help advance its generic sterile injectables portfolio. In addition, GEP may also engage in targeted business development to further enable its commercial strategies. GEP has the knowledge and resources within R&D to develop small molecules, including injectables, and biosimilars. On September 3, 2015, we acquired Hospira, and its commercial operations are now included within GEP.

For a further discussion of these operating segments, see the Innovative Products and Established Products 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 2015 Financial Report, which are incorporated by reference.

In addition, other business activities within Pfizer include Pfizer CentreSource, our contract manufacturing and bulk pharmaceutical chemical sales operation, which in 2015 includes revenues related to our manufacturing and supply agreements with Zoetis Inc.

Following the closing of the pending combination with Allergan, the Vaccines and Oncology businesses are expected to be combined with the Global Innovative Pharmaceutical business and we expect to create a new global business, Global Specialty and Consumer Brands, that includes our Consumer Healthcare business and Allergan's ophthalmology and aesthetics businesses, as well as Botox Therapeutic and Cosmetic. Allergan's Anda distribution capabilities and brands in women's health and anti-infectives are expected to be combined with the Global Established Pharmaceutical business.

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## INNOVATIVE PRODUCTS

We recorded direct product sales of more than \$1 billion for each of five Innovative products in 2015, 2014 and 2013 (Lyrica (outside all of Europe, Russia, Turkey, Israel and Central Asia countries), Enbrel (outside the U.S. and Canada), Viagra (U.S. and Canada), Prevnar/Prevenar 13 and Sutent), and for GIP Alliance revenues in 2015 (primarily Eliquis) and 2013. See Item 1A. Risk Factors—Dependence on Key In-Line Products below.

Geographic Revenues for Innovative Products\*

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

For additional information regarding the revenues of our Innovative Products business, including revenues of major Innovative 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 2015 Financial Report; and for additional information on the key operational revenue drivers of our Innovative Products business, see the Analysis of Operating Segment Information—Global Innovative Pharmaceutical Operating Segment and —Global Vaccines, Oncology and Consumer Healthcare Operating Segment sections of our 2015 Financial Report.

The Innovative Products business is composed of the GIP and VOC segments. A discussion of the key products within these segments, or a reference to such discussion in the 2015 Financial Report, is included below.

### Global Innovative Products

For a discussion of certain of our key GIP products, including Lyrica (outside all of Europe, Russia, Turkey, Israel and Central Asia countries), Enbrel (outside the U.S. and Canada), Viagra (U.S. and Canada), BeneFIX, Chantix/Champix, Refacto AF/Xyntha, Xeljanz and Eliquis (jointly developed and commercialized with BMS), see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2015 Financial Report.

### Vaccines

For a discussion of certain of our key Vaccine products, including Prevnar/Prevenar 13, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2015 Financial Report.

### Oncology

For a discussion of certain of our key Oncology products, including Sutent, Ibrance, Xalkori and Inlyta, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2015 Financial Report.

## Consumer Healthcare

According to Euromonitor International's retail sales data, in 2015, 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 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, 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 Relief & Pain, Dimetapp and ChapStick.

### ESTABLISHED PRODUCTS

We recorded direct product sales of more than \$1 billion for each of three Established products in 2015 (Lipitor, Lyrica (Europe, Russia, Turkey, Israel and Central Asia) and the Premarin family of products) and six Established products in 2014 and 2013 (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 Established Products\*

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

For additional information regarding the revenues of our Established Products business, including revenues of major Established 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 2015 Financial Report; and for additional information on the key operational revenue drivers of our Established Products business, see the Analysis of Operating Segment Information—Global Established Pharmaceutical Operating Segment section of our 2015 Financial Report.

## Global Established Products

The product categories in our Global Established Products segment include:

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

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

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

**Infusion Systems:** includes medication management systems products composed of infusion pumps and related software and services, as well as I.V. infusion products, including large volume I.V. solutions and their associated administration sets;

**Biosimilars:** includes Inflectra (biosimilar infliximab) in Canada, Mexico, Australia and certain European markets, Nivestim (biosimilar filgrastim) in Australia and certain European and Asian markets and Retacrit (biosimilar epoetin) in certain European markets; and

**Other Established Products:** includes legacy Hospira's One-to-One contract manufacturing and bulk pharmaceutical chemical sales organizations.

For a discussion of certain of our key GEP products, including Lipitor, Lyrica (Europe, Russia, Turkey, Israel and Central Asia), the Premarin family of products, Norvasc, Zyvox, Celebrex and Pristiq, see the Analysis of the Consolidated Statements of Income—Revenues—Selected Product Descriptions section in our 2015 Financial Report. ALLIANCE REVENUES

We are party to collaboration and/or co-promotion agreements relating to certain biopharmaceutical products, such as Enbrel (in the U.S. and Canada), Spiriva and Rebif, each of which has expired or will expire in 2016 in certain markets. In addition, Eliquis was developed and is being commercialized in collaboration with BMS. 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. 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 2015 Financial Report and Item 1A. Risk Factors—Dependence on Key In-Line Products below.

## 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.

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 WRD organization is generally responsible for research projects until proof-of-concept is achieved and then for transitioning those projects to the appropriate business unit for possible clinical and commercial development. The WRD organization also has responsibility for certain science-based and other platform-services organizations, which provide technical expertise

and other services to the various R&D projects. WRD is also responsible for facilitating all regulatory submissions and interactions with regulatory agencies, including all safety-event activities.

Our R&D primarily focuses on six high-priority areas that have a mix of small molecules and large molecules—immunology and inflammation; cardiovascular and metabolic diseases; oncology; vaccines; neuroscience and pain; and rare diseases. Another area of focus is biosimilars. With the acquisition of Hospira, we have expanded our biosimilars pipeline and added R&D capabilities for sterile injectables and infusion systems.

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. Collaboration, alliance and license agreements and equity- or debt-based investments allow us to share risk and cost, to access external scientific and technological expertise, and enable us to advance our own products as well as in-licensed or acquired products.

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.

As of February 2, 2016, 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 new 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 2015 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.

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. Our R&D priorities include delivering a pipeline of differentiated therapies with the greatest scientific 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.

For additional information regarding our R&D operations, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Research Operations and Costs and Expenses—Research and Development (R&D) Expenses—Description of Research and Development Operations sections in our 2015 Financial Report.





## INTERNATIONAL OPERATIONS

We have significant operations outside the U.S. Since 2014, operations in developed and emerging markets have been managed through our three operating segments: GIP, GEP and VOC. 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.

