PFIZER INC

Form 10-K

February 23, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 10-K

(Mark

One)

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

For the fiscal year ended December 31, 2016

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

For the transition period from

Commission file number 1-3619

PFIZER INC.

(Exact name of registrant as specified in its charter)

Delaware 13-5315170

to

(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 x No o

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

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

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. o

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, July 3, 2016, was approximately \$216 billion. This excludes shares of common stock held by directors and executive officers at July 3, 2016. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant. The registrant has no non-voting common stock.

The number of shares outstanding of the registrant's common stock as of February 21, 2017 was 5,951,872,174 shares of common stock, all of one class.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2016 Annual Report to Shareholders

Parts I, II and IV

Portions of the Proxy Statement for the 2017 Annual Meeting of Shareholders

Part III

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#### **DEFINED TERMS**

Unless the context requires otherwise, references to "Pfizer," "the Company," "we," "us" or "our" in this 2016 Form 10-K (defined below) refer to Pfizer Inc. and its subsidiaries. We also have used several other terms in this 2016 Form 10-K, most of which are explained or defined below.

2016 Financial

Report Exhibit 13 to this 2016 Form 10-K

2016 Form 10-K This Annual Report on Form 10-K for the fiscal year ended December 31, 2016

2017 Proxy

Statement

Proxy Statement for the 2017 Annual Meeting of Shareholders

ACA

U.S. Patient Protection and Affordable Care Act, as amended by the Health Care and Education

Reconciliation Act

Alliance Revenues from alliance agreements under which we co-promote products discovered or developed

revenues by other companies or us
Anacor Anacor Pharmaceuticals, Inc.
ANDA Abbreviated New Drug Application

Astellas Astellas Pharma US, Inc.

BLA Biologics License Application

BMS Bristol-Myers Squibb Company

cGMPs current Good Manufacturing Practices

CFDA China Food and Drug Administration

DEA U.S. Drug Enforcement Agency

Developed U.S., Western Europe, Japan, Canada, Australia, Scandinavian countries, South Korea, Finland and

Markets New Zealand

EFPIA European Federation of Pharmaceutical Industries and Associations

EH Essential Health

EMA European Medicines Agency

Emerging Includes, but is not limited to, the following markets: Asia (excluding Japan and South Korea), Latin

Markets America, Africa, Eastern Europe, Central Europe, the Middle East and Turkey

EU European Union

Exchange Act Securities Exchange Act of 1934, as amended

FCPA U.S. Foreign Corrupt Practices Act
FDA U.S. Food and Drug Administration
FFDCA U.S. Federal Food, Drug and Cosmetic Act
GPD Global Product Development organization

HIS Hospira Infusion Systems

Hospira Hospira, Inc.
ICU Medical ICU Medical, Inc.
IH Innovative Health

IPR&D In-process Research and Development

LOE Loss of Exclusivity

MCO Managed Care Organization

Medivation Medivation, Inc.

NDA New Drug Application

NYSE New York Stock Exchange

OTC over-the-counter

PBM Pharmacy Benefit Manager

PMDA Pharmaceuticals and Medical Device Agency in Japan

R&D Research and Development

SEC U.S. Securities and Exchange Commission

U.K. United Kingdom U.S. United States

WRD Worldwide Research and Development

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

- <u>8</u> Products with Direct Product Sales of Greater than \$1 Billion and IH Alliance Revenues of Greater than \$1 Billion in 2016
- <u>2</u> Distinct Business Segments Pfizer Innovative Health (<u>~\$29.2 Billion 2016 Revenues</u>) / Pfizer Essential Health (<u>~\$23.6 Billion 2016 Revenues</u>)
- <u>6</u> Primary Therapeutic Areas in Pfizer Innovative Health Internal Medicine, Vaccines, Oncology, Inflammation & Immunology, Rare Diseases and Consumer Healthcare
- <u>5</u> Pfizer Essential Health Product Categories Global Brands (Legacy Established Products & Peri-LOE Products), Sterile Injectable Pharmaceuticals, Infusion Systems (through February 2, 2017), Biosimilars and Pfizer CentreOne
- >125 Countries Where We Sell Our Products
- 96 Projects in Clinical Research & Development(1)
- ~\$7.9 Billion 2016 R&D Expense
- 63 Manufacturing Sites Worldwide Operated by PGS(2)
- ~96,500 Employees Globally<sup>(2)</sup>
- (1) As of January 31, 2017
- (2) As of December 31, 2016

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

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PART I ITEM 1.BUSINESS GENERAL

