

AbbVie Inc.  
Form 10-K  
February 17, 2017

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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

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

For the fiscal year ended December 31, 2016

Commission file number 001-35565

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware

32-0375147

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. employer  
identification number)

1 North Waukegan Road

(847) 932-7900

North Chicago, Illinois 60064-6400

(Telephone number)

(Address of principal executive offices) (Zip Code)

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

Title of Each Class

Name of Each Exchange on Which  
Registered

Common Stock, par value \$0.01 per share

New York Stock Exchange  
Chicago Stock Exchange

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 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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.   
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   
(Do not check if a smaller reporting company)

Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

The aggregate market value of the 1,610,874,586 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of AbbVie Inc.'s most recently completed second fiscal quarter (June 30, 2016), was \$99,729,245,619. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2017: 1,593,920,285

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the 2017 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 20, 2017.

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ABBVIE INC.  
 FORM 10-K  
 FOR THE YEAR ENDED DECEMBER 31, 2016  
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PART I  
ITEM 1. BUSINESS

Overview

AbbVie<sup>(1)</sup> is a global, research-based biopharmaceutical company. AbbVie develops and markets advanced therapies that address some of the world's most complex and serious diseases. AbbVie's products are focused on treating conditions such as chronic autoimmune diseases in rheumatology, gastroenterology and dermatology; oncology, including blood cancers; virology, including hepatitis C (HCV) and human immunodeficiency virus (HIV); neurological disorders, such as Parkinson's disease and multiple sclerosis; metabolic diseases, including thyroid disease and complications associated with cystic fibrosis; as well as other serious health conditions. AbbVie also has a pipeline of promising new medicines, including more than 50 investigational programs in clinical development across such important medical specialties as immunology, virology, oncology and neurology, with additional targeted investment in cystic fibrosis and women's health.

AbbVie was incorporated in Delaware on April 10, 2012. On January 1, 2013, AbbVie became an independent company as a result of the distribution by Abbott Laboratories (Abbott) of 100% of the outstanding common stock of AbbVie to Abbott's shareholders.

On June 1, 2016, AbbVie acquired all of the outstanding equity interests in Stemcentrx, Inc. (Stemcentrx), a privately held biotechnology company. The aggregate upfront consideration paid by AbbVie in connection with the acquisition was approximately \$5.8 billion. The transaction expands AbbVie's oncology pipeline by adding the late-stage asset rovalpituzumab tesirine (Rova-T), four additional early-stage clinical compounds in solid tumor indications and a significant portfolio of pre-clinical assets. Rova-T is currently in registrational trials for small cell lung cancer and in early-stage clinical development for other solid tumors.

Segments

AbbVie operates in one business segment—pharmaceutical products. See Note 15 to the Consolidated Financial Statements and the sales information related to HUMIRA included under Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations."

Products

AbbVie's portfolio of products includes a broad line of therapies that address some of the world's most complex and serious diseases.

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(1) As used throughout the text of this report on Form 10-K, the terms "AbbVie" or "the company" refer to AbbVie Inc., a Delaware corporation, or AbbVie Inc. and its consolidated subsidiaries, as the context requires.

**HUMIRA.** HUMIRA (adalimumab) is a biologic therapy administered as a subcutaneous injection. It is approved to treat the following autoimmune diseases in the United States, Canada and Mexico (collectively, North America) and in the European Union:

Condition	Principal Markets
Rheumatoid arthritis (moderate to severe)	North America, European Union
Psoriatic arthritis	North America, European Union
Ankylosing spondylitis	North America, European Union
Adult Crohn's disease (moderate to severe)	North America, European Union
Plaque psoriasis (moderate to severe chronic)	North America, European Union
Juvenile idiopathic arthritis (moderate to severe polyarticular)	North America, European Union
Ulcerative colitis (moderate to severe)	North America, European Union
Axial spondyloarthritis	European Union
Pediatric Crohn's disease (moderate to severe)	North America, European Union
Hidradenitis Suppurativa (moderate to severe)	North America, European Union
Pediatric enthesitis-related arthritis	European Union
Non-infectious intermediate, posterior and panuveitis	North America, European Union

HUMIRA is also approved in Japan for the treatment of intestinal Behçet's disease.

HUMIRA is sold in numerous other markets worldwide, including Japan, China, Brazil and Australia, and accounted for approximately 63% of AbbVie's total net revenues in 2016.

AbbVie continues to dedicate substantial research and development efforts to expanding indications for HUMIRA, including in the fields of rheumatology, gastroenterology (pediatric ulcerative colitis), and dermatology (pediatric psoriasis). The indication for non-infectious intermediate, posterior, and panuveitis was approved by the United States Food and Drug Administration on June 2016. AbbVie continues to work on HUMIRA formulation and delivery enhancements to improve convenience and the overall patient experience.

**Oncology products.** AbbVie's oncology products target some of the most complex and difficult-to-treat cancers, including hematologic and solid cancers.

**IMBRUVICA.** IMBRUVICA (ibrutinib) is a first-in-class, oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase (BTK). IMBRUVICA is currently approved for the treatment of patients with chronic lymphocytic leukemia (CLL), CLL patients who have del 17p and patients with Waldenström's macroglobulinemia. IMBRUVICA is also approved for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for the MCL indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials. In January 2017, the FDA also approved IMBRUVICA for the treatment of patients with relapsed/refractory marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. IMBRUVICA was one of the first medicines to receive a U.S. Food and Drug Administration (FDA) approval after being granted a Breakthrough Therapy Designation and IMBRUVICA is one of the few therapies to receive four separate designations.

**Venclexta.** Venclexta (venetoclax) is approved to treat people with chronic lymphocytic leukemia (CLL) with 17p deletion, who have received at least one prior treatment. Venclexta is the first FDA-approved treatment that targets the B-cell lymphoma 2 (BCL-2) protein, which supports cancer cell growth and is overexpressed in many patients with CLL. Venclexta has recently been approved in the EU for the treatment of chronic lymphocytic leukemia (CLL) in patients with 17p deletion or TP53 mutation and are unsuitable for or have failed a B-cell receptor pathway inhibitor and for the treatment of CLL in absence of 17p deletion or TP53 mutation who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.

**Virology Products.** AbbVie's virology products address unmet needs for patients living with the hepatitis C virus and HIV-1.

HCV products. VIEKIRA PAK (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) is an all-oral, short-course, interferon-free therapy, with or without ribavirin, for the treatment of adult patients with genotype 1 chronic HCV, including those with compensated cirrhosis. In Europe, AbbVie's HCV treatment is marketed as VIEKIRAX + EXVIERA

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and is approved for use in patients with genotype 1 and genotype 4 HCV. In July 2015, the FDA approved AbbVie's TECHNIVIE (ombitasvir, paritaprevir and ritonavir) for use in combination with ribavirin for the treatment of adults with genotype 4 HCV infection in the United States.

Additional Virology products. AbbVie's additional virology products include:

Kaletra. Kaletra (lopinavir/ritonavir), which is also marketed as Aluvia in emerging markets, is a prescription anti-HIV-1 medicine that contains two protease inhibitors: lopinavir and ritonavir. Kaletra is used with other anti-HIV-1 medications as a treatment that maintains viral suppression in people with HIV-1.

Norvir. Norvir (ritonavir) is a protease inhibitor that is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Synagis. Synagis (palivizumab) is a product marketed by AbbVie outside of the United States that protects at-risk infants from severe respiratory disease caused by RSV.

Metabolics/Hormones products. Metabolic and hormone products target a number of conditions, including testosterone deficiency due to certain underlying conditions, exocrine pancreatic insufficiency and hypothyroidism.

These products include:

AndroGel. AndroGel (testosterone gel) is a testosterone replacement therapy for males diagnosed with symptomatic low testosterone due to certain underlying conditions that is available in two strengths: 1 percent and 1.62 percent.

Creon. Creon (pancrelipase) is a pancreatic enzyme therapy for exocrine pancreatic insufficiency, a condition that occurs in patients with cystic fibrosis, chronic pancreatitis and several other conditions.

Synthroid. Synthroid (levothyroxine sodium tablets, USP) is used in the treatment of hypothyroidism.

AbbVie has the rights to sell AndroGel, Creon and Synthroid only in the United States.

Endocrinology products. Lupron (leuprolide acetate), which is also marketed as Lucrin and Lupron Depot, is a product for the palliative treatment of advanced prostate cancer, treatment of endometriosis and central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids. Lupron is approved for daily subcutaneous injection and one-month, three-month, four-month and six-month intramuscular injection.

Other products. AbbVie's other products include:

Duopa and Duodopa (carbidopa and levodopa). AbbVie's levodopa-carbidopa intestinal gel for the treatment of advanced Parkinson's disease is marketed as Duopa in the United States and as Duodopa outside of the United States.

Anesthesia products. Sevoflurane (sold under the trademarks Ultane and Sevorane) is an anesthesia product that AbbVie sells worldwide for human use.

ZINBRYTA. ZINBRYTA (daclizumab) is a once-monthly, self-administered, subcutaneous treatment for relapsing forms of multiple sclerosis (MS), which was approved by the FDA in May 2016. Because of its safety profile, the use of ZINBRYTA is generally reserved for patients who have had an inadequate response to two or more therapies indicated for the treatment of MS. The European Commission granted marketing authorization for ZINBRYTA in July 2016.

#### Marketing, Sales and Distribution Capabilities

AbbVie utilizes a combination of dedicated commercial resources, regional commercial resources and distributorships to market, sell and distribute its products worldwide.

AbbVie directs its primary marketing efforts toward securing the prescription, or recommendation, of its brand of products by physicians, key opinion leaders and other health care providers. Managed care providers (for example, health maintenance organizations and pharmacy benefit managers), hospitals and state and federal government agencies (for example, the United States Department of Veterans Affairs and the United States Department of Defense) are also important customers. AbbVie also markets directly to consumers themselves, although in the United States all of the company's products must be sold pursuant to a prescription. Outside of the United States, AbbVie focuses its marketing efforts on key opinion leaders, payors, physicians and country regulatory bodies. AbbVie also provides patient support programs closely related to its products.



AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. Although AbbVie's business does not have significant seasonality, AbbVie's product revenues may be affected by end customer and retail buying patterns, fluctuations in wholesaler inventory levels and other factors. In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies and patients. In 2016, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation) accounted for substantially all of AbbVie's sales in the United States. No individual wholesaler accounted for greater than 41% of AbbVie's 2016 gross revenues in the United States. Outside the United States, sales are made either directly to customers or through distributors, depending on the market served. These wholesalers purchase product from AbbVie under standard terms and conditions of sale.

Certain products are co-marketed or co-promoted with other companies. AbbVie has no single customer that, if the customer were lost, would have a material adverse effect on the company's business.

No material portion of AbbVie's business is subject to renegotiation of profits or termination of contracts at the election of the government.

Orders are generally filled on a current basis and order backlog is not material to AbbVie's business.

#### Competition

The markets for AbbVie's products are highly competitive. AbbVie competes with other research-based pharmaceuticals and biotechnology companies that discover, manufacture, market and sell proprietary pharmaceutical products and biologics. For example, HUMIRA competes with anti-TNF products and other competitive products intended to treat a number of disease states and AbbVie's virology products compete with other available hepatitis C treatment options. The search for technological innovations in pharmaceutical products is a significant aspect of competition. The introduction of new products by competitors and changes in medical practices and procedures can result in product obsolescence. Price is also a competitive factor. In addition, the substitution of generic pharmaceutical products for branded pharmaceutical products creates competitive pressures on AbbVie's products that do not have patent protection. New products or treatments brought to market by AbbVie's competitors could cause revenues for AbbVie's products to decrease due to price reductions and sales volume decreases.

**Biosimilars.** Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as "biosimilars." For example, the FDA has approved a biosimilar of HUMIRA in the United States and final approval of a biosimilar of HUMIRA in the EU is imminent. Biologics have added major therapeutic options for the treatment of many diseases, including some for which therapies were unavailable or inadequate. The advent of biologics has also raised complex regulatory issues and significant pharmacoeconomic concerns because the cost of developing and producing biologic therapies is typically dramatically higher than for conventional (small molecule) medications, and because many expensive biologic medications are used for ongoing treatment of chronic diseases, such as rheumatoid arthritis or inflammatory bowel disease, or for the treatment of previously untreatable cancer. Significant investments in biologics infrastructure and manufacturing are necessary to produce biologic products, as are significant investments in marketing, distribution, and sales organization activities, which may limit the number of biosimilar competitors.

In the United States, the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and implementing regulations. The enactment of federal health care reform legislation in March 2010 provided a pathway for approval of biosimilars under the Public Health Service Act, but the approval process for, and science behind, biosimilars is more complex than the approval process for, and science behind, generic or other follow-on versions of small molecule products. This added complexity is due to steps needed to ensure that the safety and efficacy of biosimilars is highly similar to that of an original biologic, such as HUMIRA. Ultimate approval by the FDA is dependent upon many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity and potency. The types of data that could ordinarily be required in an application to show similarity may include analytical data and studies to demonstrate chemical similarity, animal studies (including toxicity studies) and clinical studies. The law also requires that the biosimilar must be for a condition of use approved for the original biologic and that the

manufacturing facility meets the standards necessary to assure that the biosimilar is safe, pure and potent. Furthermore, the law provides that only a biosimilar product that is determined to be "interchangeable" will be considered substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or

switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The law continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning remains subject to substantial uncertainty.

In the European Union, while a pathway for the approval of biosimilars has existed since 2005, the products that have come to market to date have had a mixed impact on the market share of incumbent products, with significant variation by product.

**Other Competitive Products.** Although a number of competitive biologic branded products have been approved since HUMIRA was first introduced in 2003, most have gained only a modest share of the worldwide market. AbbVie will continue to face competitive pressure from these biologics and from orally administered products.

#### **Intellectual Property Protection and Regulatory Exclusivity**

Generally, upon approval, products may be entitled to certain kinds of exclusivity under applicable intellectual property and regulatory regimes. AbbVie's intellectual property is materially valuable to the company and AbbVie seeks patent protection, where available, in all significant markets and/or countries for each product in development. In the United States, the expiration date for patents is 20 years after the filing date. Given that patents relating to pharmaceutical products are often obtained early in the development process, and given the amount of time needed to complete clinical trials and other development activities required for regulatory approval, the length of time between product launch and patent expiration is significantly less than 20 years. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) permits a patent holder to seek a patent extension, commonly called a "patent term restoration," for patents on products (or processes for making the product) regulated by the Federal Food, Drug, and Cosmetic Act. The length of the patent extension is roughly based on 50 percent of the period of time from the filing of an Investigational New Drug Application for a compound to the submission of the NDA for such compound, plus 100 percent of the time period from NDA submission to regulatory approval. The extension, however, cannot exceed five years and the patent term remaining after regulatory approval cannot exceed 14 years. Biological products licensed under the Public Health Service Act are similarly eligible for terms of patent restoration.

Pharmaceutical products may be entitled to other forms of legal or regulatory exclusivity upon approval. The scope, length, and requirements for each of these exclusivities vary both in the United States and in other jurisdictions. In the United States, if the FDA approves a drug product that contains an active ingredient not previously approved, the product is typically entitled to five years of non-patent regulatory exclusivity. Other products may be entitled to three years of exclusivity if approval was based on the FDA's reliance on new clinical studies essential to approval submitted by the NDA applicant. If the NDA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days the longest existing exclusivity (patent or regulatory) related to the product. For products that are either used to treat conditions that afflict a relatively small population or for which there is not a reasonable expectation that the research and development costs will be recovered, the FDA may designate the pharmaceutical as an orphan drug and grant it seven years of market exclusivity.