Revenues from operations outside the U.S. of \$27.1 billion accounted for 56% of our total revenues in 2015. 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 2015 Financial Report, and the table captioned Revenues by Segment and Geographic Area in our 2015 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 2015 Financial Report, as well as the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2015 Financial Report. Those sections of our 2015 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 communicates 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. For our infusion systems business, we promote directly to nurses, physicians, pharmacists, biomedical engineers, and their respective representatives.

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 individual provider offices, the Centers for Disease Control and Prevention and wholesalers. 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 2015, our top three biopharmaceutical wholesalers accounted for approximately 34% of our total revenues (and 74% of our total U.S. revenues).

#### % of 2015 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 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.



| Drug                   | U.S. Basic Product Patent Expiration Year | Major EU Basic Product Patent Expiration Year | Japan Basic Product Patent Expiration Year |
|------------------------|---|---|--|
| Viagra                 | 2012 <sup>(1)</sup>                       | 2013  | 2013 <sup>(1)</sup>                        |
| Enbrel                 | N/A <sup>(2)</sup>                        | 2015  | 2015                                       |
| Celebrex               | 2014 <sup>(3)</sup>                       | 2014 <sup>(3)</sup>                           | 2019                                       |
| Zyvox                  | 2015                                      | 2016  | 2019                                       |
| Lyrica                 | 2018                                      | 2014 <sup>(4)</sup>                           | 2022                                       |
| Chantix                | 2020                                      | 2021  | 2022                                       |
| Inlyta                 | 2020                                      | 2025  | 2025                                       |
| Xeljanz                | 2020                                      | N/A <sup>(5)</sup>                            | 2025                                       |
| Sutent                 | 2021                                      | 2021  | 2024                                       |
| Eliquis <sup>(6)</sup> | 2023                                      | 2026  | 2026                                       |
| Ibrance                | 2023                                      | N/A <sup>(7)</sup>                            | N/A <sup>(7)</sup>                         |
| Prevnar 13/Prevenar 13 | 2026                                      | 2026 <sup>(8)</sup>                           | 2029                                       |
| 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 <sup>(1)</sup>(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.

Pfizer markets Enbrel outside the U.S. and Canada. For additional information, see the Overview of Our <sup>(2)</sup>Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—Industry-Specific Challenges—Intellectual Property Rights and Collaboration/Licensing Rights section in our 2015 Financial Report. In January 2016, the European Commission approved an etanercept biosimilar referencing Enbrel.

<sup>(3)</sup> In December 2014, generic versions of Celebrex became available pursuant to settlement agreements with several generic manufacturers.

<sup>(4)</sup> For Lyrica, regulatory exclusivity in the EU expired in July 2014.

<sup>(5)</sup> Xeljanz is not approved in the EU.

<sup>(6)</sup> Eliquis was developed and is being commercialized in collaboration with BMS.

<sup>(7)</sup> Ibrance is awaiting marketing authorization in the EU and Japan.

The EU patent that covers the combination of the 13 serotype conjugates of Prevenar 13 has been revoked <sup>(8)</sup>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.

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 2016, 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 2015 Financial Report and Item 1A. Risk Factors—Dependence on Key In-Line Products below.

Companies have filed applications with the FDA seeking approval of products that we believe infringe our patents covering, among other products, Sutent, EpiPen, Toviaz, Tygacil extended-release capsules and Precedex Premix. For additional information, see the Notes to Consolidated Financial Statements—Note 17A1. Commitments and

Contingencies—Legal Proceedings—Patent Litigation in our 2015 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; and 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 competition in the future 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 FFDCA.

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 the FDA has issued draft guidance on subjects such as nonproprietary naming of biologic products and reference product exclusivity, and final guidance on a number of subjects such as scientific considerations in demonstrating biosimilarity. Moreover, in 2015, the FDA approved the first biosimilar and currently has several other biosimilar applications under review. See Government Regulation and Price Constraints—Biosimilar Regulation below for additional information on the ACA's approval framework for biosimilars.

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. In Japan, the regulatory authority has granted marketing authorizations for certain biosimilars, including our monoclonal antibody infliximab, 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 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 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.

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. In the U.S., Pfizer's Greenstone subsidiary and Pfizer Injectables team sell generic versions of Pfizer's, as well as certain competitors', solid oral dose and sterile injectable pharmaceutical products, respectively, upon loss of exclusivity, as appropriate. Additionally, as a result of the Hospira acquisition, Pfizer also sells generic versions of sterile injectable products as well as biosimilars globally. 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.

Our infusion systems business faces competition from companies that manufacture and distribute similar products to our infusion systems. For our infusion systems business, we seek to differentiate our products through technological innovation and an integrated approach to drug delivery.

#### 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.

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.

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

universally, successful in having our major products included on MCO formularies. However, increasingly our branded products are being placed on the higher tiers or in a non-preferred status.

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

The ACA has accelerated payment reform by distributing risk across MCOs and other stakeholders in care delivery with the intent of improving quality while reducing costs, which creates pressure on MCOs to tie reimbursement to defined outcomes.

#### 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 such competitors make a regular practice of challenging our product patents before their expiration. Unlike us, 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 2015, and none are expected in 2016. 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 and medical device companies are subject to extensive laws and regulations by national, state and local agencies 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 2015 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 FFDCA and its implementing regulations with respect to drugs, as well as the Public Health Service Act and its implementing regulations with respect to biologics. The FDA also regulates our Consumer Healthcare products.

Other U.S. federal agencies, including the DEA, also regulate certain of our products. The FTC 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, in 2015, approved the first biosimilar. Through that approval 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.

**Device Regulation.** In the U.S., the FDA regulates medical devices under the authority of the FDCA and its regulations. The FDA classifies U.S. medical devices into one of three classes (Class I, II or III) based on the statutory framework described in the FDCA. Our medical device business includes Class I and II devices, which are reviewed by the FDA under the 510(k) process.

During the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is "substantially equivalent" to "predicate devices." If the intended use and technological characteristics are comparable to a predicate device, the device may be cleared for marketing. If the device has the same intended use as a predicate device and different technological characteristics, but data is submitted to the FDA showing that the device is at least

as safe and effective as the legally marketed device, it may also be cleared for marketing. In reviewing a premarket notification, the FDA may request additional information, including clinical data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require Premarket Approval. The FDA requires each manufacturer to make this determination in the first instance, but the agency can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or Premarket Approval. The FDA can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or Premarket Approval is obtained. Additionally, the manufacturer may be subject to significant regulatory fines or penalties.

Postmarket Device Regulation. The medical devices that we manufacture and distribute are subject to continuing regulation by the FDA and other regulatory authorities. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with FDA regulations relating to cGMPs. These regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting which requires us to report to the FDA any incident in any of our products that may have caused or contributed to a death or serious injury, or required an unnecessary intervention for a patient, or in which any of our products malfunctioned and, if such malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the FTC. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. We are subject to routine inspection by the FDA

and other regulatory authorities for compliance with Quality System Regulation and Medical Devices Reporting requirements, as well as other applicable regulations. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend prosecution to the U.S. Department of Justice.