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

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

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

On February 3, 2017, we completed the sale of our global infusion therapy net assets, HIS, to ICU Medical for up to approximately \$900 million, composed of cash and contingent cash consideration, ICU Medical common stock and seller financing. HIS includes IV pumps, solutions and devices. Under the terms of the agreement, we received 3.2 million newly issued shares of ICU Medical common stock, which we valued at approximately \$430 million (based upon the closing price of ICU Medical common stock on the closing date less a discount for lack of marketability), a promissory note from ICU Medical in the amount of \$75 million and net cash of approximately \$200 million before customary adjustments for net working capital. In addition, we are entitled to receive a contingent amount of up to an additional \$225 million in cash based on ICU Medical's achievement of certain cumulative performance targets for the combined company through December 31, 2019. After receipt of the ICU Medical shares, we own approximately 16.4% of ICU Medical as of the closing date. We have agreed to certain restrictions on transfer of our ICU Medical shares for 18 months. For additional information, see Notes to Consolidated Financial Statements—Note 2B. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Assets and Liabilities Held for Sale in our 2016 Financial Report.

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

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

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

On June 24, 2016, we acquired Anacor for approximately \$4.9 billion in cash (\$4.5 billion net of cash acquired), plus \$698 million debt assumed. Anacor is now a wholly-owned subsidiary of Pfizer. Anacor is a biopharmaceutical company focused on novel small-molecule therapeutics derived from its boron chemistry platform. Anacor's crisaborole, a non-steroidal topical PDE-4 inhibitor with anti-inflammatory properties, was approved by the FDA on December 14, 2016 under the trade name, Eucrisa. For additional information, see the Notes to Consolidated Financial Statements—Note 2A. Acquisitions, Assets and Liabilities Held for Sale, Licensing Agreements, Research and Development and Collaborative Arrangements, Equity-Method Investments and Cost-Method Investment: Acquisitions in our 2016 Financial Report.

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

For a further discussion of our strategy and our business development initiatives, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Our Business Development Initiatives section in our 2016 Financial Report.

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

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

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### AVAILABLE INFORMATION AND PFIZER WEBSITE

Our website is located at www.pfizer.com. This 2016 Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available (free of charge) on our website, in text format and, where applicable, in interactive data file format, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

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

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

Information relating to corporate governance at Pfizer, including our Corporate Governance Principles; Director Qualification Standards; Pfizer Policies on Business Conduct (for all of our employees, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer); Code of Business Conduct and Ethics for Members of the Board of Directors; information concerning our Directors; ways to communicate by e-mail with our Directors; Board Committees; Committee Charters; Charter of the Lead Independent Director; and transactions in Pfizer securities by Directors and Officers; as well as Chief Executive Officer and Chief Financial Officer certifications, are available on our website. We will provide any of the foregoing information without charge upon written request to our Corporate Secretary, Pfizer Inc., 235 East 42nd Street, New York, NY 10017-5755. We will disclose any future amendments to, or waivers from, provisions of the Pfizer Policies on Business Conduct affecting our Chief Executive Officer, Chief Financial Officer and Controller on our website as promptly as practicable, as may be required under applicable SEC and NYSE rules. Information relating to shareholder services, including the Computershare Investment Program, book-entry share ownership and direct deposit of dividends, is also available on our website.

The information contained on our website, our Facebook, YouTube and LinkedIn pages or our Twitter accounts does not, and shall not be deemed to, constitute a part of this 2016 Form 10-K. Pfizer's references to the URLs for websites are intended to be inactive textual references only.

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## **COMMERCIAL OPERATIONS**

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

Some additional information about our business segments follows:

Pfizer Innovative Health

Pfizer Essential Health

IH focuses on developing and commercializing novel, value-creating medicines and vaccines as products for consumer healthcare. vaccines, oncology, inflammation & immunology, rare diseases and consumer

EH includes legacy brands that have lost or will soon lose market that significantly improve patients' lives, as well exclusivity in both developed and emerging markets, branded generics, generic sterile injectable products, biosimilars and, Key therapeutic areas include internal medicine, through February 2, 2017, infusion systems. EH also includes an R&D organization, as well as our contract manufacturing business.

#### Leading brands include:

- Prevnar 13

healthcare.

