

AbbVie Inc.  
Form 10-K  
February 19, 2016

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D. C. 20549  
**FORM 10-K**

(MARK  
ONE)

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

OR

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

**For the fiscal year ended December 31, 2015  
Commission file number 001-35565**

**AbbVie Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**32-0375147**

(I.R.S. employer  
identification number)

**1 North Waukegan Road**

**North Chicago, Illinois 60064-6400**

(Address of principal executive offices) (Zip Code)

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

**(847) 932-7900**

(Telephone number)

**Title of Each Class**

Common Stock, par value \$0.01 per share

**Name of Each Exchange on Which Registered**

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

## Edgar Filing: AbbVie Inc. - Form 10-K

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.

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer  Smaller Reporting Company   
(Do not check if a 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 1,637,027,201 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, 2015), was \$109,991,857,664. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2016: 1,611,238,226

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2016 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 21, 2016.

## PART I

### ITEM 1. BUSINESS

#### Separation from Abbott Laboratories

AbbVie<sup>(1)</sup> 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 percent of the outstanding common stock of AbbVie to Abbott's shareholders. AbbVie's common stock began trading "regular-way" under the ticker symbol "ABBV" on the New York Stock Exchange on January 2, 2013.

#### Overview

AbbVie 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; 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 compounds or indications in clinical development across such important medical specialties as immunology, virology/liver disease, oncology, neurological diseases and women's health.

On May 26, 2015, AbbVie completed its acquisition of Pharmacyclics, Inc., a biopharmaceutical company that develops and commercializes novel therapies for people impacted by cancer, and its flagship asset IMBRUVICA, a highly effective treatment for hematologic malignancies, for approximately \$20.8 billion, consisting of cash consideration of \$12.4 billion and equity consideration of \$8.4 billion.

#### Segments

AbbVie operates in one business segment pharmaceutical products. Incorporated herein by reference is Note 15 entitled "Segment and Geographic Area Information" of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" 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.

---

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

## Edgar Filing: AbbVie Inc. - Form 10-K

**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
Crohn's disease (moderate to severe)	North America, European Union
Plaque psoriasis (moderate to severe)	North America, European Union
Juvenile idiopathic arthritis	North America, European Union
Ulcerative colitis (moderate to severe)	United States, European Union
Axial spondyloarthritis	United States, European Union
Pediatric Crohn's disease (severe)	United States, European Union
Hidradenitis Suppurativa	United States, European Union
Pediatric enthesitis-related arthritis	European Union

HUMIRA is also approved in over 60 other markets, including Japan, China, Brazil, and Australia. HUMIRA was introduced to the market in January 2003. HUMIRA is AbbVie's largest product and accounted for approximately 61 percent of AbbVie's total net revenues in 2015. The United States composition of matter (that is, compound) patent covering adalimumab (which is sold under the trademark HUMIRA) is expected to expire in December 2016, and the equivalent European Union patent is expected to expire in the majority of European Union countries in October 2018. In addition, in the United States, non-composition of matter patents covering adalimumab expire no earlier than 2022.

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 ophthalmology (uveitis). A regulatory application for uveitis has been filed in the United States. AbbVie continues to work on HUMIRA formulation and delivery enhancements to improve convenience and the overall patient experience.

**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) who have received at least one prior therapy, 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. 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 three separate designations.

**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. VIEKIRA PAK was approved by the FDA in December 2014. In Europe, AbbVie's HCV treatment is marketed as VIEKIRAX + EXVIERA and is approved for use in patients with genotype 1 and genotype 4 HCV. The European Commission granted marketing authorization for this treatment in January 2015. 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.

## Edgar Filing: AbbVie Inc. - Form 10-K

**Additional Virology products.** AbbVie's additional virology products include KALETRA and Norvir for the treatment of HIV infection and Synagis for the prevention of respiratory syncytial virus (RSV) infection in high risk infants.

**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, exocrine pancreatic insufficiency and hypothyroidism. These products include:

**AndroGel.** AndroGel (testosterone gel) is a testosterone replacement therapy for males diagnosed with symptomatic low testosterone 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 (levuprolide 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 the following:

**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.

**Dyslipidemia products.** AbbVie's dyslipidemia products (TriCor (fenofibrate), Trilipix (fenofibric acid), and Niaspan (niacin extended-release)) address the range of metabolic conditions characterized by high cholesterol and/or high triglycerides.

**Zemplar.** Zemplar (paricalcitol) is a product sold worldwide for the treatment of secondary hyperparathyroidism associated with Stage 3, 4, and 5 chronic kidney disease (CKD).

## Research and Development Activities

AbbVie 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.

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 \$4.3 billion in 2015, \$3.3 billion in 2014, and \$2.9 billion in 2013 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.

## 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 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 filed on or after June 8, 1995 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

## Edgar Filing: AbbVie Inc. - Form 10-K

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.

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 minimum and maximum periods of exclusivity that might be achieved in any individual case would not be expected to exceed three and 14 years, respectively. 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, and in the European Union, it has also reduced 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 2016 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 is expected to expire in December 2016, and the equivalent

## Edgar Filing: AbbVie Inc. - Form 10-K

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.

### 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 2015, 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 43 percent of AbbVie's 2015 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.



## Edgar Filing: AbbVie Inc. - Form 10-K

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

### 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," of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data," and has certain agreements with Abbott as discussed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations Transition from Abbott and Cost to Operate as an Independent Company."

### 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 for forecasted sales.

### 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 and operating expenditures for pollution control in 2015 were approximately \$5 million and \$23 million, respectively. Capital and operating expenditures for pollution control in 2016 are estimated to be approximately \$2 million and \$25 million, respectively.

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.

## 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 a number of anti-TNF and other products that are approved for a number of disease states and AbbVie's virology products compete with protease inhibitors and other anti-HIV treatments. 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.

**Biosimilars.** Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as "biosimilars." 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, potency, and in vitro characterization. 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 is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning will likely be subject to substantial uncertainty for years to come.

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.

## 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 three 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.

**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.

## Edgar Filing: AbbVie Inc. - Form 10-K

*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 recently 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.

In March 2010, Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (together, the Affordable Care Act). Under the Affordable Care Act, AbbVie pays a fee related to its pharmaceuticals sales to government programs. Also in 2011, AbbVie began providing a discount of 50 percent 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 starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 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 2016 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.

## Edgar Filing: AbbVie Inc. - Form 10-K

**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.

### Employees

AbbVie employed approximately 28,000 persons as of January 31, 2016. 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 three groups: risks related to AbbVie's business, risks related to AbbVie's separation from Abbott, 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 \$14.0 billion in 2015, is expected to expire 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 61 percent of AbbVie's total net revenues in 2015. 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 Biogen to develop a treatment for the relapsing remitting form of multiple sclerosis. It is also collaborating with Roche Holding AG to discover, develop, and commercialize a next-generation Bcl-2 inhibitor, ABT-199 (venetoclax), for patients with relapsed/refractory chronic lymphocytic leukemia.

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 may become subject to competition from biosimilars.***

The Biologics Price Competition and Innovation Act was passed on March 23, 2010 as Title VII to the Patient Protection and Affordable Care Act. The law created 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, Amgen has submitted a marketing authorization application to the European Medicines Agency for a biosimilar of HUMIRA and the United States FDA has accepted for review Amgen's application for a HUMIRA biosimilar. If 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 a number of anti-TNF products that are approved for a number of disease states and AbbVie's virology products compete with protease inhibitors and other anti-HIV treatments. 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, dyslipidemia, 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.

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 41 percent of AbbVie's total net revenues in 2015. The risks associated with AbbVie's operations outside the United States include:

fluctuations in currency exchange rates;

changes in medical reimbursement policies and programs;

## Edgar Filing: AbbVie Inc. - Form 10-K

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

## Edgar Filing: AbbVie Inc. - Form 10-K

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 2015, 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. 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, 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

## Edgar Filing: AbbVie Inc. - Form 10-K

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 percent 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 percent 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 percent 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 principal 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	Sligo, Ireland
Worcester, Massachusetts	

\*

Leased property.

In addition to the above, AbbVie has other manufacturing facilities in the United States and 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 four research and development facilities in the United States located at: Abbott Park, Illinois; North Chicago, Illinois; Redwood City, California; and Worcester, Massachusetts. Outside the United States, AbbVie's principal research and development facilities are located in Ludwigshafen, Germany.

Except as noted, the principal 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 entitled "Legal Proceedings and Contingencies" of the Notes to 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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Richard A. Gonzalez	62	Chairman of the Board and Chief Executive Officer
Carlos Alban	53	Executive Vice President, Commercial Operations
William J. Chase	48	Executive Vice President, Chief Financial Officer
Henry O. Gosebruch*	43	Executive Vice President and Chief Strategy Officer
Laura J. Schumacher	52	Executive Vice President, External Affairs, General Counsel and Corporate Secretary
Michael E. Severino, M.D.**	50	Executive Vice President, Research and Development, Chief Scientific Officer
Timothy J. Richmond	49	Senior Vice President, Human Resources
Azita Saleki-Gerhardt, Ph.D.	52	Senior Vice President, Operations
Thomas A. Hurwich	55	Vice President, Controller

\*  
First appointed as a corporate officer in December 2015.