**Sales and Marketing.** The marketing practices of U.S. biopharmaceutical and medical device 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 or medical device 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 reimbursed 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 and medical device 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 or medical device 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. 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 2015 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 2015 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 providing coverage for Medicaid recipients contracting for the provision of services in the state. 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.

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 and medical device industries, such as:

- 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;
- imposing an annual fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid; and
- imposing an annual excise tax on manufacturers and importers of medical devices offered for sale in the U.S.

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 2015 revenues.



Additionally, policy efforts designed specifically to reduce patient out-of-pocket costs for medicines could result in new mandatory rebates and discounts or other pricing restrictions. A number of the candidates for the 2016 U.S. presidential elections have introduced such policy proposals, and a November 2015 U.S. Department of Health and Human Services forum dedicated to drug pricing could lead to further proposals. 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 in an effort to ensure access to medicines within an efficient and affordable healthcare system. In addition, certain regulatory changes to be implemented in 2016 may affect Pfizer's obligations under the Medicaid drug rebate program, but the impact of those changes is not yet known.

Adoption of other new legislation at the federal or state level could further affect demand for, or pricing of, our products.

**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. 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.

#### 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 EEA countries, Norway, Iceland and Liechtenstein. The use of these procedures generally provides a more rapid and consistent approval process across the Member States than was the case when the approval processes were operating independently within each country.

In Japan, the PMDA is the point of entry for businesses looking to sell drugs and medical devices 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 medical devices 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 five years behind first marketing in the U.S. and Europe, because China only issues 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 clinical trial waivers. Generics, on the other hand, only need to undergo bioequivalence studies upon a filing for record with the CFDA. 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 2012, new pharmacovigilance legislation came into force in the EU. Key changes include the establishment of a new Pharmacovigilance Risk Assessment Committee within the EMA, with responsibility for reviewing and making recommendations on product safety issues for the EU authorities. It also introduces the possibility for regulators to require pharmaceutical companies to conduct post-authorization efficacy studies at the time of approval, or at any time afterwards in light of scientific developments. There are also additional 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 typically less extensive.

**Medical Device Regulation.** The EU has adopted the European Medical Device Directives as a common legal framework for all EU Member States. These directives require companies that wish to manufacture and distribute medical devices in EU member countries to meet certain quality system and safety requirements and obtain a "CE" marking (i.e., a mandatory conformity marking for certain products sold within the EEA) for their products. The applicable authorities of the EU countries, generally in the form of their ministries or departments of health, are responsible for market surveillance of products once they are placed on the market. We are required to report device failures and injuries potentially related to product use to these authorities in a timely manner. Various penalties exist for non-compliance with the laws implementing the European Medical Device Directives.

Medical device laws and regulations similar to those described above are also in effect in many of the other countries/regions in which we distribute our medical device products.

**Pricing and Reimbursement.** In certain international markets, such as Europe, Japan, China, Canada, and South Korea, 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 also have resulted from exchange rate fluctuations that are exacerbated by international reference pricing systems. The downward pricing pressure resulting from this dynamic can be expected to continue as a result of reforms to international reference pricing policies, emergency measures targeting pharmaceuticals in some European countries and ongoing exchange rate fluctuations.

China historically controlled prices of pharmaceutical products mainly by setting their maximum retail prices. Since June 1, 2015, government-set price caps have been lifted for the vast majority of drug products. However, the government will continue to exercise indirect price control by setting reasonable reimbursement standards determined by the social insurance administrations, through a negotiation mechanism between drug manufacturers and social insurance administrations.

**EU Regulatory Changes.** The EU adopted a new Clinical Trials Regulation in May 2014, which is expected to come into effect by December 2017. 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. Under this policy, the EMA will proactively publish 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.

**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. 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 and medical device 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 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 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 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 committed 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. Canada is also signatory of the 2015 Trans-Pacific Trade Partnership (TPP), and Canada may enhance its intellectual property regime in line with its TPP obligations. The patent utility doctrine developed by the Canadian courts remains an important concern which is currently not being addressed by the Canadian government.

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 2015. 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, and restrictive standards for patentability of pharmaceutical products have made it difficult to protect many of our inventions. India maintains a system of pre-grant patent oppositions that delays the granting of patents and adds an additional challenge in our ability to protect our products through patents. Indian law includes special restrictions on the types of pharmaceutical inventions that may be patented which may limit our ability to protect our products. Recent use by the Indian government of compulsory licensing and patent revocation mechanisms heightens the risk of additional patent challenges targeting innovative pharmaceutical products, especially in areas perceived as being important to the public health of the population, such as infectious diseases, cancer and diabetes. In September 2012, Pfizer's patent covering Sutent was revoked by the Indian Patent Office and other challenges against Pfizer patents 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 2015 Financial Report. As a result, we incurred capital and operational expenditures in 2015 for environmental compliance purposes and for the clean-up of certain past industrial activity as follows:

•environment-related capital expenditures— \$23 million; and

•other environment-related expenses— \$144 million.

While capital expenditures or operating costs for environmental compliance, including compliance with laws related to climate change, 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 potential physical risks to our facilities and supply chain due to more frequent and severe weather events and water availability. 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 robust 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 2015 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, 2015, we employed approximately 97,900 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 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 2015, 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 2015 are required to be disclosed pursuant to ITRSHRA.

## 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 2015 Form 10-K and in our 2015 Annual Report to Shareholders contain forward-looking statements that set forth anticipated results based on management's plans and assumptions. 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," "goal," "objective," "aim" and other 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 recent acquisition of Hospira, our pending combination with Allergan, 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 2016 section in our 2015 Financial Report; the anticipated costs and cost savings set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook and Costs and Expenses—Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives sections in our 2015 Financial Report and in Notes to Consolidated Financial Statements—Note 3. Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives; the benefits, including synergies, expected from our recent acquisition of Hospira, the expected timing of completion, tax treatment and benefits of our pending combination with Allergan and the expected timing of a decision regarding a potential separation of our Innovative Products and Established Products businesses, set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook section in our 2015 Financial Report; 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 2015 Financial Report; and the contributions that we expect to make from our general assets to the Company's pension and postretirement plans during 2016 set forth in the Analysis of Financial Condition, Liquidity and Capital Resources—Selected Measures of Liquidity and Capital Resources—Contractual Obligations and in the Notes to Consolidated Financial Statements—Note 11. Pension and Postretirement Benefit Plans and Defined Contribution Plans in our 2015 Financial Report section in our 2015 Financial Report.