Applicable laws and regulations dictate the scope of any exclusivity to which a product is entitled upon its approval in any particular country. In certain instances, regulatory exclusivity may protect a product where patent protection is no longer available or for a period of time in excess of patent protection. It is not possible to estimate for each product in development the total period and scope of exclusivity to which it may become entitled until regulatory approval is obtained. However, given the length of time required to complete clinical development of a pharmaceutical product, the periods of exclusivity that might be achieved in any individual case would not be expected to exceed a minimum of three years and a maximum of 14 years. These estimates do not consider other factors, such as the difficulty of recreating the manufacturing process for a particular product or other proprietary knowledge that may delay the introduction of a generic or other follow-on product after the expiration of applicable patent and other regulatory exclusivity periods.

Biologics may be entitled to exclusivity under the Biologics Price Competition and Innovation Act, which was passed on March 23, 2010 as Title VII to the Patient Protection and Affordable Care Act. The law provides a pathway for approval of biosimilars following the expiration of 12 years of exclusivity for the innovator biologic and a potential

additional 180 day-extension term for conducting pediatric studies. Biologics are also eligible for orphan drug exclusivity, as discussed above. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar. The European Union has also created a pathway for approval of biosimilars and has published guidelines for approval of certain biosimilar products. The more complex nature of biologics and biosimilar products has led to greater regulatory scrutiny and more rigorous requirements for approval of follow-on biosimilar products than for small molecule generic pharmaceutical products, which can reduce the effect of biosimilars on sales of the innovator biologic as compared to the sales erosion caused by generic versions of small molecule pharmaceutical products.

AbbVie owns or has licensed rights to a substantial number of patents and patent applications. AbbVie licenses or owns a patent portfolio of thousands of patent families, each of which includes United States patent applications and/or issued patents, and may also contain the non-United States counterparts to these patents and applications. These patents and applications, including various patents that expire during the period 2017 to the late 2030s, in aggregate are believed to be of material importance in the operation of AbbVie's business. However, AbbVie believes that no single patent, license, trademark (or related group of patents, licenses, or trademarks), except for those related to adalimumab (which is sold under the trademark HUMIRA), are material in relation to the company's business as a whole. The United States composition of matter (that is, compound) patent covering adalimumab expired in December 2016, and the equivalent European Union patent is expected to expire in the majority of European Union countries in October 2018. In the United States, non-composition of matter patents covering adalimumab expire no earlier than 2022.

In addition, the following patents, licenses, and trademarks are significant: those related to ibrutinib (which is sold under the trademark IMBRUVICA), those related to ombitasvir/paritaprevir/ritonavir and dasabuvir (which are sold under the trademarks VIEKIRA PAK, VIEKIRAX, EXVIERA, and HOLKIRA PAK), and those related to testosterone (which is sold under the trademark AndroGel). The United States composition of matter patent covering ibrutinib is expected to expire in 2027. The United States composition of matter patents covering ombitasvir, paritaprevir and dasabuvir are expected to expire in 2032, 2031 and 2029, respectively.

AbbVie may rely, in some circumstances, on trade secrets to protect its technology. However, trade secrets are difficult to protect. AbbVie seeks to protect its technology and product candidates, in part, by confidentiality agreements with its employees, consultants, advisors, contractors, and collaborators. These agreements may be breached and AbbVie may not have adequate remedies for any breach. In addition, AbbVie's trade secrets may otherwise become known or be independently discovered by competitors. To the extent that AbbVie's employees, consultants, advisors, contractors, and collaborators use intellectual property owned by others in their work for the company, disputes may arise as to the rights in related or resulting know-how and inventions.

#### Licensing and Other Arrangements

In addition to its independent efforts to develop and market products, AbbVie enters into arrangements such as licensing arrangements, strategic alliances, co-promotion arrangements, co-development and co-marketing agreements, and joint ventures. These licensing and other arrangements typically include, among other terms and conditions, non-refundable upfront license fees and milestone payments. See Note 5 to the Consolidated Financial Statements for additional information on AbbVie's licensing and other agreements.

#### Third Party Agreements

AbbVie has agreements with third parties for process development, analytical services and manufacturing of certain products. AbbVie procures certain products and services from a limited number of suppliers and, in some cases, a single supply source. For example, the filling and packaging of HUMIRA syringes to be sold outside of the United States and Puerto Rico is performed by a single supplier at its two different facilities. AbbVie does not currently believe that this agreement is material because AbbVie's business is not substantially at risk without access to these facilities. AbbVie maintains significant inventory of HUMIRA syringes to reduce the risk of any supply disruption and its own syringe-filling and packaging facility in the United States is approved to supply syringes to primary markets outside of the United States and Puerto Rico. In addition, AbbVie has agreements with third parties for active pharmaceutical ingredient and product manufacturing, formulation and development services, fill, finish and packaging services, transportation and distribution and logistics services for certain products. AbbVie does not believe that these manufacturing related agreements are material because AbbVie's business is not substantially dependent on any individual agreement. In most cases, AbbVie maintains alternate supply relationships that it can utilize without undue disruption of its manufacturing processes if a third party fails to perform its contractual obligations. AbbVie also maintains sufficient inventory of product to minimize the impact of any supply disruption.

AbbVie is also party to certain collaborations and other arrangements, as discussed in Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

#### Sources and Availability of Raw Materials

AbbVie purchases, in the ordinary course of business, raw materials and supplies essential to its operations from numerous suppliers around the world. In addition, certain medical devices and components necessary for the manufacture of AbbVie products are provided by unaffiliated third party suppliers. AbbVie has not experienced any recent significant availability problems or supply shortages that impacted fulfillment of product demand.

## Research and Development Activities

AbbVie makes a significant investment in research and development and has numerous compounds in clinical development, including potential treatments for complex, life-threatening diseases. AbbVie's ability to discover and develop new compounds is enhanced by the company's use of integrated discovery and development project teams, which include chemists, biologists, physicians and pharmacologists who work on the same compounds as a team. AbbVie also partners with third parties, such as biotechnology companies, other pharmaceutical companies and academic institutions to identify and prioritize promising new treatments that complement and enhance AbbVie's existing portfolio.

The research and development process generally begins with discovery research which focuses on the identification of a molecule that has a desired effect against a given disease. If preclinical testing of an identified compound proves successful, the compound moves into clinical development which generally includes the following phases:

Phase 1—involves the first human tests in a small number of healthy volunteers or patients to assess safety, tolerability and potential dosing.

Phase 2—tests the drug's efficacy against the disease in a relatively small group of patients.

Phase 3—tests a drug that demonstrates favorable results in the earlier phases in a significantly larger patient population to further demonstrate efficacy and safety based on regulatory criteria.

The clinical trials from all of the development phases provide the data required to prepare and submit a New Drug Application (NDA), a Biological License Application (BLA) or other submission for regulatory approval to the FDA or similar government agencies outside the United States. The specific requirements (e.g., scope of clinical trials) for obtaining regulatory approval vary across different countries and geographic regions.

The research and development process from discovery through a new drug launch typically takes 8 to 12 years and can be even longer. The research and development of new pharmaceutical products has a significant amount of inherent uncertainty. There is no guarantee when, or if, a molecule will receive the regulatory approval required to launch a new drug or indication.

In addition to the development of new products and new formulations, research and development projects also may include Phase 4 trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug. AbbVie spent approximately \$4.4 billion in 2016, \$4.3 billion in 2015 and \$3.3 billion in 2014 on research to discover and develop new products, indications and processes and to improve existing products and processes. These expenses consisted primarily of salaries and related expenses for personnel, license fees, consulting payments, contract research, clinical drug supply manufacturing, the costs of laboratory equipment and facilities, clinical trial costs and collaboration fees and expenses.

## Regulation—Discovery and Clinical Development

United States. Securing approval to market a new pharmaceutical product in the United States requires substantial effort and financial resources and takes several years to complete. The applicant must complete preclinical tests and submit protocols to the FDA before commencing clinical trials. Clinical trials are intended to establish the safety and efficacy of the pharmaceutical product and typically are conducted in sequential phases, although the phases may overlap or be combined. If the required clinical testing is successful, the results are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA or BLA to determine whether a product is safe and effective for its intended use and whether its manufacturing is compliant with current Good Manufacturing Practices (cGMP).

Even if an NDA or a BLA receives approval, the applicant must comply with post-approval requirements. For example, holders of an approval must report adverse reactions, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional materials and activities. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and certain changes to the manufacturing procedures and finished product must be included in the NDA or BLA, and approved by the FDA. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and record keeping requirements. In addition, as a condition of approval, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety or efficacy after

commercialization, which may require additional clinical trials or patient registries, or additional work on chemistry, manufacturing and controls. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future.

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Outside the United States. AbbVie is subject to similar regulatory requirements outside the United States. AbbVie must obtain approval of a clinical trial application or product from the applicable regulatory authorities before it can commence clinical trials or marketing of the product. The approval requirements and process for each country can vary, and the time required to obtain approval may be longer or shorter than that required for FDA approval in the United States. For example, AbbVie may submit marketing authorizations in the European Union under either a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products and provides for a single marketing authorization that is valid for all European Union member states. Under the centralized procedure, a single marketing authorization application is submitted to the European Medicines Agency. After the agency evaluates the application, it makes a recommendation to the European Commission, which then makes the final determination on whether to approve the application. The decentralized procedure provides for mutual recognition of individual national approval decisions and is available for products that are not subject to the centralized procedure.

In Japan, applications for approval of a new product are made through the Pharmaceutical and Medical Devices Agency (PMDA). Bridging studies to demonstrate that the non-Japanese clinical data applies to Japanese patients may be required. After completing a comprehensive review, the PMDA reports to the Ministry of Health, Labour and Welfare, which then approves or denies the application.

The regulatory process in many emerging markets continues to evolve. Many emerging markets, including those in Asia, generally require regulatory approval to have been obtained in a large developed market (such as the United States or Europe) before the country will begin or complete its regulatory review process. Some countries also require that local clinical studies be conducted in order to obtain regulatory approval in the country.

The requirements governing the conduct of clinical trials and product licensing also vary. In addition, post-approval regulatory obligations such as adverse event reporting and cGMP compliance generally apply and may vary by country. For example, after a marketing authorization has been granted in the European Union, periodic safety reports must be submitted and other pharmacovigilance measures may be required (such as Risk Management Plans).

#### Regulation—Commercialization, Distribution and Manufacturing

The manufacture, marketing, sale, promotion and distribution of AbbVie's products are subject to comprehensive government regulation. Government regulation by various national, regional, federal, state and local agencies, both in the United States and other countries, addresses (among other matters) inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, labeling, packaging, marketing and promotion, pricing and reimbursement, sampling, distribution, quality control, post-marketing surveillance, record keeping, storage and disposal practices. AbbVie's operations are also affected by trade regulations in many countries that limit the import of raw materials and finished products and by laws and regulations that seek to prevent corruption and bribery in the marketplace (including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act, which provide guidance on corporate interactions with government officials) and require safeguards for the protection of personal data. In addition, AbbVie is subject to laws and regulations pertaining to health care fraud and abuse, including state and federal anti-kickback and false claims laws in the United States. Prescription drug manufacturers such as AbbVie are also subject to taxes, as well as application, product, user, establishment and other fees.

Compliance with these laws and regulations is costly and materially affects AbbVie's business. Among other effects, health care regulations substantially increase the time, difficulty and costs incurred in obtaining and maintaining approval to market newly developed and existing products. AbbVie expects compliance with these regulations to continue to require significant technical expertise and capital investment to ensure compliance. Failure to comply can delay the release of a new product or result in regulatory and enforcement actions, the seizure or recall of a product, the suspension or revocation of the authority necessary for a product's production and sale and other civil or criminal sanctions, including fines and penalties.

In addition to regulatory initiatives, AbbVie's business can be affected by ongoing studies of the utilization, safety, efficacy and outcomes of health care products and their components that are regularly conducted by industry participants, government agencies and others. These studies can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the

discontinuance of, or limitations on, marketing of such products domestically or worldwide, and may give rise to claims for damages from persons who believe they have been injured as a result of their use.

Access to human health care products continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations in the United States and other countries. A major focus is cost containment. Efforts to reduce health care costs are also being made in the private sector, notably by health care payors and providers, which have instituted various cost reduction and containment measures. AbbVie expects insurers and providers to continue attempts to reduce the cost of health care products. Outside the United States, many countries control the price of health care products

directly or indirectly, through reimbursement, payment, pricing, coverage limitations, or compulsory licensing. Budgetary pressures in the United States and in other countries may also heighten the scope and severity of pricing pressures on AbbVie's products for the foreseeable future.

**United States.** Specifically, U.S. federal laws require pharmaceutical manufacturers to pay certain statutorily-prescribed rebates to state Medicaid programs on prescription drugs reimbursed under state Medicaid plans, and the efforts by states to seek additional rebates affect AbbVie's business. Similarly, the Veterans Health Care Act of 1992, as a prerequisite to participation in Medicaid and other federal health care programs, requires that manufacturers extend additional discounts on pharmaceutical products to various federal agencies, including the United States Department of Veterans Affairs, Department of Defense and Public Health Service entities and institutions. In addition, recent legislative changes would require similarly discounted prices to be offered to TRICARE program beneficiaries. The Veterans Health Care Act of 1992 also established the 340B drug discount program, which requires pharmaceutical manufacturers to provide products at reduced prices to various designated health care entities and facilities.

In the United States, most states also have generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed. In addition, the federal government follows a diagnosis-related group (DRG) payment system for certain institutional services provided under Medicare or Medicaid and has implemented a prospective payment system (PPS) for services delivered in hospital outpatient, nursing home and home health settings. DRG and PPS entitle a health care facility to a fixed reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many health care products.

Medicare reimburses Part B drugs based on average sales price plus a certain percentage to account for physician administration costs, which have been reduced in the hospital outpatient setting. Medicare enters into contracts with private plans to negotiate prices for most patient-administered medicine delivered under Part D.

Under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (together, the Affordable Care Act), AbbVie pays a fee related to its pharmaceuticals sales to government programs. In addition, AbbVie provides a discount of 50% for branded prescription drugs sold to patients who fall into the Medicare Part D coverage gap, or "donut hole."

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs and biologics covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring disclosure of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

AbbVie expects debate to continue during 2017 at all government levels worldwide over the marketing, availability, method of delivery and payment for health care products and services. AbbVie believes that future legislation and regulation in the markets it serves could affect access to health care products and services, increase rebates, reduce prices or the rate of price increases for health care products and services, change health care delivery systems, create new fees and obligations for the pharmaceuticals industry, or require additional reporting and disclosure. It is not possible to predict the extent to which AbbVie or the health care industry in general might be affected by the matters discussed above.

AbbVie is subject to a Corporate Integrity Agreement (CIA) entered into by Abbott on May 7, 2012 that requires enhancements to AbbVie's compliance program and contains reporting obligations, including disclosure of financial payments to doctors. If AbbVie fails to comply with the CIA, the Office of Inspector General for the United States Department of Health and Human Services may impose monetary penalties or exclude AbbVie from federal health care programs, including Medicare and Medicaid.

**European Union.** The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the European Union and permits member states to supplement these

standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent to launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical products. Differences between national pricing regimes create price differentials within the European Union that can lead to significant parallel trade in pharmaceutical products.

Most governments also promote generic substitution by mandating or permitting a pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed and by permitting or mandating that health care professionals prescribe generic versions in certain circumstances. In addition, governments use reimbursement lists to limit the pharmaceutical products that are eligible for reimbursement by national health care systems.

**Japan.** In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the Ministry of Health, Labour and Welfare sets the prices of the products on this list. The government generally introduces price cut rounds every other year and also mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. The government has also promoted the use of generics, where available.