\*\*  
First appointed as a corporate officer in June 2014.

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 (now Hospira, Inc.), 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

## Edgar Filing: AbbVie Inc. - Form 10-K

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, 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

	2015		2014	
	high	low	high	low
First Quarter	\$ 68.29	\$ 54.78	\$ 54.73	\$ 46.42
Second Quarter	\$ 70.75	\$ 56.33	\$ 56.90	\$ 45.50
Third Quarter	\$ 71.60	\$ 51.88	\$ 60.02	\$ 51.37
Fourth Quarter	\$ 64.30	\$ 45.45	\$ 70.76	\$ 52.06

## Stockholders

There were 53,653 stockholders of record of AbbVie common stock as of January 31, 2016.

## Dividends

Four quarterly dividends were paid on common stock in 2015 and 2014. The first quarter 2015 cash dividend of \$0.49 per share was payable February 13, 2015 and the second, third and fourth quarter 2015 dividends of \$0.51 per share were payable May 15, 2015, August 14, 2015 and November 16, 2015, respectively. The first quarter 2014 cash dividend of \$0.40 per share was payable February 14, 2014 and the second, third and fourth quarter 2014 dividends of \$0.42 per share were payable May 15, 2014, August 15, 2014 and November 17, 2014, respectively.

On October 30, 2015, AbbVie's board of directors declared an increase in the quarterly cash dividend from \$0.51 per share to \$0.57 per share, payable on February 16, 2016 to stockholders of record as of January 15, 2016. 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, 2015. 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.

## COMPARISON OF CUMULATIVE TOTAL RETURN

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 our filings under the Securities Act of 1933, as amended.

## Issuer Purchases of Equity Securities

<b>Period</b>	<b>(a) Total Number of Shares (or Units) Purchased</b>	<b>(b) Average Price Paid per Share (or Unit)</b>	<b>(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</b>	<b>(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs</b>
October 1, 2015 - October 31, 2015	1,949 <sup>(1)</sup>	\$ 38.02		\$ 3,450,133,355 <sup>(2)</sup>
November 1, 2015 - November 30, 2015	10,423,835 <sup>(1)</sup>	\$ 61.75	10,418,732	\$ 2,806,648,800 <sup>(2)</sup>
December 1, 2015 - December 31, 2015	15,129,432 <sup>(1)</sup>	\$ 58.26	15,088,646	\$ 1,927,160,135 <sup>(2)</sup>
<b>Total</b>	<b>25,555,216<sup>(1)</sup></b>	<b>\$ 59.68</b>	<b>25,507,378</b>	<b>\$ 1,927,160,135<sup>(2)</sup></b>



## Edgar Filing: AbbVie Inc. - Form 10-K

In addition to AbbVie shares repurchased on the open market under a publicly announced program, these shares include the following:

- (i) the shares deemed surrendered to AbbVie to pay the exercise price in connection with the exercise of employee stock options 1,949 in October; 5,103 in November; and 18,615 in December; and
- (ii) the shares purchased on the open market for the benefit of participants in the AbbVie Employee Stock Purchase Plan 0 in October; 0 in November; and 22,171 in December.

2.

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. 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.

**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, 2015, 2014 and 2013; and (ii) audited combined financial statements as of and for the years ended December 31, 2012 and 2011. 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)**

	2015	2014	2013	2012	2011
<b>Statement of earnings data</b>					
Net revenues	\$ 22,859	\$ 19,960	\$ 18,790	\$ 18,380	\$ 17,444
Net earnings <sup>(a)(b)</sup>	\$ 5,144	\$ 1,774	\$ 4,128	\$ 5,275	\$ 3,433
Basic earnings per share <sup>(a)(b)</sup>	\$ 3.15	\$ 1.11	\$ 2.58	\$ 3.35	\$ 2.18
Diluted earnings per share <sup>(a)(b)</sup>	\$ 3.13	\$ 1.10	\$ 2.56	\$ 3.35	\$ 2.18
Cash dividends declared per share	\$ 2.10	\$ 1.75	\$ 2.00 <sup>(c)</sup>	n/a	n/a
Weighted-average basic shares outstanding <sup>(d)</sup>	1,625	1,595	1,589	1,577	1,577
Weighted-average diluted shares outstanding <sup>(d)</sup>	1,637	1,610	1,604	1,577	1,577
<b>Balance sheet data</b>					
Total assets <sup>(e)</sup>	\$ 53,050	\$ 27,513	\$ 29,241	\$ 27,058	\$ 19,521
Long-term debt and lease obligations <sup>(e)(f)</sup>	\$ 31,265	\$ 14,552	\$ 14,353	\$ 14,702	\$ 48

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.

(b)

Results for 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 in November 2012, a higher tax rate and other incremental costs of operating as an independent company. Refer to "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 2015, 2014 and 2013.

## Edgar Filing: AbbVie Inc. - Form 10-K

- (c) AbbVie declared regular quarterly cash dividends in 2013 aggregating \$1.60 per share of common stock. In 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.
- (d) 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 based on the number of shares of AbbVie common stock outstanding on the distribution date. Refer to Note 4 to the audited consolidated financial statements included under Item 8, "Financial Statements and Supplementary Data" for information regarding the calculation of basic and diluted earnings per common share for 2015, 2014 and 2013.
- (e) On May 26, 2015, AbbVie acquired Pharmacyclics, Inc. 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 unsecured senior notes, of which approximately \$11.5 billion were used to finance the acquisition of Pharmacyclics Inc. and approximately \$5.0 billion were used to finance an accelerated share repurchase agreement. Refer to Notes 5, 9 and 12 to the audited consolidated financial statements included under Item 8, "Financial Statements and Supplementary Data" for information regarding the acquisition of Pharmacyclics, Inc., the senior notes and the accelerated share repurchase program, respectively.
- (f) Also includes current portion of 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, 2015 and 2014 and results of operations for each of the three years in the period ended December 31, 2015. 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; 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/liver disease, oncology, neurology, 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 28,000 employees. AbbVie operates in one business segment pharmaceutical products.

On May 26, 2015, AbbVie completed its acquisition of Pharmacyclics, Inc. (Pharmacyclics), a biopharmaceutical company that develops and commercializes novel therapies for people impacted by cancer, and its flagship asset IMBRUVICA® (ibrutinib), a novel, orally active, selective covalent inhibitor of Bruton's Tyrosine Kinase (BTK). As part of a worldwide collaboration and license agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical companies of Johnson & Johnson (Janssen), IMBRUVICA is approved for use in the United States, Canada, and the European Union (EU) as well as in other countries worldwide. In the United States, AbbVie co-markets IMBRUVICA for four indications approved by the U.S. Food and Drug Administration (FDA) prior to the acquisition date: (i) for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy; (ii) for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy; (iii) for the treatment of CLL patients with deletion of the short arm chromosome 17 (del 17p CLL); and (iv) for the treatment of patients with Waldenstrom's macroglobulinemia. In the EU, Janssen markets IMBRUVICA. At the date of the acquisition, IMBRUVICA was indicated in the EU for the treatment of adult patients with relapsed or refractory MCL, or adult patients with CLL who have received at least one prior therapy, or in first-line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemoimmunotherapy.

The acquisition will accelerate AbbVie's clinical and commercial presence in oncology, strengthen its pipeline, and establish a leadership position in hematological oncology. The acquisition will also accelerate AbbVie's revenue and earnings growth and further diversify its revenue base. AbbVie expects the acquisition to be accretive to earnings beginning in 2017. Refer to Note 5 entitled "Licensing, Acquisitions and Other Arrangements" of the Notes to Condensed Consolidated Financial Statements included under

Part II, Item 8, "Financial Statements and Supplementary Data" for further information regarding the acquisition of Pharmacyclics.

## 2015 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 2015, AbbVie's worldwide net revenues grew by 15 percent to \$22.9 billion, driven primarily by the continued strength of HUMIRA, both in the United States and internationally, the global launch of AbbVie's interferon-free HCV treatment, revenue growth in other key products including Creon and Duodopa, and post-acquisition revenues related to IMBRUVICA. These increases were partially offset by a decline in net revenues of AndroGel, principally due to continued market declines and the entry of generic competition for the AndroGel 1% formulation, as well as the continued decline of the company's lipid franchise, and the unfavorable impact of foreign exchange.