We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. 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 in our Form 10-Q and 8-K reports and our other filings with the SEC. 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 and 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 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. 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 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 expiration or loss 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 current Innovative products are expected to face significantly increased generic competition over the next few years.

Also, the patents covering several of our medicines, including Sutent, EpiPen, Toviaz, Tygacil extended-release capsules and Precedex Premix in the U.S. are being challenged by generic manufacturers. 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 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. Products that compete with ours, including some of our best-selling medicines, are launched from time to time. 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 generic or biosimilar market formation is important to that product’s profitability. Prices for products typically decline, sometimes dramatically, following market formation, as additional companies receive approvals to market that product and competition intensifies. If a company can be “first-to-market” such that the branded drug is the only other competition for a period of time, higher levels of sales and profitability can be achieved until other 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. If we are unable to bring our generic or biosimilar products to market on a timely basis, and secure “first-to-market” positions, our sales and profit opportunities could be adversely impacted.

#### DEPENDENCE ON KEY IN-LINE PRODUCTS

We recorded direct product revenues of more than \$1 billion for each of seven biopharmaceutical products: Prevnar/Prevenar 13, Lyrica, Enbrel, Lipitor, Viagra, Sutent and the Premarin family of products, as well as more than \$1 billion in Alliance revenues (primarily Eliquis) in 2015. Those products and Alliance revenues accounted for 44% of our total revenues in 2015. 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, in December 2014, generic versions of Celebrex became available pursuant to settlement agreements with several generic manufacturers. 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 2015 Financial Report.

Further, our Alliance revenues have been and will continue to 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, 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 Collaboration Rights section in our 2015 Financial Report.

## 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 the future and the delivery of shareholder return remains a major challenge. 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 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 that 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 past and future 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 candidate can have a substantial impact on the marketing strategy and payer reimbursement possibilities once the drug receives regulatory approval. For example, more detailed studies can lead to approval for a broader set of indications that may impact the marketing and payer reimbursement process, but each additional indication must be balanced against the time and resources required to demonstrate benefit and the potential delays to approval of the primary indication. We try to plan clinical

trials prudently and to reasonably foresee 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 these 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 three operating segments: GIP, VOC and GEP. 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, which, 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 assessment in markets around the world, U.S. PBMs seeking to negotiate greater discounts, deteriorating finances of certain governments and the uptake of biosimilars as they become available.

## 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 suspension of manufacturing, seizure of product or voluntary recall of a product.

## OUTSOURCING AND ENTERPRISE RESOURCE PLANNING

We outsource certain services to third parties in areas including transaction processing, accounting, information technology, manufacturing, clinical trial execution, non-clinical research, safety services and other areas. For example, in 2015, 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 also expose us to sub-optimal quality of service delivery or deliverables, which may result in missed deadlines or other timeliness issues, supply disruptions, non-compliance (including with applicable legal requirements and industry standards) or reputational harm, all 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.

#### 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 WHOLESALE DISTRIBUTORS

In 2015, our largest wholesale distributor accounted for approximately 14% of our total revenues (and 30% of our total U.S. revenues), and our top three wholesale distributors accounted for approximately 34% of our total revenues (and 74% of our total U.S. revenues). If one of our significant wholesale distributors should encounter financial or other difficulties, such distributor might decrease the amount of business that it does with us, and we might be unable to collect all the amounts that the distributor 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 (including the pending combination with Allergan) 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 importation of medicines across borders; 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.

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 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 mandating price controls and limitations on patient access to 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 and medical device 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. Private third-party payers, such as health plans, increasingly challenge pharmaceutical and medical device 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 provide healthcare at low direct cost to patients and regulate pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored healthcare system, and we have seen government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs in those markets, particularly under recent global economic 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 its provisions become effective on various dates. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a significant effect on our expenses and profitability in the future. 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 2015 Financial Report and in Item 1. Business under the caption Government Regulation and Price Constraints—In the United States. We also face the uncertainties that might result from any modification, repeal or invalidation of any 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. In addition, certain regulatory changes to be implemented in 2016 may affect Pfizer's obligations under the Medicaid drug rebate program, but the impact of those changes is not yet known.

Other U.S. federal or state legislative or regulatory action 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, 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

Any significant spending reductions or cost controls affecting Medicare, Medicaid or other publicly funded or subsidized health 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, 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 the realization of R&D and product-related, forward-looking statements. 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 perceived side effects or uncertainty regarding efficacy and, in some cases, could result in updated labeling, restrictions on use, product

withdrawal or recall.

#### CHANGING REGULATION OF MEDICAL DEVICES

In 2014, the FDA issued a final guidance document entitled “Infusion Pumps Total Product Life Cycle.” Through this final guidance, the FDA has established additional pre-market requirements for infusion pumps. At the same time, the FDA is also generally enhancing its pre-market requirements for medical devices. Although we cannot predict with certainty the future impact of these initiatives, it appears likely that the process for obtaining regulatory approvals to market infusion pumps and medical devices will become more costly and time consuming.

#### 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 laws and regulations, including, among others, changes in accounting standards, taxation requirements (including tax rate changes, new 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.

## 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 2015 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 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.

#### 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 with our employees and others, 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 distinctive 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, our patent rights with respect to certain products constitute unfair competition and/or violations of antitrust laws. In various jurisdictions, we are party to other patent damages suits pursuant to which generic drug manufacturers, payers, governments or other parties are seeking damages from us for alleged delay of generic entry related to patent enforcement litigation. 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 same. As our products mature, our reliance on our trademarks 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 Established Products 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 their intellectual property rights. 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 companies over our attempts to market generic pharmaceutical products. Once we have final regulatory approval of the related generic pharmaceuticals, we may decide to commercially market these products even though associated legal proceedings have not been resolved. If those proceedings ultimately determine that our products infringe the patent rights of another company, we may face damages, including a requirement to pay 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 for a period of time. 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:

##### HOSPIRA ACQUISITION

We may fail to realize all of the anticipated benefits from our acquisition of Hospira.

The success of our acquisition of Hospira will depend, in part, on our ability to realize the anticipated benefits and cost savings from combining our businesses. Anticipated benefits and cost savings may not be realized fully or at all, or may take longer to realize than expected. The integration process 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. In addition, Hospira has experienced manufacturing disruptions, device remediations and increased regulatory scrutiny due to quality issues. Future 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.

##### PENDING COMBINATION WITH ALLERGAN

We and Allergan must obtain required shareholder approvals and governmental and regulatory consents to consummate the merger, which, if delayed or not granted or granted with unacceptable conditions, may prevent, delay or impair the consummation of the merger, result in additional expenditures of money and resources and/or reduce the anticipated benefits of the merger.