**Emerging Markets.** Many emerging markets take steps to reduce pharmaceutical product prices, in some cases through direct price controls and in others through the promotion of generic alternatives to branded pharmaceuticals. Since AbbVie markets its products worldwide, certain products of a local nature and variations of product lines must also meet other local regulatory requirements. Certain additional risks are inherent in conducting business outside the United States, including price and currency exchange controls, changes in currency exchange rates, limitations on participation in local enterprises, expropriation, nationalization and other governmental action.

#### Environmental Matters

AbbVie believes that its operations comply in all material respects with applicable laws and regulations concerning environmental protection. Regulations under federal and state environmental laws impose stringent limitations on emissions and discharges to the environment from various manufacturing operations. AbbVie's capital expenditures for pollution control in 2016 were approximately \$5 million and operating expenditures were \$28 million. In 2017, capital expenditures for pollution control are estimated to be \$15 million and operating expenditures are estimated to be approximately \$30 million.

Abbott was identified as one of many potentially responsible parties in investigations and/or remediations at several locations in the United States, including Puerto Rico, under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. Some of these locations were transferred to AbbVie in connection with the separation and distribution, and AbbVie has become a party to these investigations and remediations. Abbott was also engaged in remediation at several other sites, some of which have been transferred to AbbVie in connection with the separation and distribution, in cooperation with the Environmental Protection Agency or similar agencies. While it is not feasible to predict with certainty the final costs related to those investigations and remediation activities, AbbVie believes that such costs, together with other expenditures to maintain compliance with applicable laws and regulations concerning environmental protection, should not have a material adverse effect on the company's financial position, cash flows, or results of operations.

#### Employees

AbbVie employed approximately 30,000 persons as of January 31, 2017. Outside the United States, some of AbbVie's employees are represented by unions or works councils. AbbVie believes that it has good relations with its employees.

#### Internet Information

Copies of AbbVie's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through AbbVie's investor relations website ([www.abbvieinvestor.com](http://www.abbvieinvestor.com)) as soon as reasonably practicable after AbbVie electronically files the material with, or furnishes it to, the Securities and Exchange Commission (SEC).

AbbVie's corporate governance guidelines, outline of directorship qualifications, code of business conduct and the charters of AbbVie's audit committee, compensation committee, nominations and governance committee and public policy committee are all available on AbbVie's investor relations website ([www.abbvieinvestor.com](http://www.abbvieinvestor.com)).

#### ITEM 1A. RISK FACTORS

You should carefully consider the following risks and other information in this Form 10-K in evaluating AbbVie and AbbVie's common stock. Any of the following risks could materially and adversely affect AbbVie's results of operations, financial condition or cash flows. The risk factors generally have been separated into two groups: risks related to AbbVie's business and risks related to AbbVie's common stock. Based on the information currently known to it, AbbVie believes that the following information identifies the most significant risk factors affecting it in each of these categories of risks. However, the

risks and uncertainties AbbVie faces are not limited to those set forth in the risk factors described below and may not be in order of importance or probability of occurrence. Additional risks and uncertainties not presently known to AbbVie or that AbbVie currently believes to be immaterial may also adversely affect its business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods.

If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on AbbVie's business, results of operations, financial condition or cash flows. In such case, the trading price of AbbVie's common stock could decline.

#### Risks Related to AbbVie's Business

The expiration or loss of patent protection and licenses may adversely affect AbbVie's future revenues and operating earnings.

AbbVie relies on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of its products. In particular, patent protection is, in the aggregate, important in AbbVie's marketing of pharmaceutical products in the United States and most major markets outside of the United States. Patents covering AbbVie products normally provide market exclusivity, which is important for the profitability of many of AbbVie's products.

As patents for certain of its products expire, AbbVie will or could face competition from lower priced generic products. The expiration or loss of patent protection for a product typically is followed promptly by substitutes that may significantly reduce sales for that product in a short amount of time. If AbbVie's competitive position is compromised because of generics or otherwise, it could have a material adverse effect on AbbVie's business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs. Any such proposals that are enacted into law could increase the impact of generic competition.

AbbVie's principal patents and trademarks are described in greater detail in Item 1, "Business—Intellectual Property Protection and Regulatory Exclusivity" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations," and litigation regarding these patents is described in Item 3, "Legal Proceedings." The United States composition of matter patent for HUMIRA, which is AbbVie's largest product and had worldwide net revenues of approximately \$16.1 billion in 2016, expired in December 2016, and the equivalent European Union patent is expected to expire in the majority of European Union countries in October 2018. Because HUMIRA is a biologic and biologics cannot be readily substituted, it is uncertain what impact the loss of patent protection would have on the sales of HUMIRA.

AbbVie's major products could lose patent protection earlier than expected, which could adversely affect AbbVie's future revenues and operating earnings.

Third parties or government authorities may challenge or seek to invalidate or circumvent AbbVie's patents and patent applications. For example, manufacturers of generic pharmaceutical products file, and may continue to file, Abbreviated New Drug Applications with the FDA seeking to market generic forms of AbbVie's products prior to the expiration of relevant patents owned or licensed by AbbVie by asserting that the patents are invalid, unenforceable and/or not infringed. In addition, petitioners have filed, and may continue to file, challenges to the validity of AbbVie patents under the 2011 Leahy-Smith America Invents Act, which created inter partes review and post grant review procedures for challenging patent validity in administrative proceedings at the United States Patent and Trademark Office.

Although most of the challenges to AbbVie's intellectual property have come from other businesses, governments may also challenge intellectual property rights. For example, court decisions and potential legislation relating to patents, such as legislation regarding biosimilars, and other regulatory initiatives may result in further erosion of intellectual property protection. In addition, certain governments outside the United States have indicated that compulsory licenses to patents may be sought to further their domestic policies or on the basis of national emergencies, such as HIV/AIDS. If triggered, compulsory licenses could diminish or eliminate sales and profits from those jurisdictions and negatively affect AbbVie's results of operations.

AbbVie normally responds to challenges by vigorously defending its patents, including by filing patent infringement lawsuits. Patent litigation, administrative proceedings and other challenges to AbbVie's patents are costly and unpredictable and may deprive AbbVie of market exclusivity for a patented product. To the extent AbbVie's intellectual property is successfully challenged or circumvented or to the extent such intellectual property does not allow AbbVie to compete effectively, AbbVie's business will suffer. To the extent that countries do not enforce AbbVie's intellectual property rights or require compulsory licensing of AbbVie's intellectual property, AbbVie's future revenues and operating earnings will be reduced.



A third party's intellectual property may prevent AbbVie from selling its products or have a material adverse effect on AbbVie's future profitability and financial condition.

Third parties may claim that an AbbVie product infringes upon their intellectual property. Resolving an intellectual property infringement claim can be costly and time consuming and may require AbbVie to enter into license agreements. AbbVie cannot guarantee that it would be able to obtain license agreements on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject AbbVie to significant damages or an injunction preventing the manufacture, sale, or use of the affected AbbVie product or products. Any of these events could have a material adverse effect on AbbVie's profitability and financial condition.

Any significant event that adversely affects HUMIRA revenues could have a material and negative impact on AbbVie's results of operations and cash flows.

HUMIRA accounted for approximately 63% of AbbVie's total net revenues in 2016. Any significant event that adversely affects HUMIRA's revenues could have a material adverse impact on AbbVie's results of operations and cash flows. These events could include loss of patent protection for HUMIRA, the approval of biosimilars of HUMIRA, the discovery of previously unknown side effects or impaired efficacy, increased competition from the introduction of new, more effective or less expensive treatments and discontinuation or removal from the market of HUMIRA for any reason.

AbbVie's research and development efforts may not succeed in developing and marketing commercially successful products and technologies, which may cause its revenues and profitability to decline.

To remain competitive, AbbVie must continue to launch new products and new indications and/or brand extensions for existing products, and such launches must generate revenue sufficient both to cover its substantial research and development costs and to replace revenues of profitable products that are lost to or displaced by competing products or therapies. Failure to do so would have a material adverse effect on AbbVie's revenue and profitability. Accordingly, AbbVie commits substantial effort, funds, and other resources to research and development and must make ongoing substantial expenditures without any assurance that its efforts will be commercially successful. A high rate of failure in the biopharmaceutical industry is inherent in the research and development of new products, and failure can occur at any point in the research and development process, including after significant funds have been invested. Products that appear promising in development may fail to reach the market for numerous reasons, including failure to demonstrate effectiveness, safety concerns, superior safety or efficacy of competing therapies, failure to achieve positive clinical or pre-clinical outcomes beyond the current standards of care, inability to obtain necessary regulatory approvals or delays in the approval of new products and new indications, limited scope of approved uses, excessive costs to manufacture, the failure to obtain or maintain intellectual property rights, or infringement of the intellectual property rights of others.

Decisions about research studies made early in the development process of a pharmaceutical product candidate can affect the marketing strategy once such candidate receives approval. More detailed studies may demonstrate additional benefits that can help in the marketing, but they also consume time and resources and may delay submitting the pharmaceutical product candidate for approval. AbbVie cannot guarantee that a proper balance of speed and testing will be made with respect to each pharmaceutical product candidate or that decisions in this area would not adversely affect AbbVie's future results of operations.

Even if AbbVie successfully develops and markets new products or enhancements to its existing products, they may be quickly rendered obsolete by changing clinical preferences, changing industry standards, or competitors' innovations. AbbVie's innovations may not be accepted quickly in the marketplace because of existing clinical practices or uncertainty over third-party reimbursement. AbbVie cannot state with certainty when or whether any of its products under development will be launched, whether it will be able to develop, license, or otherwise acquire compounds or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause AbbVie's products to become obsolete, causing AbbVie's revenues and operating results to suffer.

A portion of AbbVie's near-term pharmaceutical pipeline relies on collaborations with third parties, which may adversely affect the development and sale of its products.

AbbVie depends on alliances with pharmaceutical and biotechnology companies for a portion of the products in its near-term pharmaceutical pipeline. For example, AbbVie is collaborating with Roche Holding AG to develop and commercialize a next-generation Bcl-2 inhibitor, Venclexta (venetoclax), for patients with relapsed/refractory chronic lymphocytic leukemia and AbbVie is investigating its efficacy for additional indications.

Failures by these parties to meet their contractual, regulatory, or other obligations to AbbVie, or any disruption in the relationships between AbbVie and these third parties, could have an adverse effect on AbbVie's pharmaceutical pipeline and business. In addition, AbbVie's collaborative relationships for research and development extend for many years and may give rise to disputes regarding the relative rights, obligations and revenues of AbbVie and its collaboration partners, including the ownership of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations. The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell biologics—including HUMIRA—could adversely impact AbbVie's business and results of operations.

AbbVie's biologic products are subject to competition from biosimilars.

The Biologics Price Competition and Innovation Act creates a framework for the approval of biosimilars in the United States and could allow competitors to reference data from biologic products already approved. 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 addition, companies are developing biosimilars in other countries that could compete with AbbVie's biologic products. For example, the FDA has approved a biosimilar of HUMIRA in the United States and final approval of a biosimilar of HUMIRA in the EU is imminent, and Boehringer Ingelheim's marketing authorization application to the EMA and its application to the United States FDA have been accepted for review. As competitors are able to obtain marketing approval for biosimilars referencing AbbVie's biologic products, AbbVie's products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of AbbVie's applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, AbbVie could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to its biologic products.

New products and technological advances by AbbVie's competitors may negatively affect AbbVie's results of operations.

AbbVie competes with other research-based pharmaceutical and biotechnology companies that discover, manufacture, market, and sell proprietary pharmaceutical products and biologics. For example, HUMIRA competes with anti-TNF products and other competitive products intended to treat a number of disease states and AbbVie's virology products compete with other available hepatitis C treatment options. These competitors may introduce new products or develop technological advances that compete with AbbVie's products in therapeutic areas such as immunology, virology/liver disease, oncology and neuroscience. AbbVie cannot predict with certainty the timing or impact of the introduction by competitors of new products or technological advances. Such competing products may be safer, more effective, more effectively marketed or sold, or have lower prices or superior performance features than AbbVie's products, and this could negatively impact AbbVie's business and results of operations.

The manufacture of many of AbbVie's products is a highly exacting and complex process, and if AbbVie or one of its

suppliers encounters problems manufacturing AbbVie's products, AbbVie's business could suffer.

The manufacture of many of AbbVie's products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for AbbVie's products, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of

products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and AbbVie may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

AbbVie uses a number of products in its pharmaceutical and biologic manufacturing processes that are sourced from single suppliers, and an interruption in the supply of those products could adversely affect AbbVie's business and results of operations.

AbbVie uses a number of products in its pharmaceutical and biologic manufacturing processes that are sourced from single suppliers. The failure of these single-source suppliers to fulfill their contractual obligations in a timely manner or as a result of regulatory noncompliance or physical disruption at a manufacturing site may impair AbbVie's ability to deliver its products to customers on a timely and competitive basis, which could adversely affect AbbVie's business and results of operations. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. AbbVie cannot guarantee that it will be able to reach agreement with alternative providers or that regulatory authorities would approve AbbVie's use of such alternatives. AbbVie does, however, carry business interruption insurance, which provides a degree of protection in the case of a failure by a single-source supplier.

Significant safety or efficacy issues could arise for AbbVie's products, which could have a material adverse effect on AbbVie's revenues and financial condition.

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Investigators may also conduct additional, and perhaps more extensive, studies. If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase 4 trials), or if governments change standards regarding safety, efficacy or labeling, AbbVie may be required to amend the conditions of use for a product. For example, AbbVie may voluntarily provide or be required to provide updated information on a product's label or narrow its approved indication, either of which could reduce the product's market acceptance. If safety or efficacy issues with an AbbVie product arise, sales of the product could be halted by AbbVie or by regulatory authorities. Safety or efficacy issues affecting suppliers' or competitors' products also may reduce the market acceptance of AbbVie's products.

New data about AbbVie's products, or products similar to its products, could negatively impact demand for AbbVie's products due to real or perceived safety issues or uncertainty regarding efficacy and, in some cases, could result in product withdrawal. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of AbbVie's products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of AbbVie's products.

AbbVie is subject to product liability claims and lawsuits that may adversely affect its business and results of operations.

In the ordinary course of business, AbbVie is the subject of product liability claims and lawsuits alleging that AbbVie's products or the products of other companies that it promotes have resulted or could result in an unsafe condition for or injury to patients. Product liability claims and lawsuits and safety alerts or product recalls, regardless of their ultimate outcome, may have a material adverse effect on AbbVie's business, results of operations and reputation and on its ability to attract and retain customers. Consequences may also include additional costs, a decrease in market share for the product in question, lower income and exposure to other claims. Product liability losses are self-insured.

AbbVie is subject to cost-containment efforts and pricing pressures that could cause a reduction in future revenues and operating earnings, and changes in the terms of rebate and chargeback programs, which are common in the pharmaceuticals industry, could have a material adverse effect on AbbVie's operations.

Cost-containment efforts by governments and private organizations are described in greater detail in Item 1, "Business—Regulation—Commercialization, Distribution and Manufacturing." To the extent these cost containment efforts are not offset by greater demand, increased patient access to health care, or other factors, AbbVie's future revenues and operating earnings

will be reduced. In the United States, the European Union and other countries, AbbVie's business has experienced downward pressure on product pricing, and this pressure could increase in the future.

AbbVie is subject to increasing public and legislative pressure with respect to pharmaceutical pricing. In the United States, practices of managed care groups, and institutional and governmental purchasers, and United States federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act, contribute to pricing pressures. The potential for continuing changes to the health care system in the United States and the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid and private sector beneficiaries could result in additional pricing pressures.

In numerous major markets worldwide, the government plays a significant role in funding health care services and determining the pricing and reimbursement of pharmaceutical products. Consequently, in those markets, AbbVie is subject to government decision-making and budgetary actions with respect to its products. In particular, many European countries have ongoing government-mandated price reductions for many pharmaceutical products, and AbbVie anticipates continuing pricing pressures in Europe. Differences between countries in pricing regulations could lead to third-party cross-border trading in AbbVie's products that results in a reduction in future revenues and operating earnings.