The company's financial performance in 2015 included delivering fully diluted earnings per share of \$3.13, including after-tax costs totaling \$410 million incurred in connection with the acquisition and integration of Pharmacyclics, a \$350 million after-tax charge for the purchase of a rare pediatric disease priority review voucher (PRV) from United Therapeutics Corporation, a \$100 million after-tax charge as a result of entering into an exclusive worldwide license agreement with C<sub>2</sub>N Diagnostics (C<sub>2</sub>N), after-tax foreign exchange losses of \$170 million as a result of the liquidation in 2015 of remaining foreign currency positions related to the terminated proposed combination with Shire plc (Shire) in 2014, after-tax charges of \$129 million to increase the company's litigation reserves, and an \$83 million after-tax charge due to the achievement of a development milestone under the global collaboration with Infinity Pharmaceuticals, Inc. (Infinity). Refer to Note 5 for further information regarding these items. AbbVie's financial performance in 2015 also reflected an improvement in gross margin to 80 percent of net revenues, primarily due to favorable product mix across the product portfolio, operating efficiencies, and the impact of foreign exchange rates. Financial results for 2015 also reflected continued funding in support of AbbVie's emerging mid-and late-stage pipeline assets, continued investment in AbbVie's growth brands, and the global launch of AbbVie's interferon-free HCV treatment, VIEKIRA PAK.

In 2015, the company generated cash flows from operations of \$7.5 billion. These cash flows enabled the company to pay cash dividends to shareholders of \$3.3 billion, repurchase approximately 46 million shares for \$2.8 billion in the open market (excluding the shares repurchased under an accelerated repurchase agreement), and continue to enhance its pipeline through licensing and collaboration activities including a \$500 million payment to Calico Life Sciences LLC (Calico) as a result of the satisfaction of certain conditions under the research and development (R&D) collaboration with Calico for which a charge to acquired in-process research and development (IPR&D) was recorded in 2014. In addition, AbbVie issued \$16.7 billion aggregate principal amount of senior notes the proceeds of which were used to finance the acquisition of Pharmacyclics and a \$5.0 billion accelerated share repurchase agreement (ASR) pursuant to which AbbVie paid \$5.0 billion for an aggregate 73 million shares of AbbVie's common stock. In October 2015, AbbVie's board of directors declared a quarterly cash dividend of \$0.57 per share of common stock payable in February 2016. This reflects an increase of approximately 12 percent over the previous quarterly rate of \$0.51 per share of common stock.

## 2016 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, IMBRUVICA and VIEKIRA PAK, as well as growth from pipeline products; (ii) expanding gross and operating margins; (iii) continued investment in its pipeline

## Edgar Filing: AbbVie Inc. - Form 10-K

in support of opportunities in immunology, oncology, and virology, 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 2016.

AbbVie expects to achieve its revenue growth objectives as follows:

HUMIRA sales growth by driving biologic penetration across disease categories, increasing market leadership, strong commercial execution and expansion to new indications for hidradenitis suppurativa (regulatory approval in the United States and EU achieved in 2015) and uveitis (regulatory submissions in the United States and the EU are under review with approval expected in 2016).

IMBRUVICA revenue growth driven by increasing market share within its four currently approved indications as well as indication expansion of IMBRUVICA as a first-line therapy for CLL (currently under priority review by the FDA). Revenues for 2016 will also benefit from a full year of IMBRUVICA revenue.

VIEKIRA PAK revenue growth driven by continued uptake across geographies, including Japan, the second largest HCV market globally, as well as indication expansion for a once-daily, fixed-dosed formulation of VIEKIRA PAK to treat genotype 1 (GT1) HCV (currently under review).

The favorable impact of pipeline products approved in 2015 or currently under regulatory review where approval is expected in 2016 including venetoclax, Empliciti (elotuzumab), and ZINBRYTA (daclizumab). These pipeline products are described in greater detail in the section labeled "Research and Development" included as part of this Item 7.

In 2016, AbbVie remains committed to driving continued expansion of gross and 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 at 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/liver disease, and neurology along with targeted investments in renal disease, 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 during 2016.

*Significant Clinical Programs Approved or Submitted*

AbbVie submitted for review or received approval for the following significant late-stage development programs:

*Immunology*

The FDA granted HUMIRA orphan drug designation for the treatment of moderate-to-severe hidradenitis suppurativa (HS), a painful, chronic inflammatory skin disease. AbbVie's supplemental Biological License Application (BLA) in the United States and its marketing authorization in the EU were approved by the FDA and the European Medicines Agency (EMA) in 2015, respectively. Approval for this indication represents the thirteenth indication for HUMIRA in major geographies around the world.

In April 2015 AbbVie announced that the European Commission (EC) granted marketing authorization for HUMIRA for the treatment of severe chronic plaque psoriasis in children and adolescence from four years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. With the EC decision, HUMIRA is now approved for use in this indication in all member states of the EU.

AbbVie submitted regulatory applications in the United States and the EU for the use of HUMIRA in the treatment of uveitis. AbbVie expects to receive regulatory approval in 2016.

*Oncology*

In July 2015, AbbVie announced that the EC granted marketing authorization for IMBRUVICA as the first treatment option specifically approved for treatment of adult patients with Waldenström's macroglobulinemia, a rare, slow growing blood cancer. Pharmacyclics received FDA approval for IMBRUVICA for patients with Waldenström's macroglobulinemia in January 2015. The EC approval triggered a \$20 million milestone payment from Janssen.

In September 2015, AbbVie announced that it submitted a Supplemental New Drug Application (sNDA) to the FDA for IMBRUVICA for treatment-naïve CLL patients. The sNDA is based on results from the Phase 3 RESONATE -2 study, which evaluated efficacy and safety of IMBRUVICA versus traditional chemotherapy, chlorambucil, in treatment-naïve CLL patients aged 65 years or older. The application has received a priority review.

In November 2015, AbbVie submitted a sNDA to the FDA for labeling considerations based on safety and efficacy results from the Phase 3 HELIOS trial investigating the use of IMBRUVICA, bendamustine, and rituximab, versus placebo plus bendamustine and rituximab, in patients with relapsed/refractory CLL or small lymphocytic lymphoma.

In February 2016, the FDA granted IMBRUVICA orphan drug designation for the treatment of patients with extranodal marginal zone lymphoma.

AbbVie submitted regulatory applications in the United States and the EU for venetoclax (ABT-199), an inhibitor of the B-cell lymphoma-2 (Bcl-2) protein developed in collaboration with Genentech and Roche Holding AG. Priority review status was granted by the FDA and validation provided by the EMA for these submissions. Venetoclax is also in Phase 3 development for patients with relapsed/refractory CLL. In addition, venetoclax was granted three Breakthrough Therapy Designations by the FDA: (i) for the treatment of CLL in previously treated (relapsed/refractory) patients with the 17p deletion mutation; (ii) in combination with rituximab for the treatment of patients with relapsed/refractory CLL, including patients with chromosome 17p deletion; and (iii) in combination with hypomethylating agents for the treatment of patients with untreated (treatment-naïve) acute

## Edgar Filing: AbbVie Inc. - Form 10-K

myeloid leukemia who are ineligible to receive standard induction therapy (high-dose chemotherapy).

Registration submissions were submitted to the FDA and the EC for Empliciti (elotuzumab), a Signaling Lymphocyte Activation Molecule (SLAMF7)-directed immunostimulatory antibody developed in partnership with Bristol-Myers Squibb (BMS) for first-line and relapsed/refractory multiple myeloma (MM). Subsequently, the EMA validated for review the marketing authorization application for Empliciti (elotuzumab) for the treatment of MM as combination therapy in adult patients who have received one or more prior therapies. The application was granted accelerated assessment by the EMA's Committee for Medicinal Products for Human Use (CHMP). In addition, the FDA approved Empliciti (elotuzumab) for the treatment of MM as a combination therapy in patients who have received one to three prior therapies. This is the first FDA approval for an immune-stimulatory antibody for MM in this indication. Empliciti will be marketed by BMS.

### *Virology/Liver Disease*

On January 16, 2015, AbbVie announced that the EC granted marketing authorizations for its all-oral, short-course, interferon-free treatment VIEKIRAX (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA (dasabuvir tablets). The treatment was approved with or without ribavirin (RBV) for patients with GT1 chronic HCV infection, including those with compensated liver cirrhosis, HIV-1 co-infection, patients on opioid substitution therapy and liver transplant recipients. Additionally, VIEKIRAX/EXVIERA was approved for use with RBV in genotype 4 (GT4) chronic HCV patients.

AbbVie's regulatory application in Japan for the company's all-oral, RBV and interferon-free, 12-week, two direct-acting antiviral treatment of ombitasvir/paritaprevir/ritonavir (OBV/PTV/r), dosed once daily, was approved in September 2015 for the treatment of patients with GT1 chronic HCV infection.

In July 2015, the FDA approved AbbVie's regulatory application for TECHNIVIE (OBV/PTV/r tablets) in combination with RBV for the treatment of adults with GT4 chronic HCV infection who do not have cirrhosis. TECHNIVIE is the first and only all-oral, interferon-free, direct-acting antiviral treatment approved in the United States for adult patients with GT4 chronic HCV infection.

AbbVie submitted a regulatory application in the United States for a once-daily, fixed-dosed formulation of VIEKIRA PAK to treat GT1 HCV. The proposed dosing for the fixed-dose formulation is three oral tablets, taken once daily with a meal, with or without RBV. AbbVie anticipates regulatory action on the new formulation in 2016.