On November 23, 2015, we announced that we have entered into a definitive merger agreement with Allergan under which we have agreed to combine with Allergan. Completion of the proposed transaction with Allergan is subject to certain closing conditions, including, among others, the receipt of required approvals of our shareholders and Allergan shareholders, clearance of the merger by certain governmental and regulatory authorities, including the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act and other filings or approvals as may be required pursuant to the antitrust and competition laws of certain foreign jurisdictions, including the EU. The governmental agencies with which we and Allergan will make these filings and seek certain of these approvals and consents have broad discretion in administering the governing regulations. We can provide no assurance that all required approvals and consents will be obtained. Moreover, as a condition to their approval of the

transaction, certain governmental agencies may impose requirements, limitations or costs or require divestitures or place restrictions on the conduct of the business of the combined company after the closing of the merger. Any one of these requirements, limitations, costs, divestitures or restrictions could jeopardize or delay the effective time of the merger or reduce the anticipated benefits of the transaction. Further, no assurance can be given that the required shareholder approvals will be obtained or that the required closing conditions will be satisfied, and, if all required consents and approvals are obtained and the closing conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals or clearances. Finally, the closing of the merger is subject to the closing of Allergan's pending divestiture of its generics business to Teva Pharmaceuticals Industries Ltd., which itself is subject to certain closing conditions, including receipt of governmental and regulatory consents, and no assurance can be given that the closing of such divestiture will occur on a timely basis or at all. If we and Allergan agree to any requirements, limitations, costs, divestitures or restrictions in order to obtain any approvals or clearances required to consummate the transaction, these requirements, limitations, costs, divestitures or restrictions could adversely affect the integration of the two companies' operations and/or reduce the anticipated benefits of the merger. In addition, future potential changes to the tax laws, if adopted prior to closing, could give rise to a right of Pfizer or Allergan to terminate the merger agreement. The occurrence of any of the foregoing could result in a failure to consummate the merger or have a material adverse effect on the business and results of operations of the combined company.

If the merger is not completed for any reason, we may be subjected to a number of material risks. The price of our common stock may decline to the extent that current market prices reflect a market assumption that the merger will be completed. In

addition, some costs related to the merger must be paid whether or not the merger is completed. We may also experience negative reactions from our shareholders, customers and employees. In addition, in specified circumstances, we could be required to reimburse expenses of Allergan or pay Allergan a termination fee of up to \$3.5 billion.

While the merger is pending, we and Allergan will be subject to business uncertainties that could adversely affect our respective businesses and operations. These uncertainties could also adversely affect the combined company following the completion of the merger.

Uncertainty about the effect of the merger on employees, customers and suppliers may have an adverse effect on us and Allergan. These uncertainties may impair our or Allergan's ability to attract, retain and motivate key personnel until the merger is consummated and for a period of time thereafter, and could cause customers, suppliers and others who deal with us or Allergan to seek to change existing business relationships with us and/or Allergan. Employee retention may be challenging during the pendency of the merger, as certain employees may experience uncertainty about their future roles. If key employees depart because of issues related to the uncertainty and difficulty of integration or a desire not to remain with the businesses, the business of the combined company following the merger could be seriously harmed.

In addition, until the merger is completed, the merger agreement restricts us and Allergan from taking specified actions without the consent of the other party. These restrictions may, among other things, prevent us or Allergan from pursuing attractive business opportunities that may arise prior to the completion of the merger.

We may fail to realize all of the anticipated benefits of the merger or those benefits may take longer to realize than expected. The combined company may also encounter significant difficulties in integrating the two businesses.

Our ability to realize the anticipated benefits of the merger will depend, to a large extent, on the combined company's ability to integrate the two businesses. The combination of two independent businesses is a complex, costly and time-consuming process. As a result, we will be required to devote significant management attention and resources to integrating our business practices and operations with Allergan's business practices and operations. The integration process may be disruptive to the businesses and, if implemented ineffectively, may restrict the full realization of expected benefits. The failure to meet the challenges involved in integrating the two businesses and to realize the anticipated benefits of the transactions could cause an interruption of, or a loss of momentum in, the activities of the combined company and could adversely affect the results of operations of the combined company.

In addition, the overall integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer and other business relationships and diversion of management attention. The difficulties of combining the operations of the companies include, among others:

- the diversion of management attention to integration matters;
- difficulties in integrating operations and systems;
- challenges in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;
- difficulties in assimilating employees and in attracting and retaining key personnel;
- challenges in keeping existing customers and obtaining new customers;

•

difficulties in achieving anticipated cost savings, synergies, accretion targets, business opportunities and growth prospects from the combination;

• difficulties in managing the expanded operations of a significantly larger and more complex company and in coordinating a geographically dispersed organization; and

• potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the merger.

Many of these factors are outside of our control and/or will be outside the control of the combined company, and any one of them could result in increased costs, decreased expected revenues and diversion of management time and energy, which could materially impact the business, financial condition and results of operations of the combined company. In addition, even if the operations of the businesses are integrated successfully, the full benefits of the merger may not be realized, including the anticipated synergies, cost savings and sales or growth opportunities. These benefits may not be achieved within the anticipated time frame, or at all. Further, additional unanticipated costs may be incurred in the integration of the businesses, as well as prior to the consummation of the combination. All of these factors could cause dilution to the earnings per share of the combined company, decrease or delay the expected accretive effect of the merger and negatively impact the price of the combined company ordinary shares. As a result, it cannot be assured that the pending combination with Allergan will result in the full realization of the benefits anticipated from the transaction within the anticipated time frames or at all.

In addition, although the combined company is expected, under current law, to be treated as a foreign corporation for U.S. federal income tax purposes, the IRS may not agree with this treatment. Even if treated as a foreign corporation, certain adverse tax consequences may apply to the combined company that could erode some of the synergies expected from the combination. Similarly, future changes in tax law could affect the combined company's status as a foreign corporation for U.S. federal income tax purposes or could otherwise materially and adversely affect some of the synergies expected from the combination. Any such changes in law or treatment by the IRS could have prospective or retroactive application, and may apply even if enacted or asserted after the merger is consummated. Moreover, various U.S. federal and state legislative and other proposals that would deny governmental contracts to U.S. companies (and subsidiaries of U.S. companies) that move (or have moved) their corporate location abroad may affect Pfizer if adopted. Any such changes in law or treatment by the IRS or other governmental agencies could have a material adverse effect on the anticipated results of the operations of the combined company.

Finally, our expectations regarding the timing and amount of accretion following consummation of the merger reflect the impact of anticipated share repurchases by us. The actual timing and size of any such share repurchases will depend on actual and expected financial results and the sufficiency of distributable reserves, as well as assessments at the time regarding capital allocation alternatives. Reduced or delayed share repurchase activity may result in less accretion.