Rebates related to government programs, such as fee-for-service Medicaid or Medicaid managed care programs, arise from laws and regulations. AbbVie cannot predict if additional government initiatives to contain health care costs or other factors could lead to new or modified regulatory requirements that include higher or incremental rebates or discounts. Other rebate and discount programs arise from contractual agreements with private payers. Various factors, including market factors and the ability of private payers to control patient access to products, may provide payers the leverage to negotiate higher or additional rebates or discounts that could have a material adverse effect on AbbVie's operations.

AbbVie is subject to numerous governmental regulations, and it can be costly to comply with these regulations and to develop compliant products and processes.

AbbVie's products are subject to rigorous regulation by numerous international, supranational, federal and state authorities, as described in Item 1, "Business—Regulation—Discovery and Clinical Development." The process of obtaining regulatory approvals to market a pharmaceutical product can be costly and time consuming, and approvals might not be granted for future products, or additional indications or uses of existing products, on a timely basis, if at all. Delays in the receipt of, or failure to obtain approvals for, future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues and substantial additional costs.

In addition, AbbVie cannot guarantee that it will remain compliant with applicable regulatory requirements once approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling and advertising and post-marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns. AbbVie must incur expense and spend time and effort to ensure compliance with these complex regulations.

Possible regulatory actions could result in substantial modifications to AbbVie's business practices and operations; refunds, recalls, or seizures of AbbVie's products; a total or partial shutdown of production in one or more of AbbVie's or its suppliers' facilities while AbbVie or its supplier remedies the alleged violation; the inability to obtain future approvals; and withdrawals or suspensions of current products from the market. Any of these events could disrupt AbbVie's business and have a material adverse effect on its business and results of operations.

Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations in the future.

The health care industry is subject to various federal, state and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act and individual state laws relating to pricing and sales and marketing practices. Violations of

these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.



AbbVie could be subject to increased monetary penalties and/or other sanctions, including exclusion from federal health care programs, if it fails to comply with the terms of the May 7, 2012 resolution of the Department of Justice's investigation into sales and marketing activities for Depakote.

On May 7, 2012, Abbott settled United States federal and 49 state investigations into its sales and marketing activities for Depakote by pleading guilty to a misdemeanor violation of the Food, Drug and Cosmetic Act, agreeing to pay approximately \$700 million in criminal fines and forfeitures and approximately \$900 million to resolve civil claims, and submitting to a term of probation. The term of probation ended January 1, 2016 upon AbbVie satisfying all of the probation conditions. However, if AbbVie violates any remaining terms of the plea agreement, it may face additional monetary sanctions and other such remedies as the court deems appropriate.

In addition, Abbott entered into a five-year CIA with the Office of Inspector General for the United States Department of Health and Human Services (OIG). The effective date of the CIA is October 11, 2012. The obligations of the CIA have transferred to and become fully binding on AbbVie. The CIA requires enhancements to AbbVie's compliance program, fulfillment of reporting and monitoring obligations, management certifications and resolutions from AbbVie's board of directors, among other requirements. Compliance with the requirements of the settlement will impose additional costs and burdens on AbbVie, including in the form of employee training, third party reviews, compliance monitoring, reporting obligations and management attention. If AbbVie fails to comply with the CIA, the OIG may impose monetary penalties or exclude AbbVie from federal health care programs, including Medicare and Medicaid. AbbVie and Abbott may be subject to third party claims and shareholder lawsuits in connection with the settlement, and AbbVie may be required to indemnify all or a portion of Abbott's costs.

The international nature of AbbVie's business subjects it to additional business risks that may cause its revenue and profitability to decline.

AbbVie's business is subject to risks associated with doing business internationally, including in emerging markets. Net revenues outside of the United States make up approximately 38% of AbbVie's total net revenues in 2016. The risks associated with AbbVie's operations outside the United States include:

- fluctuations in currency exchange rates;
- changes in medical reimbursement policies and programs;
- multiple legal and regulatory requirements that are subject to change and that could restrict AbbVie's ability to manufacture, market and sell its products;
- differing local product preferences and product requirements;
- trade protection measures and import or export licensing requirements;
- difficulty in establishing, staffing and managing operations;
- differing labor regulations;
- potentially negative consequences from changes in or interpretations of tax laws;
- political and economic instability, including sovereign debt issues;
- price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization and other governmental action;
- inflation, recession and fluctuations in interest rates;
- potential deterioration in the economic position and credit quality of certain non-U.S. countries, including in Europe and Latin America; and
- potential penalties or other adverse consequences for violations of anti-corruption, anti-bribery and other similar laws and regulations, including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act.

Events contemplated by these risks may, individually or in the aggregate, have a material adverse effect on AbbVie's revenues and profitability.



AbbVie's ability to realize the anticipated benefits of its merger with Pharmacyclics will depend on its ability to effectively and profitably commercialize IMBRUVICA® (ibrutinib).

The anticipated benefits of AbbVie's merger with Pharmacyclics will depend on AbbVie's ability to: effectively and profitably commercialize IMBRUVICA, including AbbVie's ability to create and meet continued market demand, achieve market acceptance and generate product sales; ensure that the active pharmaceutical ingredient for IMBRUVICA and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with acceptable quality and pricing to meet commercial demand; and ensure that the entire supply chain efficiently and consistently delivers IMBRUVICA to AbbVie's customers. The commercialization of IMBRUVICA may not be successful due to, among other things, unexpected challenges from competitors, new safety issues or concerns being reported that may impact or narrow the approved indications, the relative price of IMBRUVICA as compared to alternative treatment options, and changes to the label for IMBRUVICA that further restrict its marketing. If the commercialization of IMBRUVICA is unsuccessful, AbbVie's ability to generate revenue from product sales and realize the anticipated benefits of the merger will be adversely affected.

AbbVie may acquire other businesses, license rights to technologies or products, form alliances, or dispose of assets, which could cause it to incur significant expenses and could negatively affect profitability.

AbbVie may pursue acquisitions, technology licensing arrangements, and strategic alliances, or dispose of some of its assets, as part of its business strategy. AbbVie may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and may not realize the expected benefits. If AbbVie is successful in making an acquisition, the products and technologies that are acquired may not be successful or may require significantly greater resources and investments than originally anticipated. AbbVie may not be able to integrate acquisitions successfully into its existing business and could incur or assume significant debt and unknown or contingent liabilities. AbbVie could also experience negative effects on its reported results of operations from acquisition or disposition-related charges, amortization of expenses related to intangibles and charges for impairment of long-term assets. These effects could cause a deterioration of AbbVie's credit rating and result in increased borrowing costs and interest expense. Additionally, changes in AbbVie's structure, operations, revenues, costs, or efficiency resulting from major transactions such as acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives, may result in greater than expected costs, may take longer than expected to complete or encounter other difficulties, including the need for regulatory approval where appropriate.

AbbVie is dependent on wholesale distributors for distribution of its products in the United States and, accordingly, its results of operations could be adversely affected if they encounter financial difficulties.

In 2016, three wholesale distributors—AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation—accounted for substantially all of AbbVie's net revenues in the United States. If one of its significant wholesale distributors encounters financial or other difficulties, such distributor may decrease the amount of business that it does with AbbVie, and AbbVie may be unable to collect all the amounts that the distributor owes it on a timely basis or at all, which could negatively impact AbbVie's business and results of operations.

AbbVie has debt obligations that could adversely affect its business and its ability to meet its obligations.

The amount of debt that AbbVie has incurred and intends to incur could have important consequences to AbbVie and its investors. These consequences include, among other things, requiring a portion of AbbVie's cash flow from operations to make interest payments on this debt and reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow AbbVie's business. To the extent AbbVie incurs additional indebtedness, these risks could increase. In addition, AbbVie's cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and AbbVie may not be able to borrow money, sell assets, or otherwise raise funds on acceptable terms, or at all, to refinance its debt.

AbbVie may need additional financing in the future to meet its capital needs or to make opportunistic acquisitions, and such financing may not be available on favorable terms, if at all.

AbbVie may need to seek additional financing for its general corporate purposes. For example, it may need to increase its investment in research and development activities or need funds to make acquisitions. AbbVie may be unable to obtain any

desired additional financing on terms favorable to it, if at all. If AbbVie loses its investment grade credit rating or adequate funds are not available on acceptable terms, AbbVie may be unable to fund its expansion, successfully develop or enhance products, or respond to competitive pressures, any of which could negatively affect AbbVie's business. If AbbVie raises additional funds by issuing debt or entering into credit facilities, it may be subject to limitations on its operations due to restrictive covenants. Failure to comply with these covenants could adversely affect AbbVie's business.

AbbVie depends on information technology and a failure of those systems could adversely affect AbbVie's business. AbbVie relies on sophisticated information technology systems to operate its business. These systems are potentially vulnerable to malicious intrusion, random attack, loss of data privacy, or breakdown. Data privacy or security breaches by employees or others may cause sensitive data, including intellectual property, trade secrets or personal information belonging to AbbVie, its patients, customers or business partners, to be exposed to unauthorized persons or to the public. Although AbbVie has invested in the protection of its data and information technology and also monitors its systems on an ongoing basis, there can be no assurance that these efforts will prevent breakdowns or breaches in AbbVie's information technology systems that could adversely affect AbbVie's business.

Other factors can have a material adverse effect on AbbVie's profitability and financial condition.

Many other factors can affect AbbVie's results of operations, cash flows and financial condition, including:

- changes in or interpretations of laws and regulations, including changes in accounting standards, taxation requirements, product marketing application standards and environmental laws;
- differences between the fair value measurement of assets and liabilities and their actual value, particularly for pension and post-employment benefits, stock-based compensation, intangibles and goodwill; and for contingent liabilities such as litigation and contingent consideration, the absence of a recorded amount, or an amount recorded at the minimum, compared to the actual amount;
- changes in the rate of inflation (including the cost of raw materials, commodities and supplies), interest rates, market value of AbbVie's equity investments and the performance of investments held by it or its employee benefit trusts;
- changes in the creditworthiness of counterparties that transact business with or provide services to AbbVie or its employee benefit trusts;
- changes in the ability of third parties that provide information technology, accounting, human resources, payroll and other outsourced services to AbbVie to meet their contractual obligations to AbbVie; and
- changes in business, economic and political conditions, including: war, political instability, terrorist attacks, the threat of future terrorist activity and related military action; natural disasters; the cost and availability of insurance due to any of the foregoing events; labor disputes, strikes, slow-downs, or other forms of labor or union activity; and pressure from third-party interest groups.

#### Risks Related to AbbVie's Common Stock

AbbVie cannot guarantee the timing, amount, or payment of dividends on its common stock.

Although AbbVie expects to pay regular cash dividends, the timing, declaration, amount and payment of future dividends to stockholders will fall within the discretion of AbbVie's board of directors. The board's decisions regarding the payment of dividends will depend on many factors, such as AbbVie's financial condition, earnings, capital requirements, debt service obligations, industry practice, legal requirements, regulatory constraints and other factors that the board deems relevant. For more information, see Item 5, "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities." AbbVie's ability to pay dividends will depend on its ongoing ability to generate cash from operations and access capital markets. AbbVie cannot guarantee that it will continue to pay a dividend in the future.

An AbbVie stockholder's percentage of ownership in AbbVie may be diluted in the future.

In the future, a stockholder's percentage ownership in AbbVie may be diluted because of equity issuances for capital market transactions, equity awards that AbbVie will be granting to AbbVie's directors, officers and employees, acquisitions, or other purposes. AbbVie's employees have options to purchase shares of its common stock as a result of conversion of their

Abbott stock options (in whole or in part) to AbbVie stock options. AbbVie anticipates its compensation committee will grant additional stock options or other stock-based awards to its employees. Such awards will have a dilutive effect on AbbVie's earnings per share, which could adversely affect the market price of AbbVie's common stock. From time to time, AbbVie will issue additional options or other stock-based awards to its employees under AbbVie's employee benefits plans.

In addition, AbbVie's amended and restated certificate of incorporation authorizes AbbVie to issue, without the approval of AbbVie's stockholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over AbbVie's common stock respecting dividends and distributions, as AbbVie's board of directors generally may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of AbbVie's common stock. For example, AbbVie could grant the holders of preferred stock the right to elect some number of AbbVie's directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences AbbVie could assign to holders of preferred stock could affect the residual value of the common stock.

Certain provisions in AbbVie's amended and restated certificate of incorporation and amended and restated by-laws, and of Delaware law, may prevent or delay an acquisition of AbbVie, which could decrease the trading price of AbbVie's common stock.

AbbVie's amended and restated certificate of incorporation and amended and restated by-laws contain, and Delaware law contains, provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and to encourage prospective acquirors to negotiate with AbbVie's board of directors rather than to attempt a hostile takeover. These provisions include, among others:

- the inability of AbbVie's stockholders to call a special meeting;
- the division of AbbVie's board of directors into three classes of directors, with each class serving a staggered three-year term;
- a provision that stockholders may only remove directors for cause;
- the ability of AbbVie's directors, and not stockholders, to fill vacancies on AbbVie's board of directors; and
- the requirement that the affirmative vote of stockholders holding at least 80% of AbbVie's voting stock is required to amend certain provisions in AbbVie's amended and restated certificate of incorporation and AbbVie's amended and restated by-laws relating to the number, term and election of AbbVie's directors, the filling of board vacancies, the calling of special meetings of stockholders and director and officer indemnification provisions.

In addition, Section 203 of the Delaware General Corporation Law provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or its affiliates becomes the holder of more than 15% of the corporation's outstanding voting stock.

AbbVie believes these provisions protect its stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with AbbVie's board of directors and by providing AbbVie's board of directors with more time to assess any acquisition proposal. These provisions are not intended to make the company immune from takeovers. However, these provisions apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that AbbVie's board of directors determines is not in the best interests of AbbVie and AbbVie's stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward looking statements regarding business strategies, market potential, future financial performance and other matters. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify "forward looking statements," which speak only as of the date the statements were made. The matters discussed in these forward looking statements are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those projected, anticipated or implied in the forward looking statements. In particular, information included under Item 1, "Business," Item 1A, "Risk Factors," and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" contain forward looking statements. Where, in any forward looking statement, an expectation or belief as to future results or events is expressed, such expectation or belief is based on the current plans and expectations of AbbVie management and expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the expectation or belief will result or be achieved or accomplished. Factors that could cause actual results or events to differ materially from those anticipated include the matters described under Item 1A, "Risk Factors" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations." AbbVie does not undertake any obligation to update the forward-looking statements included in this Annual Report on Form 10-K to reflect events or circumstances after the date hereof, unless AbbVie is required by applicable securities law to do so.

### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

### ITEM 2. PROPERTIES

AbbVie's corporate offices are located at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. AbbVie's manufacturing plants are in the following locations:

United States	Outside the United States
Abbott Park, Illinois*	Campoverde di Aprilia, Italy
Barceloneta, Puerto Rico	Cork, Ireland
Jayuya, Puerto Rico	Ludwigshafen, Germany
North Chicago, Illinois	Singapore*
South San Francisco, California	Sligo, Ireland
Worcester, Massachusetts*	
Wyandotte, Michigan*	

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\*Leased property.

In addition to the above, AbbVie has other manufacturing facilities worldwide. AbbVie believes its facilities are suitable and provide adequate production capacity.

In the United States, including Puerto Rico, AbbVie has one distribution center. AbbVie also has research and development facilities in the United States located at: Abbott Park, Illinois; North Chicago, Illinois; Redwood City, California; South San Francisco, California; Sunnyvale, California; Cambridge, Massachusetts; and Worcester, Massachusetts. Outside the United States, AbbVie's principal research and development facilities are located in Ludwigshafen, Germany.