The FDA accepted AbbVie's sNDA and granted priority review for VIEKIRA PAK without RBV in patients with genotype 1b (GT1b) chronic HCV infection and compensated cirrhosis (Child-Pugh A).

### *Neurology*

On January 12, 2015, AbbVie announced that the FDA approved Duopa (carbidopa and levodopa), an enteral suspension for the treatment of motor fluctuations for people with advanced Parkinson's disease. Duopa is administered using a small, portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally-placed tube. This product is sold under the name Duodopa outside the United States.

AbbVie is collaborating with Biogen to develop ZINBRYTA (daclizumab), an anti-CD25 monoclonal antibody, for the treatment of the relapsing/remitting form of multiple sclerosis (MS). In February 2015, the registration submission for ZINBRYTA was made in the United States followed by the EU submission in March 2015. In March, AbbVie and Biogen announced that the EMA had validated the companies' marketing authorization application for ZINBRYTA for the treatment of relapsing forms of MS in the EU. Validation confirms that the submission is complete and signifies the initiation of the



## Edgar Filing: AbbVie Inc. - Form 10-K

review process by the CHMP. In April 2015, AbbVie and Biogen announced that the FDA accepted for review the registration submission in the United States.

### *Other Significant Developments*

Transitions of significant programs from Phase 2 to Phase 3 development, as well as other significant developments, included the following:

#### *Immunology*

In January 2016, AbbVie announced the commencement of a Phase 3 clinical trial program to study the use of AbbVie's once-daily formulation of ABT-494, its internally developed investigational selective Janus Kinase 1 (JAK-1) inhibitor, for the treatment of rheumatoid arthritis. A Phase 2 trial of ABT-494 for the treatment of Crohn's disease is also ongoing.

In 2015, AbbVie received a decision by the EC regarding compliance with its pediatric investigation plan for HUMIRA, which ensures that necessary data are obtained through studies in children. As a result of this positive decision, the company is seeking an extension from each EU member state where a supplementary protection certificate is held. Once approved, this will extend the HUMIRA composition of matter patent in the EU by six months from April 2018 to October 2018.

#### *Oncology*

In July 2015, AbbVie initiated a Phase 3 study for the use of Veliparib (ABT-888), a PARP-inhibitor, for the treatment of ovarian cancer in combination with chemotherapy. Veliparib is also in Phase 3 development for various forms of breast and lung cancer.

AbbVie recently initiated its first Phase 3 clinical trial for IMBRUVICA in solid tumors. The trial will evaluate the safety and efficacy of IMBRUVICA in combination with gemcitabine and nab-paclitaxel for first-line treatment of patients with metastatic pancreatic adenocarcinoma.

#### *Virology/Liver Disease*

In October 2015, in consultation with the FDA, the product inserts in the United States for VIEKIRA PAK and TECHNIVIE were updated from "not recommended in Child-Pugh B patients" to a contraindication in patients with Child-Pugh B cirrhosis. Patients classified as Child-Pugh C remained contraindicated as they have been since approval.

In January 2016, AbbVie initiated a Phase 3 clinical trial program evaluating the safety and efficacy of its next-generation, all-oral, once-daily, pan-genotypic, RBV-free investigational HCV regimen, which includes ABT-493, a NS3/4A protease inhibitor, and ABT-530, an NS5A inhibitor.

#### *Other*

AbbVie is developing a novel oral gonadotropin-releasing hormone (GnRH) antagonist, Elagolix, under a collaboration with Neurocrine Biosciences (Neurocrine) for the treatment of endometriosis-related pain and uterine fibroids. 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 will make a milestone payment of \$15 million to Neurocrine upon enrollment of the first patient. Elagolix is in late-stage development for endometriosis.

In 2012, AbbVie entered into a collaboration with Galapagos NV (Galapagos) to develop filgotinib, an oral JAK1 inhibitor. In 2015, following a thorough review of available data, AbbVie announced that it will not exercise its right to in-license filgotinib from Galapagos. Pursuant to the terms of the global collaboration agreement with Galapagos, all rights to filgotinib reverted solely to Galapagos.



## Edgar Filing: AbbVie Inc. - Form 10-K

In 2015, AbbVie also augmented its pipeline through strategic licensing and partnering activities including in-licensing an anti-tau antibody (ABBV-8E12) for the treatment of Alzheimer's disease and other neurological disorders from C<sub>2</sub>N, a privately held protein diagnostic and therapeutic discovery company. Refer to Note 5 of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" for further information regarding the license agreement with C<sub>2</sub>N.

### 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 period. 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.

for the years ended (in millions)		2015	2014	2013	Percent change			
					At actual currency rates		At constant currency rates	
					2015	2014	2015	2014
United States	\$	13,561	\$ 10,845	\$ 10,181	25%	7%	25%	7%
International		9,298	9,115	8,609	2%	6%	18%	9%
Net revenues	\$	22,859	\$ 19,960	\$ 18,790	15%	6%	22%	8%

Edgar Filing: AbbVie Inc. - Form 10-K

The following table details AbbVie's worldwide net revenues:

years ended December 31 (in millions)	2015	2014	2013	Percent change			
				At actual currency rates		At constant currency rates	
	2015	2014	2013	2015	2014	2015	2014
<b>HUMIRA</b>							
United States	\$ 8,405	\$ 6,524	\$ 5,236	29%	25%	29%	25%
International	5,607	6,019	5,423	(7)%	11%	9%	13%
Total	\$ 14,012	\$ 12,543	\$ 10,659	12%	18%	19%	19%
<b>IMBRUVICA</b>							
United States	\$ 659	\$	\$	n/a	n/a	n/a	n/a
Collaboration revenues	95			n/a	n/a	n/a	n/a
Total	\$ 754	\$	\$	n/a	n/a	n/a	n/a
<b>VIEKIRA</b>							
United States	\$ 804	\$ 48	\$	n/m	100%	n/m	100%
International	835			n/a	n/a	n/a	n/a
Total	\$ 1,639	\$ 48	\$	n/m	100%	n/m	100%
<b>Creon</b>							
United States	\$ 632	\$ 516	\$ 412	22%	25%	22%	25%
<b>Synagis</b>							
International	\$ 740	\$ 835	\$ 827	(11)%	1%	1%	9%
<b>Lupron</b>							
United States	\$ 653	\$ 580	\$ 566	13%	3%	13%	3%
International	173	198	219	(13)%	(10)%	%	(5)%
Total	\$ 826	\$ 778	\$ 785	6%	(1)%	9%	%
<b>Synthroid</b>							
United States	\$ 755	\$ 709	\$ 622	6%	14%	6%	14%
<b>Kaletra</b>							
United States	\$ 163	\$ 213	\$ 244	(24)%	(13)%	(24)%	(13)%
International	537	657	718	(18)%	(9)%	(5)%	(5)%
Total	\$ 700	\$ 870	\$ 962	(20)%	(10)%	(10)%	(7)%
<b>AndroGel</b>							
United States	\$ 694	\$ 934	\$ 1,035	(26)%	(10)%	(26)%	(10)%
<b>Sevoflurane</b>							
United States	\$ 81	\$ 83	\$ 77	(3)%	7%	(3)%	7%
International	393	467	491	(16)%	(5)%	(4)%	(1)%
Total	\$ 474	\$ 550	\$ 568	(14)%	(3)%	(4)%	%

Edgar Filing: AbbVie Inc. - Form 10-K

<b>Duodopa</b>										
United States	\$	12	\$	\$	n/m	n/a	n/m	n/a		
International		219		220	178	(1)%	24%	18%	25%	
Total	\$	231	\$	220	\$	178	5%	24%	23%	25%
<b>Dyslipidemia products</b>										
United States	\$	179	\$	328	\$	1,076	(45)%	(70)%	(45)%	(70)%
All other	\$	1,223	\$	1,629	\$	1,666	(25)%	(2)%	(21)%	(1)%
Total net revenues	\$	22,859	\$	19,960	\$	18,790	15%	6%	22%	8%

n/m Not meaningful.

n/a Not applicable.

## Edgar Filing: AbbVie Inc. - Form 10-K

The following discussion and analysis of AbbVie's net revenues by product is presented on a constant currency basis.

Global HUMIRA sales increased 19 percent in both 2015 and 2014, 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 29 percent in 2015 and 25 percent in 2014, driven by prescription volume, favorable pricing, and market growth across all indications. Internationally, HUMIRA revenues increased 9 percent in 2015 and 13 percent in 2014, driven primarily by growth across indications in certain geographies. AbbVie continues to pursue several new indications 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 as well as collaboration revenues related to AbbVie's 50 percent share of IMBRUVICA profit outside of the United States following the completion of the acquisition of Pharmacyclics on May 26, 2015. AbbVie expects IMBRUVICA will be a significant contributor to revenue growth in 2016.

AbbVie launched its HCV regimen, VIEKIRA PAK, in the United States following FDA approval in mid-December 2014 and launched VIEKIRAX/EXVIERA in the EU in January 2015. In addition to growth in approved markets, international revenues continued to increase during 2015 as the product was approved in additional geographies. Net revenues of VIEKIRA PAK in 2014 reflect the shipment of launch quantities into the market to support full commercial launch in 2015.