Our shareholders cannot be sure of the value of the consideration they will receive in the merger, and may receive a form of consideration different from what they elect. Our shareholders will receive ordinary shares of the combined company as a result of the Allergan merger, which have rights different from shares of our common stock and our preferred shares.

Because the market price of Allergan ordinary shares and shares of our common stock will fluctuate, our shareholders cannot be sure of the value of the consideration they will receive in the merger. In addition, because the exchange ratio is fixed, the number of ordinary shares of the combined company to be received by holders of Pfizer common stock in the merger will not change between now and the time the merger is completed to reflect changes in the trading prices of Pfizer common stock or Allergan ordinary shares, share repurchases or other factors. Furthermore, although our shareholders will be entitled to elect to receive Allergan ordinary shares or cash consideration for their shares of our common stock, such elections will be subject to proration procedures set forth in the merger agreement, such that our existing shareholders will receive in the aggregate no less than \$6 billion and no more than \$12 billion in cash, and therefore our existing shareholders may receive a form of consideration different from what they elect.

Upon completion of the Allergan merger, the rights of our existing shareholders who receive Allergan ordinary shares, which will become the ordinary shares of the combined company, will be governed by the memorandum of association and articles of association of Allergan, which, subject to the amendments contemplated by the merger agreement, will become the memorandum of association and articles of the combined company, and by Irish law. The rights associated with shares of our common stock and our preferred shares are different from the rights associated with these ordinary shares. In addition, the laws of Ireland differ from the laws in effect in the U.S. and may afford less protection to holders of securities in the combined company.

Finally, it is expected that our existing shareholders as a group will receive shares in the merger constituting approximately 56% of the outstanding ordinary shares of the combined company on a fully diluted basis immediately following the effective time of the merger (based on the closing price of Pfizer common stock and certain other assumptions as of November 20, 2015). As a result, our shareholders will have a reduced ownership and voting interest after the merger and will exercise less influence over management.

The market value of our common stock may be adversely affected as a result of financial statement charges and cash costs associated with our proposed transaction with Allergan.

We expect to account for the proposed merger using the acquisition method of accounting, which will result in charges to our earnings that could adversely affect our reported operating results. Under this method, we will allocate the total purchase price to the assets acquired and liabilities assumed from Allergan based on their fair values as of the date of the completion of the proposed merger, and record any excess of the purchase price over those fair values as goodwill. For certain tangible and intangible assets, reevaluating fair value as of the completion date of the proposed merger will result in Pfizer incurring additional depreciation and/or amortization expense that exceed the combined amounts recorded by Pfizer and Allergan prior to the proposed merger. This increased expense will be recorded by us over the useful lives of the underlying assets. In addition, to the extent the value of goodwill or intangible assets were to become impaired, we may be required to incur charges relating to the impairment of those assets.

We expect to incur a number of non-recurring costs associated with the integration process. The substantial majority of such expenses will be composed of transaction costs, facilities and systems consolidation costs and employment-related costs, although certain additional costs may be incurred as well, such as potential costs related to litigation seeking to prevent the proposed transaction. We expect that the elimination of duplicative costs and the realization of other efficiencies related to the

integration of the businesses will allow us to more than offset incremental transaction- and integration-related costs over time, but this net benefit may not be achieved in the near term, or at all.

#### OTHER RISKS:

##### THE GLOBAL ECONOMIC ENVIRONMENT

In addition to industry-specific factors, we, like other businesses, are exposed to the economic cycle, which impacts our biopharmaceutical operations globally. We believe that patients, who are experiencing increases in co-pays and restrictions on access to medicines as payers seek to control costs, sometimes switch to generic products, delay treatments, skip doses or use less effective treatments. We are exposed to negative pricing pressure in various markets around the world. The U.S. has highly competitive insurance markets. Europe, Japan, China, Canada, South Korea and a number of other international markets have government-mandated reductions in prices and access restrictions for certain biopharmaceutical products to control costs for the government-sponsored healthcare system, particularly under recent global economic pressures. Furthermore, some government agencies and third-party payers use health technology assessments in ways that, at times, lead to restricted access to and lower prices for new medicines.

The global economic environment has not had, nor do we anticipate 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. As market conditions change, we continue to monitor our liquidity position. However, there can be no assurance that possible future 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 the credit and economic situations in several international markets, including Venezuela and Greece, where economic conditions remain challenging and uncertain. 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.

Other potential impacts of variations in the economic cycle include declining sales; increased costs; changes in foreign exchange rates; a decline in the value of, or a lower rate of return on, our financial assets and pension plan investments, which may require us to increase our pension funding obligations; adverse government actions; 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. 56% of our total 2015 revenues were derived from international operations, including 23% 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 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 example, in February 2013, the Venezuelan



government devalued its currency from an official rate of 4.3 to 6.3 of Venezuelan currency to the U.S. dollar. In the fourth quarter of 2015, we resolved that our Venezuela bolivar-denominated net monetary assets that are subject to revaluation are no longer expected to be settled at the 6.3 rate, but at the SIMADI rate of 200, resulting in a foreign currency loss. News reports state the Venezuelan government announced that, effective February 18, 2016, the official rate of 6.3 would be replaced by a rate of 10.0; and, the operation of the SIMADI rate would change. See the Analysis of Financial Condition, Liquidity and Capital Resources—Global Economic Conditions—Venezuela Operations section in our 2015 Financial Report for more information.

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 2015 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 2015 Financial Report and the Significant Accounting Policies and Application of Critical Accounting Estimates and Assumptions—Benefit Plans section in our 2015 Financial Report. Those sections of our 2015 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.

#### 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; (iv) any acquisitions, divestitures or other initiatives, such as our recent acquisition of Hospira; and (v) our pending combination with Allergan.

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 2015 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 2015, we continued to consolidate operations to achieve efficiencies and dispose of excess space. We have 595 owned and leased properties, amounting to approximately 59 million square feet. Our goal is to continue consolidation in 2016.

In 2015, excluding the impact of Hospira, we reduced the number of properties in our portfolio by 19 sites and 3.1 million square feet with the disposal of surplus real property assets and with reductions of operating space in all regions.

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

Pfizer's corporate headquarters are in New York City and Pfizer's properties extend internationally to over 75 countries.

Our WRD facilities support our R&D organizations around the world, with a heavy concentration in North America. In 2015, we continued to streamline our R&D locations, including the concentration of our Cambridge, Massachusetts operations into the Kendall Square neighborhood.