- Xeljanz

- Eliquis

- Lyrica (U.S., Japan and certain other markets)

- Enbrel (outside the U.S. and Canada)

- Viagra (U.S. and Canada)

- Ibrance

- Xtandi

- Several OTC consumer products (e.g., Advil and Centrum)

Leading brands include:

- Lipitor

- Premarin family

- Norvasc

- Lyrica (Europe, Russia, Turkey, Israel and Central Asia countries)

- Celebrex

- Pristiq

- Several sterile injectable products

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

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

For a further discussion of these operating segments, see the Innovative Health and Essential Health sections below and the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information, including the tables therein captioned Selected Income Statement Information, Geographic Information and Significant Product Revenues, the table captioned Revenues by Segment and Geographic Area in the Analysis of the Consolidated Statements of Income section, and the Analysis of Operating Segment Information section in our 2016 Financial Report, which are incorporated by reference.

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### INNOVATIVE HEALTH

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

Geographic Revenues for Innovative Health\*

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

For additional information regarding the revenues of our IH business, including revenues of major IH products, see the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information and the Analysis of the Consolidated Statements of Income—Revenues—Major Products and —Revenues—Selected Product Descriptions sections in our 2016 Financial Report; and for additional information on the key operational revenue drivers of our IH business, see the Analysis of Operating Segment Information—Innovative Health Operating Segment section of our 2016 Financial Report.

The key therapeutic areas comprising our IH business segment include:

#### Internal Medicine

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

#### Vaccines

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

## Oncology

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

#### Inflammation and Immunology

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

#### Rare Diseases

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

section in our 2016 Financial Report.

#### Consumer Healthcare

According to Euromonitor International's retail sales data, in 2016, Pfizer's Consumer Healthcare business was the fourth-largest branded multi-national, OTC consumer healthcare business in the world and produced two of the ten largest selling consumer healthcare brands (Centrum and Advil) in the world.

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

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

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

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

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

**ESSENTIAL HEALTH** 

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

Geographic Revenues for Essential Health\*

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

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For additional information regarding the revenues of our EH business, including revenues of major EH products, see the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information and the Analysis of the Consolidated Statements of Income—Revenues—Major Products and —Revenues—Selected Product Descriptions sections in our 2016 Financial Report; and for additional information on the key operational revenue drivers of our EH business, see the Analysis of Operating Segment Information—Essential Health Operating Segment section of our 2016 Financial Report.

The product categories in our EH business segment include:

Global Brands, which includes:

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

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

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

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

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

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

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

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

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

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#### RESEARCH AND DEVELOPMENT

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

Our R&D Operations

We conduct R&D internally and also through contracts with third parties, through collaborations with universities and biotechnology companies and in cooperation with other pharmaceutical firms. Our R&D spending is conducted through a number of matrix organizations. Our WRD organization is generally responsible for research projects for our IH business until proof-of-concept is achieved and then for transitioning those projects to the IH segment via the GPD organization, which was formed in early 2016, for possible clinical and commercial development.

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

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

We continue to strengthen our global R&D organization and pursue strategies intended to improve innovation and overall productivity in R&D to achieve a sustainable pipeline that will deliver value in the near term and over time. For additional information regarding our R&D operations, see the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Strategy—Research and Development Operations and Costs and Expenses—Research and Development (R&D) Expenses—Description of Research and Development Operations sections in our 2016 Financial Report.

## Our R&D Priorities and Strategy

Our R&D priorities include delivering a pipeline of differentiated therapies and vaccines with the greatest medical and commercial promise, innovating new capabilities that can position Pfizer for long-term leadership and creating new models for biomedical collaboration that will expedite the pace of innovation and productivity. To that end, our research primarily focuses on:

Biosimilars;

Inflammation and Immunology;

Metabolic Disease and Cardiovascular Risks;

Neuroscience;

Oncology;

Rare Diseases; and

Vaccines.

We also seek out promising chemical and biological lead molecules and innovative technologies developed by third parties to incorporate into our discovery and development processes or projects, as well as our product lines, by

entering into collaborations and alliance and license agreements with other companies, as well as leveraging acquisitions and equity- or debt-based investments. These agreements enable us to co-develop, license or acquire promising compounds, technologies or capabilities. We also enter into agreements pursuant to which a third party agrees to fund a portion of the development costs of one or more of our pipeline products in exchange for rights to receive potential milestone payments, revenue sharing payments, profit sharing payments and/or royalties. Collaboration, alliance, license and funding agreements and equity- or debt-based investments allow us to share risk and cost and to access external scientific and technological expertise, and enable us to advance our own products as well as in-licensed or acquired products.

#### Our R&D Pipeline and Competition

Innovation is critical to the success of our company, and drug discovery and development is time-consuming, expensive and unpredictable. According to the Pharmaceutical Benchmarking Forum, out of 20 compounds entering preclinical development, only one is approved by a regulatory authority in a major market (U.S., the EU or Japan). The process from early discovery or design to development to regulatory approval can take more than ten years. Drug candidates can fail at any stage of the process, and candidates may not receive regulatory approval even after many years of research and development.