Net revenues for Creon increased 22 percent in 2015 and 25 percent in 2014, driven primarily by continued market growth and higher market share. Creon maintains market leadership in the pancreatic enzyme market.

Synagis is a seasonal product with the majority of sales occurring in the first and fourth quarters. Net revenues increased 1 percent in 2015 and 9 percent in 2014. Revenues in 2015 reflected changes in demand in certain markets, as well as an unfavorable comparison to 2014 driven by a less severe respiratory syncytial virus season.

Global Lupron net revenues increased 9 percent in 2015 primarily due to increased demand and favorable pricing in the United States. Lupron continues to hold a leadership position and maintains significant share of the market.

Global Kaletra net revenues declined 10 percent in 2015 and 7 percent in 2014 primarily due to lower market share resulting from the impact of increasing competition in the HIV marketplace.

AndroGel net revenues declined 26 percent in 2015 and 10 percent in 2014, primarily due to a continued decline in the overall U.S. testosterone replacement market and the entry of generic competition for the AndroGel 1% formulation in January 2015. The company expects the U.S. testosterone replacement market will continue to decline in 2016.

Net revenues for Duodopa, AbbVie's therapy for advanced Parkinson's disease approved in Europe and other international markets, grew 23 percent in 2015. AbbVie's regulatory submission for Duopa in the United States was approved by the FDA in January 2015. AbbVie expects net revenues for Duopa in the United States will continue to gradually increase during 2016 as the product gains acceptance in the marketplace.

Net revenues for AbbVie's consolidated lipid franchise, which included TriCor, Trilipix, Niaspan, Simcor and Advicor, declined 45 percent in 2015 and 70 percent in 2014 due to the introduction of generic versions of these products in the U.S. market. Generic competition began in November 2012 for TriCor, July 2013 for Trilipix, and September 2013 for Niaspan. AbbVie has voluntarily withdrawn Simcor and Advicor from the market and discontinued distribution as of December 31, 2015.

## Edgar Filing: AbbVie Inc. - Form 10-K

All other net revenues declined 21 percent in 2015 primarily due to reduced demand driven by market and share declines and a reduction in price for several of AbbVie's mature on-market products.

### Gross Margin

years ended December 31 (in millions)	2015	2014	2013	Percent change	
				2015	2014
Gross margin	\$ 18,359	\$ 15,534	\$ 14,209	18%	9%
as a percent of net revenues	80%	78%	76%		

The gross margin for 2015, 2014 and 2013 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 includes milestone revenue of \$40 million from a collaboration partner related the company's oncology program. Gross margin in 2014 also includes 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)	2015	2014	2013	Percent change	
				2015	2014
Selling, general and administrative	\$ 6,387	\$ 7,724	\$ 5,352	(17)%	44%
as a percent of net revenues	28%	39%	28%		

Selling, general and administrative (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, as further discussed in Note 5 of the Notes to Consolidated Financial Statements. 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. Refer to Note 13 for further information.

Excluding these items, SG&A expenses increased in both 2015 and 2014, reflecting increased selling and marketing support for new products, including the global launch of VIEKIRA, as well as spending relating to new indications and geographic expansion for HUMIRA and other growth brands. SG&A expenses in 2015 also included Pharmacyclics acquisition and integration costs of \$294 million, charges aggregating \$165 million to increase the company's litigation reserves and restructuring charges of \$39 million. These increased costs were partially offset by the impact of favorable foreign exchange rates in 2015.

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

years ended December 31 (in millions)	2015	2014	2013	Percent change	
				2015	2014
Research and development	\$ 4,285	\$ 3,297	\$ 2,855	30%	15%
as a percent of net revenues	19%	17%	15%		
Acquired in-process research and development	\$ 150	\$ 352	\$ 338	(57)%	4%

R&D expenses for 2015 included Pharmacyclics acquisition and integration costs of \$152 million, a \$350 million charge related to the purchase of a priority review voucher from a third party, a \$130 million

## Edgar Filing: AbbVie Inc. - Form 10-K

charge recorded due to the achievement of a development milestone under the collaboration with Infinity, the post-acquisition R&D expenses of Pharmacyclics, and restructuring charges of \$32 million. R&D expenses in 2014 and 2013 included regulatory milestone payments of \$40 million made to a collaboration partner for regulatory milestones related to the company's HCV program and restructuring charges of \$15 million, respectively.

R&D expenses in 2015 and 2014 otherwise reflected added funding to support the company's emerging mid- and late-stage pipeline assets and the continued pursuit of additional HUMIRA indications. These increases were partially offset by the impact of favorable foreign exchange rates in 2015 and 2014.

IPR&D expenses 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. IPR&D expenses 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. IPR&D expense in 2013 included a charge of \$175 million as a result of entering into a global license agreement with Ablynx NV to develop and commercialize ALX-0061, a charge of \$70 million as a result of entering into a global collaboration with Alvine Pharmaceuticals, Inc. to develop ALV003, a charge of \$45 million as a result of entering into a global collaboration with Galapagos for cystic fibrosis therapies, and charges totaling \$48 million as a result of entering into several other arrangements. Refer to Note 5 of the Notes to Consolidated Financial Statements for additional information related to the company's collaborations and other arrangements.

### 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

Interest expense, net was \$686 million in 2015, \$391 million in 2014, and \$278 million in 2013 and was comprised primarily of interest expense on outstanding debt. Interest expense, net in 2015 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 an accelerated share repurchase program. Interest expense, net in 2015 also included \$86 million of bridge financing related fees incurred in connection with the acquisition of Pharmacyclics. Interest expense, net in 2014 included \$141 million of financing related fees incurred in connection with 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 for 2014 included losses of \$666 million associated with the Shire-related forward contracts. Net foreign exchange loss for 2015 included losses totaling \$170 million to reflect the completed liquidation of the company's remaining foreign currency positions related to the terminated proposed combination with Shire.

Other non-operating expense, net for 2015 included impairment charges totaling \$36 million related to certain of the company's equity investment securities. Other non-operating income, 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 23 percent in 2015, 25 percent in 2014, and 23 percent in 2013. The effective tax rate fluctuates from year to year due to the allocation of the company's taxable earnings among jurisdictions, as well as certain discrete factors and events in each year, including acquisitions and



collaborations. 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.

## FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

years ended December 31 (in millions)	2015	2014	2013
Cash flows provided by/(used in):			
Operating activities	\$ 7,535	\$ 3,549	\$ 6,267
Investing activities	\$ (12,936)	\$ (926)	\$ 879
Financing activities	\$ 5,752	\$ (3,293)	\$ (3,442)

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.

Cash provided by operating activities also reflected AbbVie's voluntary contributions to its main domestic defined benefit plan of \$150 million and \$370 million in 2015 and 2014, respectively. AbbVie also made a voluntary contribution of \$150 million to this plan subsequent to December 31, 2015. AbbVie also paid \$350 million to purchase a priority review voucher from United Therapeutics Corporation in 2015. Realized excess tax benefits associated with stock-based compensation in 2015, 2014 and 2013 totaled \$61 million, \$56 million, and \$38 million, respectively, 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 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 that was accrued in 2014 due to the satisfaction of certain conditions under the R&D collaboration, \$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. In 2014, cash outflows related to other acquisitions and investments totaled \$622 million, including \$275 million paid to Infinity related to a global collaboration to develop duvelisib (IPI-145), and \$250 million to fund a novel R&D collaboration with Calico. Cash flows from investing activities in 2015 and 2014 also reflected capital expenditures and net sales (purchases) of short-term investments. Capital expenditures in 2014 included the purchase of a small molecule active pharmaceutical ingredient manufacturing facility in Singapore. AbbVie incurred additional expenditures in 2015 to build a new biologics facility on the site to produce bulk drug substance for HUMIRA as well as to support AbbVie's biologic pipeline.

In 2015 and 2014, the company issued and redeemed commercial paper. The balance of commercial paper outstanding was \$400 million and \$416 million at December 31, 2015 and 2014, respectively. AbbVie may issue additional commercial paper or retire commercial paper to meet liquidity requirements as needed. In May 2015, the company issued \$16.7 billion aggregate principal amount of senior notes with various maturities between 2018 and 2045. 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 the accelerated share repurchase program described below. In September 2015, AbbVie entered into a three-year \$2 billion term loan credit facility and a 364-day \$2 billion term loan credit facility. In November

## Edgar Filing: AbbVie Inc. - Form 10-K

2015, AbbVie drew on these term facilities and used the proceeds to refinance its \$4 billion of senior notes that matured in 2015. During 2015 in connection with the acquisition of Pharmacyclics, the company paid \$86 million of costs relating to an \$18 billion, 364-Day Bridge Term Loan Credit Agreement as well as \$93 million of costs relating to the issuance of senior notes.