Our PGS division is headquartered in various locations, with leadership teams primarily in New York City, New York and in Peapack, New Jersey. PGS operates 64 plants around the world, which manufacture products for our commercial divisions. Locations with major manufacturing facilities include Belgium, China, Germany, India, Ireland, Italy, Japan, Puerto Rico, Singapore and the U.S. Our PGS division's plant network strategy is expected to result in the exit of four of these sites over the next several years. PGS also operates multiple distribution facilities around the world.

In general, we believe that our properties are well-maintained, adequate and suitable for their current requirements and for our operations in the foreseeable future. See the Notes to Consolidated Financial Statements—Note 9. Property, Plant and Equipment in our 2015 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 2015 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 2015 Financial Report, which is incorporated by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## 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 2016 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       | 62  | 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     | 54  | Group President, Global Innovative Pharma Business since February 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 | 58  | 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. 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 and the Gillen Brewer School.  |
| Mikael Dolsten    | 57  | 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.

|                     |    |  |
|---------------------|----|--|
| Charles H. Hill III | 60 | 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     | 54 | 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  | 50 | 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. |

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| Name                 | Age | Position  |
|----------------------|-----|---|
| 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.  |
| Anthony J. Maddaluna | 63  | Executive Vice President; President, Pfizer Global Supply since January 2013. President, Pfizer Global Supply from 2011 until December 2012. Senior Vice President, Strategy & Supply Network Transformation from 2009 until December 2010. Vice President, Strategy & Supply Network Transformation from 2008 until 2009. Vice President and Team Leader, Europe from 1998 until 2008 including responsibility for global logistics and strategic planning from 2005 through 2008. Mr. Maddaluna represents Pfizer on the National Association of Manufacturers (NAM) and is a member of the NAM Executive Committee. Director of Albany Molecular Research Inc. |
| Laurie J. Olson      | 52  | 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         | 54  | 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 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        | 51  | Group President, Global Established Pharma Business since January 2014. 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.  |

## 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". Our stock is also listed on the London Stock Exchange and the SIX Swiss Stock Exchange, and is traded on various U.S. regional stock exchanges. As of February 25, 2016, there were 174,703 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 2015 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 2015:

Issuer Purchases of Equity Securities<sup>(a)</sup>

| Period                                      | Total Number of Shares Purchased <sup>(b)</sup> | Average Price Paid per Share <sup>(b)</sup> | Total Number of Shares Purchased as Part of Publicly Announced Plan <sup>(a)</sup> | Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan <sup>(a)</sup> |
|---|---|---|--|--|
| September 28, 2015 through October 25, 2015 | 6,990   | \$27.89                                     | —  | \$ 5,355,862,076   |
| October 26, 2015 through November 30, 2015  | 42,521  | \$33.86                                     | —  | \$ 5,355,862,076   |
| December 1, 2015 through December 31, 2015  | 258,768   | \$32.79                                     | —  | \$ 16,355,862,076  |
| Total                                       | 308,279   | \$32.83                                     | —  |  |

On June 27, 2013, we announced that the Board of Directors had authorized a \$10 billion share-purchase plan, which was exhausted in the first quarter of 2015 (the June 2013 Stock Purchase Plan). On October 23, 2014, we announced that the Board of Directors had authorized an additional \$11 billion share-purchase plan, and share purchases commenced thereunder in January 2015 (the October 2014 Stock Purchase Plan). On February 9, 2015, we entered into an accelerated share repurchase agreement with Goldman, Sachs & Co. (GS&Co.) to repurchase shares of our common stock. This agreement was entered into under our previously announced share repurchase authorization. Pursuant to the terms of the agreement, on February 11, 2015, we paid \$5 billion to GS&Co. and received approximately 151 million shares of our common stock from GS&Co. On July 2, 2015, the accelerated share repurchase agreement with GS&Co. was completed, which, per the terms of the agreement, resulted in us owing GS&Co. a certain number of shares of Pfizer common stock or its equivalent dollar value. Pursuant to the agreement's settlement terms, we elected to settle this amount in cash and paid an additional \$160 million to GS&Co. on July 13, 2015, resulting in a total of approximately \$5.2 billion paid to GS&Co. The final average price paid for the shares delivered under the accelerated share repurchase agreement was \$34.13 per share. In November 2015, Pfizer announced that, consistent with 2015, it anticipates executing an approximately \$5 billion accelerated share repurchase program in the first half of 2016. The actual size and timing of any such share repurchases will depend on actual and expected future results. In December 2015, the Board of Directors authorized a new \$11 billion share repurchase program to be utilized over time. After giving effect to the accelerated share repurchase agreement executed in 2015, as well as other share repurchases through year-end 2015, our remaining share-purchase authorization was approximately \$16.4 billion as of December 31, 2015.

<sup>(b)</sup> These columns reflect the following transactions during the fourth fiscal quarter of 2015: (i) the surrender to Pfizer of 65,760 shares of common stock to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees; (ii) the open market purchase by the trustee of 20,062 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; (iii) the surrender to Pfizer of

185 shares of common stock to satisfy tax withholding obligations in connection with the vesting of performance share awards issued to employees; and (iv) the surrender to Pfizer of 222,272 shares of common stock to pay the exercise price and to satisfy tax withholding obligations in connection with the exercise of employee stock options.

ITEM 6. SELECTED FINANCIAL DATA

Information required by this item is incorporated by reference from the discussion under the heading Financial Summary in our 2015 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 2015 Financial Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information required by this item is incorporated by reference from the discussion under the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2015 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 2015 Financial Report and from the consolidated financial statements, related notes and supplementary data in our 2015 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 2015 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 2015 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. Pfizer acquired Hospira on September 3, 2015, and management excluded from its assessment of the effectiveness of Pfizer's internal control over financial reporting as of December 31, 2015, Hospira's and its subsidiaries' internal control over financial reporting associated with total assets of \$24.2 billion and total revenues of \$1.5 billion included in the consolidated financial statements of Pfizer Inc. and Subsidiary Companies as of and for the year ended December 31, 2015.

Changes in Internal Controls

During our most recent fiscal quarter, management remediated an identified material weakness in internal control over financial reporting related to accounting for the elimination of intercompany profit in inventory and certain other intercompany accounts. No restatement of prior period financial statements and no change in previously released financial results were required as a result of this finding. For the reporting period ended December 31, 2015, management remediated the material weakness by enhancing and adding additional reconciliation and review controls over the accounting for intercompany profit in inventory and certain other intercompany accounts. The Company will continue to monitor these new controls and implement additional enhancements in 2016.