Except as noted, the plants in the United States listed above are owned by AbbVie or subsidiaries of AbbVie. The remaining manufacturing plants and all other facilities are owned or leased by AbbVie or subsidiaries of AbbVie.



ITEM 3. LEGAL PROCEEDINGS

Information pertaining to legal proceedings is provided in Note 14, "Legal Proceedings and Contingencies" to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data," and is incorporated by reference herein.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following table lists AbbVie's executive officers, each of whom was first appointed as an AbbVie corporate officer in December 2012, except as otherwise indicated:

Name	Age	Position
Richard A. Gonzalez	63	Chairman of the Board and Chief Executive Officer
Carlos Alban	54	Executive Vice President, Commercial Operations
William J. Chase	49	Executive Vice President, Chief Financial Officer
Henry O. Gosebruch*	44	Executive Vice President and Chief Strategy Officer
Laura J. Schumacher	53	Executive Vice President, External Affairs, General Counsel and Corporate Secretary
Michael E. Severino, M.D.*	51	Executive Vice President, Research and Development and Chief Scientific Officer
Timothy J. Richmond	50	Senior Vice President, Human Resources
Azita Saleki-Gerhardt, Ph.D.	53	Senior Vice President, Operations
Thomas A. Hurwich**	56	Vice President, Controller

\*Mr. Gosebruch was first appointed as a corporate officer in December 2015 and Dr. Severino was first appointed as a corporate officer in June 2014.

\*\*As previously announced, Mr. Hurwich will resign as AbbVie's Vice President, Controller, effective February 28, 2017.

Mr. Gonzalez is AbbVie's Chairman of the Board and Chief Executive Officer. He served as Abbott's Executive Vice President, Pharmaceutical Products Group from 2010 to 2012, and was responsible for Abbott's worldwide pharmaceutical business, including commercial operations, research and development, and manufacturing. He has also served as President, Abbott Ventures Inc., Abbott's medical technology investment arm, from 2009 to 2011.

Mr. Gonzalez joined Abbott in 1977 and held various management positions before briefly retiring in 2007, including Abbott's President and Chief Operating Officer, President, Chief Operating Officer of Abbott's Medical Products Group, Senior Vice President and President of Abbott's former Hospital Products Division, Vice President and President of Abbott's Health Systems Division, and Divisional Vice President and General Manager for Abbott's Diagnostics Operations in the United States and Canada.

Mr. Alban is AbbVie's Executive Vice President, Commercial Operations. He served as Abbott's Senior Vice President, Proprietary Pharmaceutical Products, Global Commercial Operations from 2011 to 2012, as Senior Vice President, International Pharmaceuticals from 2009 to 2011, as Vice President, Western Europe and Canada from 2007 to 2009, and as Vice President, European Operations from 2006 to 2007. Mr. Alban joined Abbott in 1986.

Mr. Chase is AbbVie's Executive Vice President, Chief Financial Officer. He served as Abbott's Vice President, Licensing and Acquisitions from 2010 to 2012, as Vice President, Treasurer from 2007 to 2010, and as Divisional Vice President, Controller of Abbott International from 2004 to 2007. Mr. Chase joined Abbott in 1989.

Mr. Gosebruch is AbbVie's Executive Vice President and Chief Strategy Officer. He worked for more than 20 years in the Mergers & Acquisitions Group at J.P. Morgan Securities LLC, serving as Managing Director since 2007 and as Co-Head of M&A North America during 2015. Mr. Gosebruch joined AbbVie in 2015.

Ms. Schumacher is AbbVie's Executive Vice President, External Affairs, General Counsel and Corporate Secretary, responsible for AbbVie's externally-facing functions of Health Economics Outcomes Research, Government Affairs, Corporate Responsibility, Brand and Communications. She also leads all legal functions and biotherapeutics strategy. Prior to AbbVie's separation from Abbott, Ms. Schumacher served as Executive Vice President, General Counsel and Corporate Secretary from 2007 to 2012, and as Senior Vice President, Corporate Secretary and General Counsel from 2005 to 2007. Both at Abbott and AbbVie, Ms. Schumacher also led Licensing and Acquisition and Ventures and Early Stage Collaborations. At Abbott, Ms. Schumacher was also responsible for its Office of Ethics and Compliance. Ms. Schumacher joined Abbott in 1990. She serves on the board of General Dynamics Corporation.

Dr. Severino is AbbVie's Executive Vice President, Research and Development and Chief Scientific Officer. Dr. Severino served at Amgen Inc. as Senior Vice President, Global Development and Corporate Chief Medical Officer from 2012 to 2014, as

Vice President, Global Development from 2010 to 2012 and as Vice President, Therapeutic Area Head, General Medicine and Inflammation Global Clinical Development from 2007 to 2012. He joined AbbVie in 2014.

Mr. Richmond is AbbVie's Senior Vice President, Human Resources. He served as Abbott's Divisional Vice President of Compensation & Benefits from 2008 to 2012, as Group Vice President of Talent and Rewards from 2007 to 2008, and as Divisional Vice President of Talent Acquisition from 2006 to 2007. Mr. Richmond joined Abbott in 2006.

Dr. Saleki-Gerhardt is AbbVie's Senior Vice President, Operations. She served as Abbott's Vice President, Pharmaceuticals Manufacturing and Supply from 2011 to 2012, and as Divisional Vice President, Quality Assurance, Global Pharmaceutical Operations from 2008 to 2011. Dr. Saleki-Gerhardt joined Abbott in 1993.

Mr. Hurwich is AbbVie's Vice President, Controller. He served as Abbott's Vice President, Internal Audit from 2009 to 2012, and as Divisional Vice President, Controller, Abbott Diagnostics Division from 2003 to 2009. Mr. Hurwich joined Abbott in 1983.

The executive officers of AbbVie are elected annually by the board of directors. All other officers are elected by the board or appointed by the Chairman of the Board. All officers are either elected at the first meeting of the board of directors held after the annual stockholder meeting or appointed by the Chairman of the Board after that board meeting. Each officer holds office until a successor has been duly elected or appointed and qualified or until the officer's death, resignation, or removal. There are no family relationships between any of the executive officers listed above.

## PART II

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

## Principal Market

The principal market for AbbVie's common stock is the New York Stock Exchange (NYSE). AbbVie's common stock is also listed on the Chicago Stock Exchange and traded on various regional and electronic exchanges. Outside the United States, AbbVie's common stock is listed on NYSE Euronext Paris and the SIX Swiss Exchange.

## Market Price Per Share

	2016		2015	
	High	Low	High	Low
First Quarter	\$59.81	\$50.71	\$68.29	\$54.78
Second Quarter	\$65.37	\$56.36	\$70.75	\$56.33
Third Quarter	\$68.12	\$61.77	\$71.60	\$51.88
Fourth Quarter	\$65.05	\$55.06	\$64.30	\$45.45

## Stockholders

There were 52,270 stockholders of record of AbbVie common stock as of January 31, 2017.

## Dividends

The following table summarizes quarterly cash dividends for the years ended December 31, 2016 and 2015:

2016			2015		
Payment Date	Date Declared	Dividend Per Share	Payment Date	Date Declared	Dividend Per Share
11/15/16	09/09/16	\$ 0.57	11/16/15	09/11/15	\$ 0.51
08/15/16	06/16/16	\$ 0.57	08/14/15	06/18/15	\$ 0.51
05/16/16	02/18/16	\$ 0.57	05/15/15	02/19/15	\$ 0.51
02/16/16	10/30/15	\$ 0.57	02/13/15	10/20/14	\$ 0.49

On October 28, 2016, AbbVie's board of directors declared an increase in the quarterly cash dividend from \$0.57 per share to \$0.64 per share, payable on February 15, 2017 to stockholders of record as of January 13, 2017. The timing, declaration, amount of and payment of any dividends by AbbVie in the future is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by its board of directors. Moreover, if AbbVie determines to pay any dividend in the future, there can be no assurance that it will continue to pay such dividends or the amount of such dividends.

## Performance Graph

The following graph compares the cumulative total returns of AbbVie, the S&P 500 Index and the NYSE Arca Pharmaceuticals Index. This graph covers the period from January 2, 2013 (the first day AbbVie's common stock began "regular-way" trading on the NYSE) through December 31, 2016. This graph assumes \$100 was invested in AbbVie common stock and each index on January 2, 2013 and also assumes the reinvestment of dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

This performance graph is furnished and shall not be deemed "filed" with the SEC or subject to Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any of AbbVie's filings under the Securities Act of 1933, as amended.

#### Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2016 - October 31, 2016	1,206,700 <sup>(1)</sup>	\$ 56.03	1,197,847	\$2,059,934,326 <sup>(2)</sup>
November 1, 2016 - November 30, 2016	17,083,128 <sup>(1)</sup>	\$ 60.07	17,080,029	\$1,033,906,665 <sup>(2)</sup>
December 1, 2016 - December 31, 2016	16,231,850 <sup>(1)</sup>	\$ 61.56	16,205,010	\$36,288,894 <sup>(2)</sup>
Total	34,521,678 <sup>(1)</sup>	\$ 60.63	34,482,886	\$36,288,898 <sup>(2)</sup>

#### 1. These shares represent:

(i) in addition to AbbVie shares repurchased on the open market under a publicly announced program, if any, these shares included the shares deemed surrendered to AbbVie to pay the exercise price in connection with the exercise of employee stock options – 8,853 in October; 3,099 in November; and 6,512 in December, with average exercise prices of \$43.87 in October; \$43.60 in November; and \$44.32 in December.

(ii) the shares purchased on the open market for the benefit of participants in the AbbVie Employee Stock Purchase Plan - zero in October and November; and 20,328 in December.

These shares do not include the shares surrendered to AbbVie to satisfy minimum tax withholding obligations in connection with the vesting of restricted stock or restricted stock units.

On October 20, 2014, AbbVie announced that its board of directors authorized the purchase of up to \$5.0 billion of its common stock. The board of directors authorized increases to this repurchase program of \$5.0 billion in March 2015 and \$4.0 billion in April 2016 in anticipation of executing accelerated share repurchase agreements (ASRs) in connection with the acquisitions of Pharmacyclics and Stemcentrx. Purchases of AbbVie shares under this program may be made from time to time at management's discretion. The program has no time limit and can be discontinued at any time.

On February 16, 2017, AbbVie's board of directors authorized a \$5.0 billion increase to AbbVie's existing stock repurchase program. The stock repurchase authorization permits shares to be repurchased in open market or private transactions, has no time limit and may be discontinued at any time.

#### ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth AbbVie's selected financial information derived from its (i) audited consolidated financial statements as of and for the years ended December 31, 2016, 2015, 2014 and 2013; and (ii) audited combined financial statements as of and for the year ended December 31, 2012. The historical financial statements for periods prior to January 1, 2013 were prepared on a stand-alone basis and were derived from Abbott's consolidated financial statements and accounting records as if the former research-based pharmaceutical business of Abbott had been part of AbbVie for all periods presented. Accordingly, AbbVie's financial statements for periods prior to January 1, 2013 are presented on a combined basis and reflect AbbVie's financial position, results of operations and cash flows as its business was operated as part of Abbott prior to the separation, in conformity with generally accepted accounting principles (GAAP) in the United States.

The selected financial information should be read in conjunction with the financial statements and accompanying notes included under Item 8, "Financial Statements and Supplementary Data" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

as of and for the years ended December 31 (in millions, except per share data)	2016	2015	2014	2013	2012
Statement of earnings data					
Net revenues	\$25,638	\$22,859	\$19,960	\$18,790	\$18,380
Net earnings <sup>(a)(b)</sup>	5,953	5,144	1,774	4,128	5,275
Basic earnings per share <sup>(a)(b)</sup>	\$3.65	\$3.15	\$1.11	\$2.58	\$3.35
Diluted earnings per share <sup>(a)(b)</sup>	\$3.63	\$3.13	\$1.10	\$2.56	\$3.35
Cash dividends declared per common share	\$2.35	\$2.10	\$1.75	\$2.00	<sup>(c)</sup> n/a
Weighted-average basic shares outstanding <sup>(d)</sup>	1,622	1,625	1,595	1,589	1,577
Weighted-average diluted shares outstanding <sup>(d)</sup>	1,631	1,637	1,610	1,604	1,577
Balance sheet data					
Total assets <sup>(e)(f)</sup>	\$66,099	\$53,050	\$27,513	\$29,241	\$27,058
Long-term debt and lease obligations <sup>(e)(f)(g)</sup>	36,465	31,265	14,552	14,353	14,702

n/a—Not applicable.

(a) AbbVie's historical financial statements for periods prior to January 1, 2013 reflected an allocation of expenses related to certain Abbott corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses were allocated to AbbVie based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of revenues, headcount, square footage, number of transactions or other measures. AbbVie considers the expense allocation methodology and results to be reasonable. However, the allocations may not be indicative of the actual expenses that would have been incurred

had AbbVie operated as an independent, stand-alone, publicly-traded company for the periods presented. Accordingly, the historical financial information presented for periods prior to January 1, 2013 may not be indicative of the results of operations or financial position that would have been achieved if AbbVie had been an independent,



stand-alone, publicly-traded company during the periods shown or of AbbVie's performance for periods subsequent to December 31, 2012.

Results for 2016, 2015, 2014 and 2013 included higher expenses associated with operating as an independent, stand-alone, publicly-traded company than the historically derived financial statements for periods prior to January 1, 2013. The increases include the impact of interest expense on debt issued as a stand-alone company, a (b) higher tax rate and other incremental costs of operating as an independent company. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations" for a discussion of other items that affected the comparability of financial results for 2016, 2015 and 2014, and the 2013 Form 10-K for 2013 and 2012 financial statements.

AbbVie declared regular quarterly cash dividends in 2013 aggregating \$1.60 per share of common stock. In (c) addition, a cash dividend of \$0.40 per share of common stock was declared from pre-separation earnings on January 4, 2013 and was recorded as a reduction of additional paid-in capital.

On January 1, 2013, Abbott distributed 1,577 million shares of AbbVie common stock to shareholders of Abbott common stock. For periods prior to the separation, the weighted-average basic and diluted shares outstanding were (d) based on the number of shares of AbbVie common stock outstanding on the distribution date. See Note 4 to the Consolidated Financial Statements for information regarding the calculation of basic and diluted earnings per common share for 2016, 2015 and 2014 and the 2013 Form 10-K for 2013 and 2012.

On May 26, 2015, AbbVie acquired Pharmacyclics for approximately \$20.8 billion, including cash consideration of \$12.4 billion and equity consideration of approximately 128 million shares of AbbVie common stock valued at \$8.4 billion. In connection with the acquisition, AbbVie issued \$16.7 billion aggregate principal amount of (e) unsecured senior notes, of which approximately \$11.5 billion was used to finance the acquisition and approximately \$5.0 billion was used to finance an accelerated share repurchase (ASR) program. See Note 5 to the Consolidated Financial Statements for information regarding the acquisition of Pharmacyclics, Note 9 for information on the senior notes and Note 12 for information on the ASR.

In June 2016, AbbVie acquired Stemcentrx for approximately \$6.4 billion, including cash consideration of \$1.9 billion, equity consideration of approximately 62.4 million shares of AbbVie common stock valued at \$3.9 billion and contingent consideration of approximately \$620 million. In connection with the acquisition AbbVie issued \$7.8 (f) billion aggregate principal amount of unsecured senior notes. Of the \$7.7 billion net proceeds, approximately \$1.9 billion was used to finance the acquisition, approximately \$3.8 billion was used to finance an ASR and approximately \$2.0 billion was used to repay the company's outstanding term loan that was due to mature in November 2016. See Note 5 to the Consolidated Financial Statements for information regarding the acquisition of Stemcentrx, Note 9 for information on the senior notes and Note 12 for information on the ASR.