Cash dividend payments totaled \$3.3 billion in 2015 and \$2.7 billion in 2014. On October 30, 2015, AbbVie announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.51 per share to \$0.57 per share beginning with the dividend payable on February 16, 2016 to stockholders of record as of January 15, 2016. 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 October 2014, AbbVie's board of directors authorized a \$5.0 billion stock repurchase program. In March 2015, the board of directors authorized a \$5.0 billion increase to the existing stock repurchase program in anticipation of executing an accelerated share repurchase agreement with a financial institution in connection with the acquisition of Pharmacyclics. On May 26, 2015, AbbVie entered into and executed a \$5.0 billion ASR with Morgan Stanley & Co. LLC (Morgan Stanley). Pursuant to the terms of the ASR, Morgan Stanley made an initial delivery of approximately 68 million shares of AbbVie's common stock on May 27, 2015, which represented approximately 90 percent of the total shares expected to be delivered under the ASR. Subsequently in 2015, Morgan Stanley delivered an additional 5 million shares of AbbVie's common stock to AbbVie in final settlement of the ASR. AbbVie recorded the aggregate \$5.0 billion purchase price as a reduction to stockholders' equity.

In addition to the ASR, the company repurchased approximately 46 million shares for \$2.8 billion in the open market in 2015 and approximately 9 million shares for \$550 million in the open market in 2014. AbbVie settled \$300 million of its 2015 open market purchases in 2016. 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 \$1.9 billion as of December 31, 2015. Refer to Note 12 for additional information related to the ASR.

Cash and equivalents in 2015 and 2014 were also negatively impacted by net unfavorable exchange rate changes totaling \$300 million and \$577 million, respectively, 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. In 2014, AbbVie had an increased concentration of cash denominated in foreign currencies accumulated in anticipation of the terminated proposed combination with Shire. While a significant portion of cash and equivalents at December 31, 2015 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, 2015 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 material amount of total outstanding receivables.

AbbVie continues to do business with foreign governments in certain countries, including Greece, Portugal, Italy, and Spain, that have experienced a deterioration in credit and economic conditions. Substantially all of AbbVie's trade receivables in Greece, Portugal, Italy, and Spain are with governmental health systems. AbbVie continues to monitor the economic health of the economy in Southern Europe, as heightened economic concerns still exist. Outstanding net governmental receivables in these countries at December 31, 2015 and 2014 were as follows:

(in millions)	Net receivables		Net receivables over one year past due	
	2015	2014	2015	2014
Greece	\$ 53	\$ 30	\$	\$
Portugal	27	27	3	7
Italy	211	176	4	16
Spain	234	213		10
Total	\$ 525	\$ 446	\$ 7	\$ 33

The company also continues to do business with foreign governments in certain oil-exporting countries, which have experienced a deterioration in economic conditions, including Venezuela and Saudi Arabia. Outstanding net governmental receivables related to Saudi Arabia were \$108 million as of December 31, 2015. Refer to Item 7A, "Quantitative and Qualitative Disclosures About Market Risk Foreign Currency Risk" for additional disclosures related to Venezuela. Due to the decline in the price of oil, 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 re-evaluate the collectability of its receivables and the company could potentially incur credit losses.

Currently, AbbVie does not believe the economic conditions in Southern Europe and oil-exporting countries will have a material 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, 2015.

### 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, 2015, the company was in compliance with all its credit facility covenants. Commitment fees under the credit facility were not material. There were no amounts outstanding under the credit facility as of December 31, 2015 and 2014.

#### *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

## Edgar Filing: AbbVie Inc. - Form 10-K

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 7, 2015, following the announcement of the then proposed combination with Pharmacyclics, Moody's Investor Service confirmed its Baa1 senior unsecured long-term rating and Prime-2 short-term rating and revised its ratings outlook to "negative" from "stable". On March 5, 2015, Standard & Poor's Rating Services (S&P) affirmed AbbVie's "A" corporate credit rating and senior unsecured debt rating and its "A-1" commercial paper rating and revised its ratings outlook to "negative" from "stable". There were no additional changes in the company's credit ratings in 2015.

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, 2015:

<b>(in millions)</b>	<b>Total</b>	<b>Less than one year</b>	<b>One to three years</b>	<b>Three to five years</b>	<b>More than five years</b>
Short-term borrowings	\$ 406	\$ 406	\$	\$	\$
Long-term debt and capital lease obligations, including current portion	31,539	2,025	10,049	3,778	15,687
Interest on long-term debt <sup>(a)</sup>	12,423	866	1,810	1,574	8,173
Future minimum non-cancelable operating lease commitments	1,010	119	208	164	519
Purchase obligations and other <sup>(b)</sup>	1,423	1,293	86	24	20
Other long-term liabilities <sup>(c)</sup>	880	240	171	77	392
<b>Total</b>	<b>\$ 47,681</b>	<b>\$ 4,949</b>	<b>\$ 12,324</b>	<b>\$ 5,617</b>	<b>\$ 24,791</b>

- (a) Includes estimated future interest payments on long-term debt securities and capital lease obligations. Interest payments on debt are calculated for future periods using interest rates in effect at the end of 2015. 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, 2015. Refer to Notes 9 and 10 for further discussion regarding the company's debt instruments and related interest rate agreements outstanding at December 31, 2015. Annual interest on capital lease obligations is not material.
- (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.
- (c) 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, 2015. Amounts otherwise exclude pension and other post-employment benefits and related deferred compensation cash outflows. Timing of funding is uncertain and 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. Refer to Notes 8 and 11 for further information.

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 not material 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. Refer to Note 5 to the consolidated financial statements for further discussion of 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 \$8.6 billion, \$5.9 billion and \$4.9 billion in 2015, 2014 and 2013, respectively. 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 records adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the reserve is appropriate. Historically, adjustments to rebate accruals have not been material to net earnings.

The following table is an analysis of the three largest rebate accruals and chargeback allowances, which comprise approximately 90 percent of the total consolidated rebate and chargebacks charged against

## Edgar Filing: AbbVie Inc. - Form 10-K

revenues in 2015. Remaining rebate provisions charged against gross revenues are not significant in the determination of operating earnings.

(in millions)	<b>Medicaid and Medicare Rebates</b>	<b>Managed Care Rebates</b>	<b>Wholesaler Chargebacks</b>
Balance at December 31, 2012	\$ 807	\$ 496	\$ 224
Provisions	1,028	846	2,362
Payments	(1,168)	(883)	(2,374)
Balance at December 31, 2013	667	459	212
Provisions	1,015	970	2,825
Payments	(970)	(953)	(2,784)
Balance at December 31, 2014	712	476	253
Provisions	1,716	2,215	3,866
Payments	(1,396)	(1,771)	(3,756)
Balance at December 31, 2015	\$ 1,032	\$ 920	\$ 363

### *Cash Discounts and Product Returns*

Allowances for cash discounts and product returns, which totaled \$898 million, \$610 million and \$748 million in 2015, 2014 and 2013, respectively, are recorded as a reduction to revenue in the same period the related product is sold. The reserve for cash discounts is readily determinable because the company's experience of payment history is fairly consistent. Product returns can be reliably estimated based on the company's historical return experience.

### **Pension and Other Post-Employment Benefits**

AbbVie engages outside actuaries to assist in the determination of the obligations and costs under the plans that are direct obligations of AbbVie. The valuation of the funded status and the net periodic benefit cost for these plans are calculated using actuarial assumptions. The significant assumptions, which are reviewed annually, include the discount rate, the expected long-term rate of return on plan assets, and the health care cost trend rates. The significant assumptions used in determining these calculations are disclosed in Note 11 to the consolidated financial statements.

The discount rate is selected based on current market rates on high-quality, fixed-income investments at December 31 each year. AbbVie employs a yield-curve approach for countries where a robust bond market exists. The yield curve is developed using high-quality bonds. The yield curve approach reflects the plans' specific cash flows (i.e., duration) in calculating the benefit obligations by applying the specific spot rates along the yield curve. Beginning in 2016, AbbVie will also reflect the plans' specific cash flows and apply them to the specific spot rates along the yield curve in calculating the service cost and interest cost portions of expense. For other countries, AbbVie reviews various indices such as corporate bond and government bond benchmarks to estimate the discount rate. AbbVie's assumed discount rate has a significant effect on the amounts reported for defined benefit pension and other post-employment plans as of December 31, 2015, and will be used in the calculation of net periodic benefit cost in 2016. A 50 basis

## Edgar Filing: AbbVie Inc. - Form 10-K

point change in the assumed discount rate would have had the following effects on AbbVie's calculation of net periodic benefit costs in 2016 and projected benefit obligations as of December 31, 2015:

<b>(in millions) (brackets denote a reduction)</b>	<b>50 basis point</b>	
	<b>Increase</b>	<b>Decrease</b>
<b>Defined benefit plans</b>		
Service cost and interest cost	\$ (45)	\$ 51
Projected benefit obligation	\$ (409)	\$ 461
<b>Other post-employment plans</b>		
Service cost and interest cost	\$ (5)	\$ 6
Projected benefit obligation	\$ (46)	\$ 52

Effective December 31, 2015, AbbVie elected to change the method it uses to estimate the service and interest cost components of net periodic benefit costs for the AbbVie Pension Plan and its primary other post-employment benefit plan in the United States as well as certain international defined benefit plans and other post-employment benefit plans. Based on current economic conditions, this change is expected to reduce AbbVie's net periodic benefit cost by approximately \$41 million in 2016 as a result of this change. Refer to Note 11 for further information regarding this change.