Except for the foregoing, there was no 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) in the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. We continue to integrate Hospira's operations into our internal control over financial reporting. None of these integration activities are expected to have a material impact on our system of internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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 2016 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 2016 Proxy Statement. Information about the Pfizer Policies on Business Conduct governing our employees, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer, and the Code of Business Conduct and Ethics for Members of the Board of Directors, is incorporated by reference from the discussions under the headings Governance—Other Governance Practices and Policies—Pfizer policies on business ethics and conduct and —Code of conduct for directors in our 2016 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 2017 Annual Meeting in our 2016 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 2016 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 2015 Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information about Director and executive compensation is incorporated by reference from the discussion under the headings Compensation of Non-Employee Directors; Executive Compensation; and Governance—Board Information—Board and Committee Information—Board Committees—The Compensation Committee—Compensation Committee Interlocks and Insider Participation in our 2016 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 2016 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 2016 Proxy Statement. Information about director independence is incorporated by reference from the discussion under the heading Governance—Board Information—Director Independence in our 2016 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 2015 and 2014 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 2016 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 2016 Proxy Statement.



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 2015 Financial Report are incorporated by reference into Item 8 of Part II of this 2015 Annual Report on 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 2015 Annual Report on Form 10-K. All other exhibit numbers indicate exhibits filed by incorporation by reference. Exhibit numbers 10.1 through 10.26 are management contracts or compensatory plans or arrangements.

2.1 Agreement and Plan of Merger, dated as of November 22, 2015, among Pfizer Inc., Allergan plc and Watson Merger Sub Inc. is incorporated by reference from our Current Report on Form 8-K filed on November 23, 2015 (File No. 001-03619). (Pursuant to Item 601(b)(2) of Regulation S-K, the registrant hereby agrees to supplementally furnish to the Securities and Exchange Commission upon request any omitted schedule or exhibit to the Merger Agreement.)

2.2 Agreement and Plan of Merger, dated as of February 5, 2015, among Pfizer Inc., Perkins Holding Company and Hospira, Inc. is incorporated by reference from our Current Report on Form 8-K filed on February 6, 2015 (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

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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 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 8-K report filed on October 6, 2015 (File No. 001-03619).
- 4.7 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.
- 4.8 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.
- 4.9 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).
- 4.10 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).
- 4.11 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).
- 4.12 Eighth Supplemental Indenture, dated as of October 30, 2009, between Wyeth, us and The Bank of New York Mellon (as successor to JPMorgan Chase Bank, formerly The Chase Manhattan Bank), as Trustee, to Indenture dated as of April 10, 1992 (as amended on October 13, 1992), is incorporated by reference from our Current Report on Form 8-K filed on November 3, 2009 (File No. 001-03619).
- 4.13 Except as set forth in Exhibits 4.1-12 above, the instruments defining the rights of holders of long-term debt securities of the Company and its subsidiaries have been omitted.<sup>1</sup>
- 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).

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- 10.4 Form of Stock Option Grant Notice and Summary of Key Terms is incorporated by reference from our Quarterly Report on Form 10-Q for the period ended September 26, 2004 (File No. 001-03619).
- \*10.5 Form of Executive Grant Letter.
- 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 Amended and Restated Nonfunded Deferred Compensation and Supplemental Savings Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
- 10.8 Amendment to Amended and Restated Nonfunded Deferred Compensation and Supplemental Savings Plan, dated June 20, 2013, is incorporated by reference from our 2013 Annual Report on Form 10-K (File No. 001-03619).

<sup>1</sup> 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.



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- 10.9 Amendment No. 2 to Amended and Restated Nonfunded Deferred Compensation and Supplemental Savings Plan, dated December 10, 2014, is incorporated by reference from our 2014 Annual Report on Form 10-K (File No. 001-03619).
- \*10.10 Pfizer Inc. Global Performance Plan.
- 10.11 Executive Annual Incentive Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
- 10.12 Amended and Restated Deferred Compensation Plan is incorporated by reference from our 2012 Annual Report on Form 10-K (File No. 001-03619).
- 10.13 Amendment to Amended and Restated Deferred Compensation Plan, dated June 20, 2013, is incorporated by reference from our 2013 Annual Report on Form 10-K (File No. 001-03619).
- 10.14 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).
- 10.15 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).
- 10.16 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).
- 10.17 Amended and Restated Wyeth Supplemental Executive Retirement Plan (effective as of January 1, 2005), together with all material Amendments is incorporated by reference from our 2011 Annual Report on Form 10-K (File No. 001-03619).
- 10.18 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).
- 10.19 The form of Indemnification Agreement with each of the Named Executive Officers identified in our 2015 Proxy Statement is incorporated by reference from our 1997 Annual Report on Form 10-K (File No. 001-03619).
- 10.20 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).
- 10.21 Executive Severance Plan is incorporated by referenced from our Current Report on Form 8-K filed on February 20, 2009 (File No. 001-03619).
- 10.22 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).
- 10.23

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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).

- 10.24 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).
- 10.25 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).
- 10.26 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 2015 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 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

## 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 29, 2016

By: /S/ MARGARET M. MADDEN  
Margaret M. Madden  
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<br>Ian C. Read                        | Chairman, Chief Executive Officer and Director<br>(Principal Executive Officer)                            | February 23, 2016 |
| /S/ FRANK A. D'AMELIO<br>Frank A. D'Amelio            | Executive Vice President, Business Operations and<br>Chief Financial Officer (Principal Financial Officer) | February 23, 2016 |
| /S/ LORETTA V.<br>CANGIALOSI<br>Loretta V. Cangialosi | Senior Vice President—Controller<br>(Principal Accounting Officer)   | February 23, 2016 |
| /S/ DENNIS A. AUSIELLO<br>Dennis A. Ausiello          | Director   | February 23, 2016 |
| /S/ W. DON CORNWELL<br>W. Don Cornwell                | Director   | February 23, 2016 |
| /S/ JOSEPH J.<br>ECHEVARRIA<br>Joseph J. Echevarria   | Director   | February 23, 2016 |
| /S/ FRANCES D.<br>FERGUSSON<br>Frances D. Fergusson   | Director   | February 23, 2016 |
| /S/ HELEN H. HOBBS<br>Helen H. Hobbs                  | Director   | February 23, 2016 |



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| Signature   | Title    | Date              |
|---|----------|-------------------|
| /S/ JAMES M. KILTS<br>James M. Kilts                | Director | February 23, 2016 |
| /S/ SHANTANU<br>NARAYEN<br>Shantanu Narayen         | Director | February 24, 2016 |
| /S/ SUZANNE NORA<br>JOHNSON<br>Suzanne Nora Johnson | Director | February 23, 2016 |
| /S/ STEPHEN W. SANGER<br>Stephen W. Sanger          | Director | February 24, 2016 |
| /S/ JAMES C. SMITH<br>James C. Smith                | Director | February 23, 2016 |