As of January 31, 2017, we had the following number of projects in various stages of R&D: Development of a single compound is often pursued as part of multiple programs. While these drug candidates may or may not eventually receive regulatory approval, new drug candidates entering clinical development phases are the foundation for future products. In addition to discovering and developing new products, our R&D efforts seek to add value to our existing products by improving their effectiveness, enhancing ease of dosing and by discovering potential new indications for them.

Information concerning several of our drug candidates in development, as well as supplemental filings for existing products, is set forth in the Analysis of the Consolidated Statements of Income—Product Developments—Biopharmaceutical section in our 2016 Financial Report, which is incorporated by reference.

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

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#### INTERNATIONAL OPERATIONS

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

We sell our products in over 125 countries. Revenues from operations outside the U.S. of \$26.5 billion accounted for 50% of our total revenues in 2016. Japan is our largest national market outside the U.S. For a geographic breakdown of revenues, see the table captioned Geographic Information in the Notes to Consolidated Financial Statements—Note 18. Segment, Geographic and Other Revenue Information in our 2016 Financial Report, and the table captioned Revenues by Segment and Geographic Area in our 2016 Financial Report. Those tables are incorporated by reference.

#### Revenues by National Market

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

Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or decrease the reported dollar value of our net assets and results of operations. While we cannot predict with certainty future changes in foreign exchange rates or the effect they will have on us, we attempt to mitigate their impact through operational means and by using various financial instruments, depending upon market conditions. For additional information, see the Notes to Consolidated Financial Statements—Note 7E. Financial Instruments: Derivative Financial Instruments and Hedging Activities in our 2016 Financial Report, as well as the Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management section in our 2016 Financial Report. Those sections of our 2016 Financial Report are incorporated by reference.

**MARKETING** 

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

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

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

% of 2016 Total Revenues and U.S. Revenues from

Major Biopharmaceutical Wholesalers and Other Customers

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

#### PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS

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

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

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

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

Drug	U.S. Basic Product Patent	Major EU Basic Product Patent	Japan Basic Product Patent
	Expiration Year	Expiration Year	Expiration Year
Viagra	$2012^{(1)}$	2013	2013 <sup>(1)</sup>
Lyrica	2018	$2014^{(2)}$	2022
Chantix	2020	2021	2022
Xeljanz	2020	N/A <sup>(3)</sup>	2025
Sutent	2021	2021	2024
Eliquis <sup>(4)</sup>	2023	2026	2026
Ibrance	2023	2023	N/A <sup>(5)</sup>
Inlyta	2025	2025	2025
Prevnar	2026	2026 <sup>(6)</sup>	2029
13/Prevenar 13	2026	2020(0)	2029
Eucrisa	2026	N/A <sup>(7)</sup>	N/A <sup>(7)</sup>
Xtandi <sup>(8)</sup>	2027	*(8)	*(8)
Xalkori	2029	2027	2028

In addition to the basic product patent covering Viagra, which expired in 2012, Viagra is covered by a U.S. method-of-treatment patent which, including the six-month pediatric exclusivity period associated with Revatio

- (1) (which has the same active ingredient as Viagra), expires in 2020. However, as a result of a patent litigation settlement, Teva Pharmaceuticals USA, Inc. will be allowed to launch a generic version of Viagra in the U.S. in December 2017, or earlier under certain circumstances. The corresponding method-of-treatment patent covering Viagra in Japan expired in May 2014.
- (2) For Lyrica, regulatory exclusivity in the EU expired in July 2014.
- (3) The Xeljanz marketing authorization application has been filed and is under review in the EU.
- Eliquis was developed and is being commercialized in collaboration with BMS.
- (5) The Ibrance marketing authorization application has been filed and is under review in Japan.

  The EU patent that covers the combination of the 13 serotype conjugates of Prevenar 13 has been revoked
- (6) following an opposition proceeding. This first instance decision has been appealed. There are other EU patents and pending applications covering the formulation and various aspects of the manufacturing process of Prevenar 13 that remain in force.
- (7) Eucrisa is not approved in the EU and Japan.
- (8) Xtandi is being developed and commercialized in collaboration with Astellas, who has exclusive commercialization rights for Xtandi outside the U.S.

A number of our current products have experienced patent-based expirations or loss of regulatory exclusivity in certain markets in the last few years. For additional information, including a description of certain of our co-promotion agreements and their expiration dates, and a further discussion of our products experi