The expected long-term rate of return is based on the asset allocation, historical performance, and the current view of expected future returns. AbbVie considers these inputs with a long-term focus to avoid short-term market influences. The current long-term rate of return on plan assets is supported by the historical performance of the trust's actual and target asset allocation. AbbVie's assumed expected long-term rate of return has a significant effect on the amounts reported for defined benefit pension plans as of December 31, 2015 and will be used in the calculation of net periodic benefit cost in 2016. A 1 percentage point change in assumed expected long-term rate of return on plan assets would have increased or decreased the net period benefit cost of these plans in 2016 by \$45 million.

The health care cost trend rate is selected by reviewing historical trends and current views on projected future health care cost increases. The current health care cost trend rate is supported by the historical trend experience of the plan. Assumed health care cost trend rates have a significant effect on the amounts reported for health care plans as of December 31, 2015 and will be used in the calculation of net periodic benefit cost in 2016. A 1 percentage point change in assumed health care cost trend rates would have the following effects on AbbVie's calculation of net periodic benefit costs in 2016 and the projected benefit obligation as of December 31, 2015:

<b>(in millions) (brackets denote a reduction)</b>	<b>One percentage point</b>	
	<b>Increase</b>	<b>Decrease</b>
Service cost and interest cost	\$ 20	\$ (15)
Projected benefit obligation	\$ 114	\$ (90)

### Income Taxes

AbbVie accounts for income taxes under the asset and liability method. Provisions for federal, state, and foreign income taxes are calculated on reported pretax earnings based on current tax laws. Deferred taxes are provided using enacted tax rates on the future tax consequences of temporary differences, which are the differences between the financial statement carrying amount of assets and liabilities and their respective tax bases and the tax benefits of carryforwards. A valuation allowance is established or maintained when, based on currently available information, it is more likely than not that all or a portion of a deferred tax asset will not be realized.



## Litigation

The company is subject to contingencies, such as various claims, legal proceedings and investigations regarding product liability, intellectual property, commercial, securities and other matters that arise in the normal course of business. Refer to Note 14 for further information. Loss contingency provisions are recorded for probable losses at management's best estimate of a loss, or when a best estimate cannot be made, a minimum loss contingency amount within a probable range is recorded. Accordingly, AbbVie is often initially unable to develop a best estimate of loss, and therefore the minimum amount, which could be zero, is recorded. As information becomes known, either the minimum loss amount is increased, resulting in additional loss provisions, or a best estimate can be made, also resulting in additional loss provisions. Occasionally, a best estimate amount is changed to a lower amount when events result in an expectation of a more favorable outcome than previously expected.

## Valuation of Goodwill and Intangible Assets

AbbVie has acquired and may continue to acquire significant intangible assets in connection with business combinations that AbbVie records at fair value. Transactions involving the purchase or sale of intangible assets occur with some frequency between companies in the pharmaceuticals industry, and valuations are usually based on a discounted cash flow analysis incorporating the stage of completion. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, risk, cost of capital, terminal values, and market participants. Each of these factors can significantly affect the value of the intangible asset. IPR&D acquired in a business combination is capitalized as an indefinite-lived intangible asset until regulatory approval is obtained, at which time it is accounted for as a definite-lived asset and amortized over its estimated useful life. IPR&D acquired in transactions that are not business combinations is expensed immediately, unless deemed to have an alternative future use. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life.

AbbVie reviews the recoverability of definite-lived intangible assets whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Goodwill and indefinite-lived intangible assets, which relate to IPR&D, are reviewed for impairment annually or when an event occurs that could result in an impairment. Refer to Note 2 to the consolidated financial statements for further information.

Annually, the company tests its goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. Some of the factors considered in the assessment include general macro-economic conditions, conditions specific to the industry and market, cost factors, which could have a significant effect on earnings or cash flows, the overall financial performance, and whether there have been sustained declines in the company's share price. If the company concludes it is more likely than not that the fair value of reporting unit is less than its carrying amount, a quantitative impairment test is performed. AbbVie tests indefinite-lived intangible assets using a quantitative impairment test.

For its quantitative impairment tests, the company uses an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, foreign currency exchange rates, the selection of an appropriate discount rate, asset groupings, and other assumptions and estimates. The estimates and assumptions used are consistent with the company's business plans and a market participant's views of a company and similar companies. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the assets, and potentially result in different impacts to the company's results of operations. Actual results may differ from the company's estimates.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40)*. The amendments in ASU 2014-09 supersede most current revenue recognition requirements. The core principle of the new guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. AbbVie can apply the amendments using one of the following two methods: (i) retrospectively to each prior reporting period presented, or (ii) modified retrospectively with the cumulative effect of initially applying the amendments recognized at the date of initial application. In July 2015, the FASB issued ASU No. 2015-4, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which deferred the effective date of ASU 2014-09 by one year for all entities. Accordingly, ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is permitted only for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. AbbVie is currently assessing the timing of its adoption and the impact of adopting this guidance on its consolidated financial statements and the implementation approach to be used.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This standard is effective for annual and interim periods beginning after December 15, 2015, with early adoption permitted on a retrospective basis. AbbVie elected to early adopt this new standard, effective in the three months ended June 30, 2015. As a result, AbbVie reclassified approximately \$7 million and \$27 million of net deferred financing costs as of December 31, 2014 that were previously classified as prepaid expenses and other current assets and other long-term assets, respectively, to long-term debt and lease obligations (current and non-current). Total debt issuance costs classified as a reduction of long-term debt and lease obligations (current and non-current) were \$117 million as of December 31, 2015.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*. This standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. Entities are currently required to retrospectively apply adjustments made to provisional amounts recognized in a business combination. This standard is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The guidance is to be applied prospectively to measurement period adjustments that occur after the effective date of the guidance with earlier application permitted for financial statements that have not been issued. AbbVie elected to early adopt the standard, effective in the year ended December 31, 2015. The impact of this adoption was not material.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The standard requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. Entities are currently required to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. The amendments, which require non-current presentation only (by jurisdiction), are effective for financial statements issued for annual periods beginning after December 15, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The guidance is to be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. AbbVie elected to early adopt this standard on a prospective basis, effective as of December 31, 2015 in order to simplify the presentation of deferred tax assets and liabilities. Prior periods were not retrospectively adjusted.

## Edgar Filing: AbbVie Inc. - Form 10-K

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The standard requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net income. The new guidance also changes certain disclosure requirements and other aspects of current US GAAP. Amendments are to be applied as a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. This standard is effective for fiscal years starting after December 15, 2017, including interim periods within those fiscal years. The standard does not permit early adoption with the exception of certain targeted provisions. AbbVie is currently assessing the impact and timing of adopting this guidance on its consolidated financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The company is exposed to risk that its earnings, cash flows, and equity could be adversely impacted by changes in foreign exchange rates and interest rates. Certain derivative instruments are used when available on a cost-effective basis to hedge the company's underlying economic exposures. Refer to Note 10 entitled "Financial Instruments and Fair Value Measures" of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" for further information regarding the company's financial instruments and hedging strategies.

**Foreign Currency Risk**

AbbVie's primary net foreign currency exposures are the Euro, Japanese yen and British pound. Various AbbVie foreign subsidiaries enter into foreign currency forward exchange contracts to manage exposures to changes in foreign exchange rates for anticipated transactions denominated in a currency other than the functional currency of the local entity. These contracts are designated as cash flow hedges of the variability of the cash flows due to changes in foreign currency exchange rates, and are marked-to-market with the resulting gains or losses reflected in accumulated other comprehensive income (loss) in AbbVie's consolidated balance sheets. Deferred gains or losses on these contracts are included in cost of products sold at the time the products are sold to a third party, generally not exceeding twelve months. At December 31, 2015 and 2014, AbbVie held \$1.5 billion and \$1.4 billion, respectively, in notional amounts of such contracts.

AbbVie enters into foreign currency forward exchange contracts to manage its exposure to foreign currency denominated trade payables and receivables and intercompany loans. The contracts, which are not designated as hedges, are marked-to-market, and resulting gains or losses are reflected in net foreign exchange on AbbVie's consolidated statements of earnings and are generally offset by losses or gains on the foreign currency exposure being managed. At December 31, 2015 and 2014, AbbVie held notional amounts of \$6.8 billion and \$6.8 billion, respectively, of such foreign currency forward exchange contracts.