(g) Includes current portion of both long-term debt and lease obligations.

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

The following is a discussion and analysis of the financial condition of AbbVie Inc. (AbbVie or the company) as of December 31, 2016 and 2015 and results of operations for each of the three years in the period ended December 31, 2016. This commentary should be read in conjunction with the consolidated financial statements and accompanying notes appearing in Item 8, "Financial Statements and Supplementary Data."

### EXECUTIVE OVERVIEW

#### Company Overview

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories (Abbott). AbbVie's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie's products are focused on treating conditions such as chronic autoimmune diseases in rheumatology, gastroenterology and dermatology; oncology, including blood cancers; virology, including hepatitis C (HCV) and human immunodeficiency virus (HIV); neurological disorders, such as Parkinson's disease and multiple sclerosis; metabolic diseases, including thyroid disease and complications associated with cystic fibrosis; as well as other serious health conditions. AbbVie also has a pipeline of promising new medicines across such important medical specialties as immunology, virology, oncology and neurology, with additional targeted investment in cystic fibrosis and women's health.

AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies and patients. Outside the United States, sales are made either directly to customers or through distributors, depending on the market served. Certain products are co-marketed or co-promoted with other companies. AbbVie has approximately 30,000 employees. AbbVie operates in one business segment—pharmaceutical products.

#### 2016 Financial Results

AbbVie's strategy has focused on delivering strong financial results, advancing and investing in its pipeline and returning value to shareholders while ensuring a strong, sustainable growth business over the long term. In 2016, AbbVie's worldwide net revenues grew by 12% to \$25.6 billion, driven primarily by the continued strength of HUMIRA, post-acquisition revenue growth related to IMBRUVICA and revenue growth in other key products including Creon and Duodopa. These increases were partially offset by a decline in net revenues of Kaletra and VIEKIRA.

The company's financial performance in 2016 included delivering diluted earnings per share of \$3.63. 2016 results included the following after-tax costs: (i) \$615 million related to the amortization of intangible assets; (ii) a \$298 million currency devaluation loss related to Venezuela; (iii) \$273 million related to the acquisition of Stemcentrx and Boehringer Ingelheim (BI) compounds; (iv) \$228 million for changes in contingent consideration; (v) \$200 million for acquired in-process research and development (IPR&D); (vi) \$187 million associated with a tax law change for regulations issued in the fourth quarter of 2016 that revised the treatment of foreign currency translation gains and losses for certain operations; and (vii) milestone payments of \$80 million. Additionally, 2016 financial results reflected added funding to support AbbVie's emerging mid- and late-stage pipeline assets and continued investment in AbbVie's growth brands.

In 2016, the company generated cash flows from operations of \$7.0 billion, which AbbVie utilized to continue to enhance its pipeline through licensing and collaboration activities, pay cash dividends to stockholders of \$3.7 billion and repurchase approximately 34 million shares for \$2.1 billion in the open market (excluding the shares repurchased under an accelerated repurchase agreement). In October 2016, AbbVie's board of directors declared a quarterly cash dividend of \$0.64 per share of common stock payable in February 2017. This reflects an increase of approximately 12% over the previous quarterly rate of \$0.57 per share of common stock.

In April 2016, AbbVie acquired all rights to risankizumab (BI 655066), an anti-IL-23 monoclonal biologic antibody, from BI pursuant to a global collaboration agreement. In June 2016, AbbVie acquired Stemcentrx, a privately held biotechnology company. The transaction expands AbbVie's oncology pipeline by adding the late-stage asset rovalpituzumab tesirine (Rova-T), four additional early-stage clinical compounds in solid tumor indications and a significant portfolio of pre-clinical assets. Rova-T is currently in registrational trials for small cell lung cancer and in early-stage clinical development for other solid tumors. In connection with the Stemcentrx acquisition, AbbVie's board of directors authorized a \$4.0 billion increase to

AbbVie's existing share repurchase program. Promptly following the closing of the Stemcentrx transaction, AbbVie entered into and executed a \$3.8 billion accelerated share repurchase agreement (ASR) with a third party financial institution to reacquire nearly all of the newly-issued equity. In May 2016, AbbVie issued \$7.8 billion aggregate principal amount of unsecured senior notes. Of the \$7.7 billion net proceeds, \$2.0 billion was used to repay the company's outstanding term loan that was due to mature in November 2016, approximately \$1.9 billion was used to finance the acquisition of Stemcentrx and approximately \$3.8 billion was used to finance the ASR. In November 2016, the company issued €3.6 billion aggregate principal amount of unsecured senior Euro notes and repaid the company's outstanding 1.75% senior notes that were due to mature in November 2017. See Note 5 to the Consolidated Financial Statements for additional information related to the acquisition of Stemcentrx and BI compounds, Note 9 for additional information related to the senior Euro notes and Note 12 for additional information related to the ASR.

#### 2017 Strategic Objectives

AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including: (i) growing revenues through continued strong performance from its existing portfolio of on-market products, including its flagship brands, HUMIRA and IMBRUVICA as well as growth from pipeline products; (ii) expanding operating margins; (iii) continued investment in its pipeline in support of opportunities in immunology, oncology, virology and neurology as well as continued investment in key on-market products; (iv) augmentation of its pipeline through concerted focus on strategic licensing, acquisition and partnering activity with a focus on identifying compelling programs that fit AbbVie's strategic criteria; and (v) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in the next twelve months.

AbbVie expects to achieve its strategic objectives as follows:

- HUMIRA sales growth by driving biologic penetration across disease categories, increasing market leadership and strong commercial execution.

- IMBRUVICA revenue growth driven by increasing market share within its five currently approved indications.

The favorable impact of pipeline products approved in 2016 or currently under regulatory review where approval is expected in 2017. These products are described in greater detail in the section labeled "Research and Development" included as part of this Item 7.

AbbVie remains committed to driving continued expansion of operating margins and expects to achieve this objective through productivity initiatives in supply chain, ongoing efficiency programs to optimize manufacturing, commercial infrastructure, administrative costs and general corporate expenses and continued leverage from revenue growth.

AbbVie also remains committed to returning cash to shareholders via dividends and share repurchases.

#### Research and Development

Research and innovation are the cornerstones of AbbVie's business as a global biopharmaceutical company. AbbVie's long-term success depends to a great extent on its ability to continue to discover and develop innovative pharmaceutical products and acquire or collaborate on compounds currently in development by other biotechnology or pharmaceutical companies.

AbbVie's pipeline currently includes more than 50 compounds or indications in clinical development individually or under collaboration or license agreements and is focused on such important medical specialties as immunology, oncology, virology and neurology along with targeted investments in cystic fibrosis and women's health. Of these programs, more than 30 are in mid- and late-stage development.

The following sections summarize transitions of significant programs from Phase 2 development to Phase 3 development as well as developments in significant Phase 3 and registration programs. AbbVie expects multiple Phase 2 programs to transition into Phase 3 programs in the next twelve months.

#### Significant Programs and Developments

##### Immunology

##### HUMIRA

- In May 2016, the European Medicines Agency (EMA) granted approval for HUMIRA for the treatment of pediatric patients aged six years or older, with moderate to severely active Crohn's disease.

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In June 2016, HUMIRA received both U.S. Food and Drug Administration (FDA) and EMA approval to treat adults with non-infectious intermediate, posterior and panuveitis. HUMIRA is now the first and only FDA-approved non-corticosteroid therapy available for adults with non-infectious intermediate, posterior and panuveitis. This approval marks the 10<sup>th</sup> approved indication for HUMIRA in the United States for immune-mediated disease and the 14<sup>th</sup> approved indication in all geographies.

In November 2016, AbbVie announced that the Committee for Medicinal Products for Human Use (CHMP) granted a positive opinion for HUMIRA to treat adolescents with hidradenitis suppurativa (HS). If future approval is granted by the European Commission, HUMIRA will be the first and only treatment option for patients aged 12 and older with HS. HUMIRA was approved for adults with moderate to severe HS by the European Commission in July 2015.

#### Risankizumab

In April 2016, AbbVie acquired all rights to risankizumab (BI 655066), an anti-IL-23 monoclonal biologic antibody in Phase 3 development for psoriasis, from BI pursuant to a global collaboration agreement. AbbVie is also evaluating the potential of this biologic therapy in Crohn's disease, psoriatic arthritis and asthma. In addition to risankizumab, AbbVie also gained rights to an anti-CD40 antibody, BI 655064, currently in Phase 1 development.

In November 2016, AbbVie announced that the U.S. Food and Drug Administration (FDA) granted risankizumab orphan drug designation for the treatment of pediatric patients with Crohn's disease.

#### ABT-494

AbbVie continued to make progress with ABT-494, the company's selective JAK-1 inhibitor currently in late-stage development for rheumatoid arthritis. In first quarter of 2016, AbbVie initiated three Phase 3 studies in the registrational program. In the fourth quarter of 2016, the company started a fifth pivotal trial.

#### Other

In July 2016, following an evaluation of data for the development of ABT-122, a dual-variable domain (DVD) immunoglobulin targeting TNF and IL-17 in Phase 2 trials for rheumatoid arthritis and psoriatic arthritis, AbbVie determined that further development of ABT-122 will not be pursued. While the trial data demonstrated that the DVD platform worked well, with clear evidence of biologic activity, the decision was based on a lack of differentiation from other candidates in AbbVie's development pipeline.

In October 2016, AbbVie opted not to exercise an option to license vobarilizumab, an anti-IL-6R Nanobody, from Ablynx NV based on results of a Phase 2 study in rheumatoid arthritis. AbbVie retains an option to license vobarilizumab based on results of an on-going Phase 2 study in systemic lupus erythematosus.

#### Oncology

##### IMBRUVICA

In March 2016, AbbVie announced that the FDA approved IMBRUVICA as a first-line treatment for patients with CLL. The approval was based on data from the Phase 3 RESONATE-2 trial, which evaluated efficacy and safety of IMBRUVICA versus traditional chemotherapy, chlorambucil, in treatment-naïve patients with CLL or small lymphocytic leukemia. This is the first FDA-approved chemotherapy-free treatment option for first-line CLL patients. In May 2016, AbbVie announced that the EMA approved IMBRUVICA as a first-line treatment option for adult patients with CLL. IMBRUVICA is now available to treat all lines of CLL in the European Union (EU). This is the fifth treatment indication in the EU for IMBRUVICA.

In May 2016, AbbVie announced that the FDA updated the IMBRUVICA Prescribing Information to include new data from two Phase 3 trials supporting expanded use in patients with CLL and small lymphocytic lymphoma. The label now includes overall survival results in previously-untreated CLL/small lymphocytic lymphoma patients from

the Phase 3 RESONATE-2 trial. The IMBRUVICA label has also been updated with safety and efficacy data from the Phase 3 HELIOS trial assessing the use of IMBRUVICA in combination with bendamustine and rituximab versus placebo plus rituximab in relapsed/refractory patients with CLL/small lymphocytic lymphoma. Additionally, the FDA approved a new IMBRUVICA indication to include the treatment of patients with small lymphocytic lymphoma with or without the deletion of chromosome 17p.

In June 2016, AbbVie announced that the FDA granted IMBRUVICA breakthrough therapy designation for chronic graft-versus-host-disease after failure of one or more lines of systemic therapy, a rare condition with limited treatment options. This is the fourth breakthrough therapy designation for IMBRUVICA.

In January 2017, AbbVie announced that the FDA approved IMBRUVICA for the treatment of patients with relapsed/refractory marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. MZL is a slow-growing form of non-Hodgkin's lymphoma. This marks the seventh FDA approval and fifth disease indication for IMBRUVICA since the medication's initial approval in 2013.

#### Venetoclax

In April 2016, the FDA granted accelerated approval of Venclexta (venetoclax) tablets for patients diagnosed with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy. Additionally, in January 2016, the FDA granted two additional breakthrough therapy designations for venetoclax: (i) in combination with rituximab for the treatment of patients with relapsed/refractory CLL, including patients with chromosome 17p deletion; and (ii) in combination with hypomethylating agents for the treatment of patients with untreated (treatment-naïve) acute myeloid leukemia (AML) who are ineligible to receive standard induction therapy (high-dose chemotherapy). A Phase 3 clinical trial was recently initiated to study the safety and efficacy of venetoclax in combination with azacitidine in treatment naïve elderly subjects with AML who are ineligible for standard induction therapy.

In July 2016, AbbVie announced the initiation of a Phase 3 clinical trial to study the safety and efficacy of venetoclax in combination with bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma who are considered sensitive or naïve to proteasome inhibitors and have received one to three prior lines of therapy. The combination of venetoclax, bortezomib and dexamethasone will be compared to treatment with bortezomib, dexamethasone and placebo.

In December 2016, AbbVie announced that the European Commission (EC) has granted conditional marketing authorization for VENCLYXTO (venetoclax) monotherapy for the treatment of CLL in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor; and for the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor. Conditional marketing authorization is granted to medicines that address an unmet medical need, where the benefit of its immediate availability to patients outweighs the risk of limited data availability and where comprehensive data will be provided. VENCLYXTO is a first-in-class, oral, once-daily medicine that selectively inhibits the function of the BCL-2 protein. VENCLYXTO is being developed by AbbVie and Genentech, a member of the Roche Group. It is jointly commercialized by the companies in the U.S. and by AbbVie outside of the U.S.

#### Rova-T

In June 2016, AbbVie acquired Stemcentrx and its lead late-stage asset Rova-T currently in registrational trials for small cell lung cancer (SCLC). Rova-T is a novel bio-marker-specific therapy that is derived from cancer stem cells and targets delta-like protein 3 (DLL3) that is expressed in more than 80% of SCLC patient tumors and is not present in healthy tissue. Registrational trials for third-line SCLC are expected to complete enrollment by the end of 2016.

AbbVie recently began enrollment of a Phase 1 eight-arm "basket study" in neuroendocrine tumors and a Phase 1/2 regimen selection study as a first-line treatment for SCLC. Beyond Rova-T, Stemcentrx has four novel compounds in clinical trials across several solid tumor indications and has additional pre-clinical compounds.

In July 2016, BMS and AbbVie announced a clinical trial collaboration to evaluate the safety, tolerability and efficacy of Rova-T in combination with BMS' Opdivo (nivolumab) and Opdivo + Yervoy (ipilimumab) regimen as a treatment for relapsed extensive stage SCLC. The Phase 1/2 clinical program will explore the potential of combining BMS' immune-oncology agents in conjunction with Rova-T to drive improved and sustained efficacy and tolerability above the current standard of care.



Other

In May 2016, Bristol-Myers Squibb Company (BMS) and AbbVie announced that the EMA approved Empliciti (elotuzumab) for the treatment of multiple myeloma as combination therapy with Revlimid® (lenalidomide) and dexamethasone in adult patients who have received at least one prior therapy. Empliciti is now the first and only immunostimulatory antibody approved for multiple myeloma in the EU.

In June 2016, AbbVie exercised its right to end its global collaboration with Infinity Pharmaceuticals, Inc. (Infinity), which it entered into in September 2014 to develop and commercialize duvelisib (IPI-145) for the treatment of patients with cancer. Pursuant to the terms of the global collaboration agreement, the worldwide rights to duvelisib reverted to Infinity.

#### Virology/Liver Disease

In February 2016, AbbVie announced that CHMP granted a positive opinion for the use of VIEKIRA (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA (dasabuvir tablets) without ribavirin (RBV) in chronic HCV infected genotype 1b (GT1b) patients with compensated cirrhosis (Child-Pugh A). In April 2016, AbbVie announced that the FDA approved VIEKIRA PAK (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets) without RBV in patients with GT1b chronic HCV infection and compensated cirrhosis. In July 2016, AbbVie announced that the FDA approved a New Drug Application (NDA) for VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir and ritonavir) extended-release tablets. VIEKIRA XR is a once-daily, extended-release co-formulation of the active ingredients in VIEKIRA PAK (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) and is for the treatment of patients with chronic genotype 1 (GT1) HCV, including those with compensated cirrhosis (Child-Pugh A).

In October 2016, AbbVie announced that the FDA granted breakthrough therapy designation for the investigational, pan-genotypic regimen of glecaprevir (ABT-493)/pibrentasvir (ABT-530) for the treatment of patients with HCV who failed previous therapy with direct-acting antivirals in genotype 1, including therapy with an NS5A inhibitor and/or protease inhibitor.

In January 2017, AbbVie announced that its marketing authorization application (MAA) has been validated and is now under accelerated assessment by the EMA for the company's investigational, pan-genotypic regimen of G/P for the treatment of all major chronic HCV genotypes. G/P is also intended to address the needs of patients with specific treatment challenges, including those with severe chronic kidney disease (CKD) and those not cured with previous direct-acting antiviral (DAA) treatment. In February 2017, AbbVie announced that the FDA accepted its New Drug Application (NDA) and granted priority review for the company's investigational, pan-genotypic regimen of G/P for the treatment of all major chronic HCV genotypes.

#### Neurology

In May 2016, Biogen and AbbVie announced that the FDA approved ZINBRYTA (daclizumab) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS). ZINBRYTA is a once-monthly, self-administered, subcutaneous injection. Biogen and AbbVie will co-promote ZINBRYTA in the United States. In July 2016, Biogen and AbbVie announced that the EMA granted a marketing authorization for ZINBRYTA for the treatment of adult patients with RMS. ZINBRYTA launched in the third quarter of 2016.

#### Other

In January 2016, AbbVie announced the initiation of the first of two planned Phase 3 studies evaluating the safety and efficacy of Elagolix in the treatment of patients with uterine fibroids. AbbVie made a milestone payment of \$15 million to Neurocrine Biosciences, Inc., AbbVie's collaboration partner, upon enrollment of the first patient. Elagolix is also in Phase 3 development for endometriosis.

## RESULTS OF OPERATIONS

## Net Revenues

The comparisons presented at constant currency rates reflect comparative local currency net revenues at the prior year's foreign exchange rates. This measure provides information on the change in net revenues assuming that foreign currency exchange rates had not changed between the prior and the current periods. AbbVie believes that the non-GAAP measure of change in net revenues at constant currency rates, when used in conjunction with the GAAP measure of change in net revenues at actual currency rates, may provide a more complete understanding of the company's operations and can facilitate analysis of the company's results of operations, particularly in evaluating performance from one period to another.

	2016	2015	2014	Percent change			
				At actual currency rates		At constant currency rates	
for the years ended (dollars in millions)	2016	2015	2014	2016	2015	2016	2015
United States	\$15,947	\$13,561	\$10,845	17.6%	25.0%	17.6%	25.0%
International	9,691	9,298	9,115	4.2 %	2.0 %	7.3 %	17.9%
Net revenues	\$25,638	\$22,859	\$19,960	12.2%	14.5%	13.5%	21.7%

The following table details AbbVie's worldwide net revenues:

years ended December 31 (in millions)	2016	2015	2014	Percent change		At constant		2016	2015
				At actual currency rates	2015	currency rates	2015		
<b>HUMIRA</b>									
United States	\$10,432	\$8,405	\$6,524	24.1	% 28.8	% 24.1	% 28.8	%	%
International	5,646	5,607	6,019	0.7	% (6.9)	)% 4.3	% 8.6	%	%
Total	\$16,078	\$14,012	\$12,543	14.7	% 11.7	% 16.1	% 19.1	%	%
<b>IMBRUVICA</b>									
United States	\$1,580	\$659	\$—	>100.0	% n/a	>100.0	% n/a	%	%
Collaboration revenues	252	95	—	>100.0	% n/a	>100.0	% n/a	%	%
Total	\$1,832	\$754	\$—	>100.0	% n/a	>100.0	% n/a	%	%
<b>VIEKIRA</b>									
United States	\$342	\$804	\$48	(57.4)	)% >100.0	% (57.4)	)% >100.0	%	%
International	1,180	835	—	41.3	% n/a	42.7	% n/a	%	%
Total	\$1,522	\$1,639	\$48	(7.1)	)% >100.0	% (6.4)	)% >100.0	%	%
<b>Lupron</b>									
United States	\$663	\$653	\$580	1.5	% 12.5	% 1.5	% 12.5	%	%
International	158	173	198	(8.5)	)% (12.9)	)% (5.2)	)% (0.2)	)%	)%
Total	\$821	\$826	\$778	(0.6)	)% 6.1	% 0.1	% 9.3	%	%
<b>Synagis</b>									
International	\$730	\$740	\$835	(1.5)	)% (11.3)	)% (0.4)	)% 0.6	%	%
<b>Synthroid</b>									
United States	\$763	\$755	\$709	1.1	% 6.4	% 1.1	% 6.4	%	%
<b>Creon</b>									
United States	\$730	\$632	\$516	15.5	% 22.5	% 15.5	% 22.5	%	%
<b>AndroGel</b>									
United States	\$675	\$694	\$934	(2.8)	)% (25.7)	)% (2.8)	)% (25.7)	)%	)%
<b>Kaletra</b>									
United States	\$116	\$163	\$213	(28.8)	)% (23.8)	)% (28.8)	)% (23.8)	)%	)%
International	433	537	657	(19.3)	)% (18.2)	)% (13.3)	)% (4.9)	)%	)%
Total	\$549	\$700	\$870	(21.5)	)% (19.6)	)% (16.9)	)% (9.6)	)%	)%
<b>Sevoflurane</b>									
United States	\$80	\$81	\$83	(1.0)	)% (2.5)	)% (1.0)	)% (2.5)	)%	)%
International	348	393	467	(11.4)	)% (15.9)	)% (6.9)	)% (4.0)	)%	)%
Total	\$428	\$474	\$550	(9.7)	)% (13.9)	)% (6.0)	)% (3.8)	)%	)%
<b>Duodopa</b>									
United States	\$37	\$12	\$—	>100.0	% >100.0	% >100.0	% >100.0	%	%
International	256	219	220	16.9	% (0.6)	)% 18.1	% 18.1	%	%
Total	\$293	\$231	\$220	26.9	% 4.8	% 28.1	% 23.5	%	%
All other	\$1,217	\$1,402	\$1,957	(13.2)	)% (28.3)	)% (12.3)	)% (24.9)	)%	)%
Total net revenues	\$25,638	\$22,859	\$19,960	12.2	% 14.5	% 13.5	% 21.7	%	%

n/a—Not applicable.



The following discussion and analysis of AbbVie's net revenues by product is presented on a constant currency basis. Global HUMIRA sales increased 16% in 2016 and 19% in 2015. The sales increase in 2016 was driven by market growth across therapeutic categories and geographies, favorable pricing in certain geographies and approval of new indications. The sales increase in 2015 was primarily as a result of market growth across therapeutic categories and geographies, higher market share, approval of new indications and favorable pricing in certain geographies. In the United States, HUMIRA revenues increased 24% in 2016 and 29% in 2015, driven by prescription volume, favorable pricing, market growth across all indications and higher market share. Internationally, HUMIRA revenues increased 4% in 2016 and 9% in 2015, driven primarily by growth across indications. AbbVie continues to pursue strategies to help further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA.

Net revenues for IMBRUVICA represent product revenues in the United States and collaboration revenues outside of the United States related to AbbVie's 50% share of IMBRUVICA profit. Net revenues for IMBRUVICA commenced following the completion of the Pharmacyclics acquisition on May 26, 2015. Global IMBRUVICA sales increased more than 100% in 2016 as a result of market share gains following the FDA and EMA approval of IMBRUVICA as a first-line treatment for patients with CLL as well as having a full year of sales in 2016.

Global VIEKIRA sales decreased 6% in 2016, as a result of lower market share, primarily in the United States, market contraction and price erosion. In the United States, sales decreased 57% in 2016, primarily due to lower market share resulting from a new market entrant in the first quarter of 2016 and contraction of the overall market. International revenues in 2016 reflected sales in additional geographies where the product was approved subsequent to December 31, 2015. VIEKIRA was launched in 2015, revenues increased during 2015 as the product was approved in additional geographies.

Synagis is a seasonal product with the majority of sales occurring in the first and fourth quarters. Net revenues remained constant in 2016 and increased 1% in 2015.

Net revenues for Creon increased 15% in 2016 and 22% in 2015, driven primarily by continued market growth and higher market share. Creon maintains market leadership in the pancreatic enzyme market.

Global Kaletra net revenues decreased 17% in 2016 and 10% in 2015, primarily due to lower market share resulting from the impact of increasing competition in the HIV marketplace. AbbVie expects net revenues for Kaletra to continue to decline in 2017.

Net revenues for Duodopa increased 28% in 2016 and 23% in 2015, primarily as a result of market penetration and geographic expansion. Duopa was approved in the United States in January 2015. AbbVie expects net revenues for Duopa in the United States will continue to gradually increase during 2017 as the product gains acceptance in the marketplace.

#### Gross Margin

				Percent change
years ended December 31 (in millions)	2016	2015	2014	2016/2015
Gross margin	\$19,805	\$18,359	\$15,534	8% 18%
as a percent of net revenues	77	% 80	% 78	%

Gross margin as a percentage of net revenues decreased in 2016 due to the impact of unfavorable foreign exchange rates, higher intangible asset amortization and the unfavorable impact related to the Pharmacyclics acquisition, including the profit sharing arrangement and the amortization of the fair market value step-up of acquisition-date inventory. These reductions were partially offset by the favorable impact of product mix across the portfolio and manufacturing efficiencies. Additionally, 2016 included a \$39 million charge related to the impairment of an intangible asset in the first quarter of 2016.

The gross margin for 2015 and 2014 reflected the favorable impact of product mix across the product portfolio, including HUMIRA, operational efficiencies and price increases, partially offset by the effect of unfavorable foreign exchange rates and the loss of exclusivity for the lipid franchise. Gross margin in 2015 also included milestone revenue of \$40 million from a collaboration partner related the company's oncology program. Additionally, gross

margin in 2014 included royalty income of \$81 million relating to prior periods as a result of the settlement of a licensing arrangement and lower amortization expense for intangible assets, partially offset by a \$37 million impairment charge for an intangible asset.

## Selling, General and Administrative

years ended December 31 (in millions)	2016	2015	2014	Percent change	
				2016	2015
Selling, general and administrative	\$5,855	\$6,387	\$7,724	(8)%	(17)%
as a percent of net revenues	23	% 28	% 39	%	

SG&A expenses as a percentage of net revenues decreased in 2016 due to continued leverage from revenue growth and lower costs in 2016. 2015 SG&A expenses included costs associated with the separation from Abbott of \$265 million, Pharmacylics acquisition and integration costs of \$294 million and litigation charges of \$165 million. Additionally, SG&A expense in 2015 reflected marketing support for the global launch of VIEKIRA.

SG&A expenses declined in 2015 compared to 2014, principally due to the absence of transaction-related costs totaling \$1.7 billion incurred in 2014 in connection with the termination of the proposed combination with Shire, partially offset by the 2015 items discussed above. SG&A expenses in 2014 also included a \$129 million charge related to the Branded Prescription Drug Fee due to the issuance of final rules which resulted in an additional year of expense in 2014.

## Research and Development and Acquired In-Process Research and Development

years ended December 31 (in millions)	2016	2015	2014	Percent change	
				2016	2015
Research and development	\$4,366	\$4,285	\$3,297	2 %	30 %
as a percent of net revenues	17	% 19	% 17	%	
Acquired in-process research and development	\$200	\$150	\$352	33 %	(57)%

Research and Development (R&D) expenses in 2016 increased compared to 2015 principally due to increased funding to support the company's emerging mid- and late-stage pipeline assets. These increases were partially offset by the following factors: (i) 2015 R&D expenses included a \$350 million charge related to the purchase of a priority review voucher from a third party; (ii) development milestones decreased in 2016 to \$80 million compared to \$133 million in 2015; and (iii) 2015 results included restructuring charges of \$32 million. Acquisition costs decreased in 2016 to \$140 million compared to \$152 million in 2015. In addition to the 2015 factors discussed above, R&D expense in 2014 included regulatory milestone payments of \$40 million made to a collaboration partner for regulatory milestones related to the company's HCV program.

Acquired IPR&D expense in 2016 included charges of \$200 million as a result of entering into various collaboration agreements. R&D expense in 2015 included a charge of \$100 million as a result of entering into an exclusive worldwide license agreement with C<sub>2</sub>N to develop and commercialize anti-tau antibodies for the treatment of Alzheimer's disease and other neurological disorders. Acquired IPR&D expense in 2014 included a charge of \$275 million as a result of entering into a global collaboration with Infinity to develop and commercialize duvelisib, a treatment for patients with cancer. See Note 5 to the Consolidated Financial Statements for additional information regarding the C<sub>2</sub>N and Infinity agreements.

## Other Operating Expenses

Other operating expenses in 2014 included a \$750 million charge related to an R&D collaboration agreement entered into in September 2014 with Calico to discover, develop and commercialize new therapies for patients with age-related diseases.



## Other Non-Operating Expenses

(in millions)	Years Ended		
	December 31,		
	2016	2015	2014
Interest expense	\$1,047	\$719	\$429
Interest income	(82 )	(33 )	(38 )
Interest expense, net	\$965	\$686	\$391
Net foreign exchange loss	\$303	\$193	\$678
Other expense (income), net	232	13	(27 )

Interest expense in 2016 increased due to the May 2015 issuance of \$16.7 billion aggregate principal amount of senior notes, which were issued primarily to finance the acquisition of Pharmacyclics and the May 2016 issuance of \$7.8 billion aggregate principal amount of senior notes, which were issued primarily to finance the acquisition of Stemcentrx and to repay an outstanding term loan. Additionally, interest expense in 2016 included a debt extinguishment charge of \$39 million related to the 1.75% senior notes redemption. These increases were partially offset by the absence of bridge financing-related costs of \$86 million in 2015 incurred in connection with the acquisition of Pharmacyclics. Interest income in 2016 increased due to growth in the company's investment securities. Interest expense, net in 2015 increased due to the May 2015 issuance of \$16.7 billion aggregate principal amount of senior notes. Interest expense, net in 2014 included \$141 million of financing related fees incurred in connection with the terminated proposed combination with Shire.

Net foreign exchange loss in 2016 included losses totaling \$298 million related to the devaluation of AbbVie's net monetary assets denominated in the Venezuelan bolivar. See Note 10 to the Consolidated Financial Statements for additional information regarding the Venezuelan devaluation. Net foreign exchange loss in 2015 included losses of \$170 million to complete the liquidation of the company's remaining foreign currency positions related to the terminated proposed combination with Shire. In 2014, AbbVie entered into certain undesignated forward contracts to hedge the then anticipated foreign currency cash outflows associated with the then proposed combination with Shire. Net foreign exchange loss in 2014 included losses of \$666 million associated with the Shire-related forward contracts. Other expense, net in 2016 included a charge of \$228 million related to the change in fair value of the BI and Stemcentrx contingent consideration liabilities. The fair value of contingent consideration liabilities is impacted by the passage of time and multiple other inputs, including the probability of success of achieving regulatory/commercial milestones, discount rates and other market-based factors. In 2016, the change in fair value represented mainly the passage of time, as increases to the BI contingent consideration liability due to higher probabilities of success were fully offset by the effects of rising interest rates and changes in other market-based assumptions. See Note 5 to the Consolidated Financial Statements for additional information regarding the acquisitions of Stemcentrx and BI compounds. Other expense, net for 2015 included impairment charges totaling \$36 million related to certain of the company's equity investment securities. Other expense, net in 2014 primarily consisted of income of \$34 million from the resolution of a contractual agreement.

## Income Tax Expense

The effective income tax rate was 24% in 2016, 23% in 2015 and 25% in 2014. The effective tax rate in each period differed from the statutory tax rate principally due to the benefit from foreign operations which reflects the impact of lower income tax rates in locations outside the United States, tax exemptions and incentives in Puerto Rico and other foreign tax jurisdictions, business development activities and the cost of repatriation decisions. The increase in the effective tax rate for 2016 over the prior year was principally due to changes in the jurisdictional mix of earnings, as well as certain discrete factors and events, including acquisitions and collaborations. The effective tax rate in 2016 included additional expense of \$187 million related to the recognition of the tax effect of regulations issued by the Internal Revenue Service on December 7, 2016 that changed the determination of the U.S. taxability of foreign currency gains and losses related to certain foreign operations. The effective income tax rate in 2015 included a tax benefit of \$103 million from a reduction of state valuation allowances. The effective income tax rate in 2014 included state valuation allowances of \$129 million and additional expenses of \$129 million related to the Branded Prescription

Drug Fee, which is non-deductible.

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## FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

years ended December 31 (in millions) 2016 2015 2014

Cash flows provided by/(used in):

Operating activities	\$7,041	\$7,535	\$3,549
Investing activities	(6,074 )	(12,936)	(926 )
Financing activities	(3,928 )	5,752	(3,293 )

Cash flows provided by operations in 2016 was \$7.0 billion compared to \$7.5 billion in 2015. Operating cash flows in 2016 reflected improved results of operations resulting from revenue growth and an improvement in operating margin, offset by income tax payments. Cash provided by operating activities also reflected AbbVie's voluntary contributions, primarily to its domestic defined benefit plans of \$150 million in 2016, \$150 million in 2015 and \$370 million in 2014. AbbVie also made a voluntary contribution of \$150 million to this plan subsequent to December 31, 2016. AbbVie paid \$350 million to purchase a priority review voucher from a third party in 2015. Cash flows provided by operations in 2015 was \$7.5 billion compared to \$3.5 billion in 2014. The increase was primarily due to improved results of operations due to revenue growth and an improvement in operating margin as well as the absence of after-tax transaction and financing-related and other costs of \$1.8 billion incurred in connection with the termination of the proposed combination with Shire, including net foreign exchange losses related to the settlement of undesignated forward contracts used to hedge anticipated foreign currency cash flows and the exit of certain foreign currency positions. Realized excess tax benefits associated with stock-based compensation totaled \$55 million in 2016, \$61 million in 2015 and \$56 million in 2014 and were presented in the Consolidated Statements of Cash Flows as an outflow within the operating section and an inflow within the financing section.

Investing cash flows in 2016 primarily included \$1.9 billion cash consideration paid to acquire Stemcentrx in June 2016, \$595 million upfront payment to acquire certain rights from BI in April 2016 and net purchases of investment securities totaling \$3.0 billion. Investing activities in 2015 primarily included the \$11.5 billion cash consideration paid to acquire Pharmacyclics in May 2015 (net of cash acquired of \$877 million). Investing activities in 2015 also included cash outflows related to other acquisitions and investments of \$964 million, including a \$500 million payment to Calico, \$100 million related to an exclusive worldwide license agreement with C<sub>2</sub>N to develop and commercialize anti-tau antibodies for the treatment of Alzheimer's disease and other neurological disorders and \$130 million paid to Infinity due to the achievement of a development milestone under the collaboration agreement. Investing activities in 2014 included cash outflows related to other acquisitions and investments totaling \$622 million, including \$275 million paid to Infinity and \$250 million paid to Calico. Cash flows from investing activities in 2016, 2015 and 2014 also reflected capital expenditures. AbbVie incurred additional expenditures in 2014 to purchase a manufacturing facility and in 2015 to build a new biologics facility on that site.

In 2016 and 2015, the company issued and redeemed commercial paper. The balance of commercial paper outstanding was \$377 million as of December 31, 2016 and \$400 million as of December 31, 2015. AbbVie may issue additional commercial paper or retire commercial paper to meet liquidity requirements as needed. In November 2016, the company issued €3.6 billion aggregate principal amount of unsecured senior Euro notes. The company used the proceeds to redeem \$4.0 billion aggregate principal amount of 1.75% senior notes due to mature in November 2017. In connection with the offering, AbbVie incurred \$17 million of issuance costs. In May 2016, the company issued \$7.8 billion aggregate principal amount of senior notes. Approximately \$2.0 billion of the net proceeds were used to repay an outstanding term loan that was due to mature in November 2016, approximately \$1.9 billion of the net proceeds were used to finance the acquisition of Stemcentrx and approximately \$3.8 billion of the net proceeds were used to finance an ASR. See Note 12 to the Consolidated Financial Statements for additional information on the ASR transactions. In connection with the May 2016 issuance of senior notes, AbbVie incurred \$52 million of issuance costs.

In May 2015, the company issued \$16.7 billion aggregate principal amount of unsecured senior notes. Approximately \$11.5 billion of the net proceeds were used to finance the acquisition of Pharmacyclics and \$5.0 billion of the net proceeds were used to finance an ASR. In 2015 the company paid \$86 million of costs relating to an \$18.0 billion, 364-Day Bridge Term Loan Credit Agreement (the bridge loan) as well as \$93 million of costs relating to the May

2015 issuance of senior notes. No amounts were drawn under the bridge loan, which was terminated as a result of the issuance of the senior notes. In September 2015, AbbVie entered into a three-year \$2.0 billion term loan credit facility and a 364-day \$2.0 billion term loan credit facility. In November 2015, AbbVie drew on these term facilities and used the proceeds to refinance its \$4.0 billion of senior notes that matured in 2015.

Cash dividend payments totaled \$3.7 billion in 2016 and \$3.3 billion in 2015. The increase in cash dividend payments was primarily due to an increase in the dividend rate. On October 28, 2016, AbbVie announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.57 per share to \$0.64 per share beginning with the

dividend payable on February 15, 2017 to stockholders of record as of January 13, 2017. This reflects an increase of approximately 12% over the previous quarterly rate. The timing, declaration, amount of and payment of any dividends is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by its board of directors.

In addition to the ASRs, the company repurchased approximately 34 million shares for \$2.1 billion in the open market in 2016 and approximately 46 million shares for \$2.8 billion in the open market in 2015. Purchases of AbbVie shares under this program may be made from time to time at management's discretion. The program has no time limit and can be discontinued at any time. AbbVie's remaining stock repurchase authorization was \$36 million as of December 31, 2016. See Note 12 to the Consolidated Financial Statements for additional information related to the ASR. On February 16, 2017, AbbVie's board of directors authorized a \$5.0 billion increase to AbbVie's existing stock repurchase program. The stock repurchase authorization permits shares to be repurchased in open market or private transactions, has no time limit and may be discontinued at any time.

Cash and equivalents were also negatively impacted by net unfavorable exchange rate changes totaling \$338 million in 2016 and \$300 million in 2015. The unfavorable exchange rate changes in 2016 were primarily due to the devaluation of AbbVie's net monetary assets denominated in the Venezuelan bolivar. The unfavorable exchange rate changes in 2015 were principally due to the weakening of the Euro and other foreign currencies on the translation of the company's Euro-denominated assets and cash denominated in foreign currencies. While a significant portion of cash and equivalents at December 31, 2016 are considered reinvested indefinitely in foreign subsidiaries, AbbVie does not expect such reinvestment to affect its liquidity and capital resources. If these funds were needed for operations in the United States, AbbVie would be required to accrue and pay U.S. income taxes to repatriate these funds. AbbVie believes that it has sufficient sources of liquidity to support its assumption that the disclosed amount of undistributed earnings at December 31, 2016 has been reinvested indefinitely.

#### Credit Risk

AbbVie monitors economic conditions, the creditworthiness of customers and government regulations and funding, both domestically and abroad. AbbVie regularly communicates with its customers regarding the status of receivable balances, including their payment plans and obtains positive confirmation of the validity of the receivables. AbbVie establishes an allowance against accounts receivable when it is probable they will not be collected. AbbVie also monitors the potential for and periodically has utilized factoring arrangements to mitigate credit risk although the receivables included in such arrangements have historically not been a significant amount of total outstanding receivables.

AbbVie continues to do business with foreign governments in certain countries, including Greece, Portugal, Italy and Spain, that have historically experienced challenges in credit and economic conditions. Substantially all of AbbVie's trade receivables in Greece, Portugal, Italy and Spain are with government health systems. Outstanding net governmental receivables in these countries totaled \$244 million as of December 31, 2016 and \$525 million at December 31, 2015. The company also continues to do business with foreign governments in certain oil-exporting countries, which have recently experienced a deterioration in economic conditions, including Saudi Arabia and Russia. Outstanding net governmental receivables were \$122 million related to Saudi Arabia and \$110 million related to Russia as of December 31, 2016. Due to oil market conditions in recent years, liquidity issues in certain countries may result in delays in the collection of receivables. Global economic conditions and customer-specific factors may require the company to periodically re-evaluate the collectability of its receivables and the company could potentially incur credit losses.

Currently, AbbVie does not believe the economic conditions in oil-exporting countries will have a significant impact on the company's liquidity, cash flow or financial flexibility. However, if government funding were to become unavailable in these countries or if significant adverse changes in their reimbursement practices were to occur, AbbVie may not be able to collect the entire balance outstanding as of December 31, 2016.



## Credit Facility, Access to Capital and Credit Ratings

## Credit Facility

AbbVie currently has a \$3.0 billion five-year revolving credit facility, which matures in October 2019. The revolving credit facility enables the company to borrow funds on an unsecured basis at variable interest rates and contains various covenants. At December 31, 2016, the company was in compliance with all its credit facility covenants. Commitment fees under the credit facility were insignificant. There were no amounts outstanding under the credit facility as of December 31, 2016 and 2015.

## Access to Capital

The company intends to fund short-term and long-term financial obligations as they mature through cash on hand, future cash flows from operations, or by issuing additional debt. The company's ability to generate cash flows from operations, issue debt, or enter into financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for the company's products or in the solvency of its customers or suppliers, deterioration in the company's key financial ratios or credit ratings, or other material unfavorable changes in business conditions. At the current time, the company believes it has sufficient financial flexibility to issue debt, enter into other financing arrangements and attract long-term capital on acceptable terms to support the company's growth objectives.

## Credit Ratings

On April 28, 2016, following the announcement of the proposed acquisition of Stemcentrx, S&P Global Ratings (S&P) lowered AbbVie's corporate credit rating and senior unsecured debt rating to "A-" from "A". AbbVie's "A-1" short-term rating remained unchanged. S&P revised its ratings outlook to "stable" from "negative". On June 1, 2016, Moody's Investor Service downgraded AbbVie's senior unsecured long-term rating to Baa2 from Baa1 and affirmed AbbVie's Prime-2 short-term rating. There were no additional changes in the company's credit ratings in 2016. Unfavorable changes to the ratings may have an adverse impact on future financing arrangements; however, they would not affect the company's ability to draw on its credit facility and would not result in an acceleration of scheduled maturities of any of the company's outstanding debt.

## Contractual Obligations

The following table summarizes AbbVie's estimated contractual obligations as of December 31, 2016:

(in millions)	Total	Less than one year	One to three years	Three to five years	More than five years
Short-term borrowings	\$377	\$377	\$—	\$—	\$—
Long-term debt and capital lease obligations, including current portion	37,077	25	7,503	5,562	23,987
Interest on long-term debt <sup>(a)</sup>	16,924	1,067	2,389	2,295	11,173
Future minimum non-cancelable operating lease commitments	974	131	222	172	449
Purchase obligations and other <sup>(b)</sup>	1,818	1,669	118	20	11
Other long-term liabilities <sup>(c) (d) (e)</sup>	5,159	540	437	837	3,345
Total	\$62,329	\$3,809	\$10,669	\$8,886	\$38,965

Includes estimated future interest payments on long-term debt securities and capital lease obligations. Interest payments on debt are calculated for future periods using forecasted interest rates in effect at the end of 2016.

Projected interest payments include the related effects of interest rate swap agreements. Certain of these projected interest payments may differ in the future based on changes in floating interest rates or other factors or events. The projected interest payments only pertain to obligations and agreements outstanding at December 31, 2016. See Note 9 to the Consolidated Financial Statements for additional information regarding the company's debt instruments and Note 10 for additional information on the interest rate agreements outstanding at December 31, 2016.

(b) Includes the company's significant unconditional purchase obligations. These commitments do not exceed the company's projected requirements and are made in the normal course of business.





Amounts less than one year includes a voluntary contribution of \$150 million AbbVie made to its main domestic defined benefit plan subsequent to December 31, 2016. Amounts otherwise exclude pension and other post-employment benefits and related deferred compensation cash outflows. Timing of funding is uncertain and (c) dependent on future movements in interest rates and investment returns, changes in laws and regulations and other variables. Also included in this amount are components of other long-term liabilities including restructuring. See Note 8 to the Consolidated Financial Statements for additional information on restructuring and Note 11 for additional information on the pension plan.

Excludes liabilities associated with the company's unrecognized tax benefits as it is not possible to reliably estimate (d) the timing of the future cash outflows related to these liabilities. See Note 13 to the Consolidated Financial Statements for additional information on these unrecognized tax benefits.

Includes \$4.2 billion of contingent consideration liabilities related to the acquisitions of Stemcentrx and BI compounds which are recorded at fair value on the consolidated balance sheet. Potential contingent consideration (e) payments that exceed the fair value recorded on the consolidated balance sheet are not included in the table of contractual obligations. See Notes 5 and 10 to the Consolidated Financial Statements for additional information regarding these liabilities.

AbbVie enters into R&D collaboration arrangements with third parties that may require future milestone payments to third parties contingent upon the achievement of certain development, regulatory, or commercial milestones. Individually, these arrangements are insignificant in any one annual reporting period. However, if milestones for multiple products covered by these arrangements would happen to be reached in the same reporting period, the aggregate charge to expense could be material to the results of operations in that period. From a business perspective, the payments are viewed as positive because they signify that the product is successfully moving through development and is now generating or is more likely to generate cash flows from product sales. It is not possible to predict with reasonable certainty whether these milestones will be achieved or the timing for achievement. As a result, these potential payments are not included in the table of contractual obligations. See Note 5 to the Consolidated Financial Statements for additional information on these collaboration arrangements.

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses. A summary of the company's significant accounting policies is included in Note 2 to the consolidated financial statements. Certain of these policies are considered critical as these most significantly impact the company's financial condition and results of operations and require the most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results may vary from these estimates.

##### Revenue Recognition

AbbVie recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectability of the sales price is reasonably assured. Revenue from product sales is recognized when title and risk of loss have passed to the customer.

##### Rebates

AbbVie provides rebates to pharmacy benefit managers, state government Medicaid programs, insurance companies that administer Medicare drug plans, wholesalers, group purchasing organizations and other government agencies and private entities.

Rebate and chargeback accruals are recorded as a reduction to revenue in the period the related product is sold. Rebates and chargebacks totaled \$10.8 billion in 2016, \$8.6 billion in 2015 and \$5.9 billion in 2014. Rebate amounts are typically based upon the volume of purchases using contractual or statutory prices, which may vary by product and by payer. For each type of rebate, the factors used in the calculations of the accrual for that rebate include the identification of the products subject to the rebate, the applicable price terms and the estimated lag time between sale and payment of the rebate, which can be significant.

In order to establish its rebate and chargeback accruals, the company uses both internal and external data to estimate the level of inventory in the distribution channel and the rebate claims processing lag time for each type of rebate. To

estimate the rebate percentage or net price, the company tracks sales by product and by customer or payer. The company evaluates inventory data reported by wholesalers, available prescription volume information, product pricing, historical experience and other factors in order to determine the adequacy of its reserves. AbbVie regularly monitors its reserves and