The following table reflects the total foreign currency forward contracts outstanding at December 31, 2015 and 2014:

(in millions)	2015			2014		
	Contract amount	Weighted average exchange rate	Fair and carrying value receivable/(payable)	Contract amount	Weighted average exchange rate	Fair and carrying value receivable/(payable)
Receive primarily U.S. dollars in exchange for the following currencies:						
Euro	\$ 5,880	1.103	\$ 34	\$ 6,342	1.263	\$ 114
Japanese yen	853	120.9	(2)	333	116.9	6
British pound	163	1.496	1	563	1.618	21
All other currencies	1,387	N/A	8	930	N/A	7
Total	\$ 8,283		\$ 41	\$ 8,168		\$ 148

The company estimates that a 10 percent appreciation in the underlying currencies being hedged from their levels against the U.S. dollar, with all other variables held constant, would decrease the fair value of foreign exchange forward contracts by \$822 million at December 31, 2015. If realized, this appreciation would negatively affect earnings over the remaining life of the contracts, which would be offset by gains on the underlying hedged items. A 10 percent appreciation is believed to be a reasonably possible near-term change in foreign currencies. Gains and losses on the hedging instruments offset losses and gains on the hedged transactions and reduce the earnings and stockholders' equity volatility relating to foreign exchange.

## Edgar Filing: AbbVie Inc. - Form 10-K

The functional currency of the company's Venezuela operations is the U.S. dollar due to the hyperinflationary status of the Venezuelan economy. Currency restrictions enacted in Venezuela require approval from the Venezuelan government to exchange Venezuelan bolivars (VEF) for U.S. dollars and require such exchange to be made at the official exchange rate established by the government. In the first quarter of 2014, the Venezuelan government expanded the number of exchange mechanisms to three rates of exchange. As of December 31, 2015, these were the official rate of 6.3; the Supplementary System for the Administration of Foreign Currency (SICAD) rate of approximately 13.5; and the Foreign Exchange Marginal System (SIMADI) rate of approximately 200. In the consolidated financial statements as of and for the year ended December 31, 2015, the company used the official rate of 6.3 VEF per U.S. dollar, and reported \$317 million of net monetary assets and \$210 million of net revenues denominated in the Venezuelan bolivar.

On February 17, 2016, the Venezuelan government announced that it plans to devalue the official rate of 6.3 to 10 VEF to U.S. dollars, and eliminate the SICAD rate of 13.5 VEF to U.S. dollars. The devaluation of the Venezuelan bolivar will result in a charge to AbbVie's results of operations in the first quarter of 2016. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at a rate of 10 VEF to U.S. dollars at December 31, 2015, the company would have reported a devaluation loss of \$117 million in 2015. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at the SIMADI rate of 200 at December 31, 2015, the company would have reported a devaluation loss of \$307 million in 2015.

The company cannot predict whether there will be further devaluations of the Venezuelan currency or whether the use of the official rate will continue to be supported by evolving facts and circumstances, which could result in a significant charge to AbbVie's results of operations at that time.

### Interest Rate Risk

Interest rate swaps are used to manage the company's exposure of changes in interest rates on the fair value of fixed-rate debt. The effect of these hedges is to change the fixed interest rate to a variable rate. At December 31, 2015 and 2014, AbbVie had interest rate hedge contracts totaling \$11.0 billion and \$8.0 billion, respectively. The company estimates that an increase in the interest rates of 100-basis points would decrease the fair value of our interest rate swap contracts by approximately \$464 million at December 31, 2015. If realized, the fair value reduction would affect earnings over the remaining life of the contracts. The company estimates that an increase of 100-basis points in long-term interest rates would decrease the fair value of long-term debt by \$1.9 billion at December 31, 2015. A 100-basis point change is believed to be a reasonably possible near-term change in interest rates.

### Market Price Sensitive Investments

AbbVie holds equity securities in other pharmaceutical and biotechnology companies that are traded on public stock exchanges. The fair value of these investments was approximately \$111 million and \$82 million as of December 31, 2015 and 2014, respectively. AbbVie monitors these investments for other than temporary declines in market value, and charges impairment losses to net earnings when an other than temporary decline in value occurs. A hypothetical 20 percent decrease in the share prices of these investments would decrease the fair value of these investments by \$22 million at December 31, 2015. A 20 percent decrease is believed to be a reasonably possible near-term change in share prices.

### Non-Publicly Traded Equity Securities

AbbVie holds equity securities in other pharmaceutical and biotechnology companies that are not traded on public stock exchanges. The carrying value of these investments was approximately \$33 million and \$63 million as of December 31, 2015 and 2014, respectively. AbbVie monitors these investments for other than temporary declines in market value, and charges impairment losses to net earnings when an other than temporary decline in estimated value occurs. In 2015, AbbVie recorded impairment charges totaling \$36 million related to certain of the company's investments in non-publicly traded equity securities.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

	<b>Page</b>
<b>Consolidated Financial Statements</b>	
<u>Consolidated Statements of Earnings</u>	<u>56</u>
<u>Consolidated Statements of Comprehensive Income</u>	<u>57</u>
<u>Consolidated Balance Sheets</u>	<u>58</u>
<u>Consolidated Statements of Equity</u>	<u>59</u>
<u>Consolidated Statements of Cash Flows</u>	<u>60</u>
<u>Notes to Consolidated Financial Statements</u>	<u>61</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>103</u>

**AbbVie Inc. and Subsidiaries**  
**Consolidated Statements of Earnings**

<b>years ended December 31 (in millions, except per share data)</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
<b>Net revenues</b>	\$ 22,859	\$ 19,960	\$ 18,790
Cost of products sold	4,500	4,426	4,581
Selling, general and administrative	6,387	7,724	5,352
Research and development	4,285	3,297	2,855
Acquired in-process research and development	150	352	338
Other expense		750	
<b>Total operating costs and expenses</b>	<b>15,322</b>	<b>16,549</b>	<b>13,126</b>
Operating earnings	7,537	3,411	5,664
Interest expense, net	686	391	278
Net foreign exchange loss	193	678	55
Other expense (income), net	13	(27)	(1)
Earnings before income tax expense	6,645	2,369	5,332
Income tax expense	1,501	595	1,204
<b>Net earnings</b>	<b>\$ 5,144</b>	<b>\$ 1,774</b>	<b>\$ 4,128</b>
<b>Per share data</b>			
Basic earnings per share	\$ 3.15	\$ 1.11	\$ 2.58
Diluted earnings per share	\$ 3.13	\$ 1.10	\$ 2.56
Cash dividends declared per common share	\$ 2.10	\$ 1.75	\$ 2.00 <sup>(a)</sup>
Weighted-average basic shares outstanding	1,625	1,595	1,589
Weighted-average diluted shares outstanding	1,637	1,610	1,604

(a) On January 4, 2013, a cash dividend of \$0.40 per share of common stock was declared from pre-separation earnings and was recorded as a reduction of additional paid-in capital.

The accompanying notes are an integral part of these consolidated financial statements.

**AbbVie Inc. and Subsidiaries**  
**Consolidated Statements of Comprehensive Income**

<b>years ended December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
<b>Net earnings</b>	\$ 5,144	\$ 1,774	\$ 4,128
Foreign currency translation adjustments, net of tax (benefit) expense of (\$139) in 2015, (\$158) in 2014, and \$71 in 2013	(667)	(1,073)	48
Pension and post-employment benefits, net of tax expense (benefit) of \$96 in 2015, (\$351) in 2014, and \$309 in 2013	230	(781)	598
Unrealized gains on marketable equity securities, net of tax expense of \$22 in 2015, \$1 in 2014, and \$ in 2013	44	1	1
Hedging activities, net of tax (benefit) expense of (\$6) in 2015, \$8 in 2014, and \$ in 2013	(137)	264	(77)
Other comprehensive (loss) income	(530)	(1,589)	570
<b>Comprehensive income</b>	\$ 4,614	\$ 185	\$ 4,698

The accompanying notes are an integral part of these consolidated financial statements.



**AbbVie Inc. and Subsidiaries**  
**Consolidated Balance Sheets**

<b>as of December 31 (in millions, except share data)</b>	<b>2015</b>	<b>2014</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and equivalents	\$ 8,399	\$ 8,348
Short-term investments	8	26
Accounts and other receivables, net	4,730	3,735
Inventories, net	1,719	1,124
Deferred income taxes		896
Prepaid expenses and other	1,458	1,952
<b>Total current assets</b>	<b>16,314</b>	<b>16,081</b>
Investments	145	92
Property and equipment, net	2,565	2,485
Intangible assets, net of accumulated amortization	19,709	1,513
Goodwill	13,168	5,862
Other assets	1,149	1,480
<b>Total assets</b>	<b>\$ 53,050</b>	<b>\$ 27,513</b>
<b>Liabilities and Equity</b>		
<b>Current liabilities</b>		
Short-term borrowings	\$ 406	\$ 425
Current portion of long-term debt and lease obligations	2,025	4,014
Accounts payable and accrued liabilities	8,463	6,954
<b>Total current liabilities</b>	<b>10,894</b>	<b>11,393</b>
Long-term debt and lease obligations	29,240	10,538
Deferred income taxes	5,276	159
Other long-term liabilities	3,695	3,681
Commitments and contingencies		
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value, authorized 4,000,000,000 shares, issued 1,749,027,140 and 1,609,519,046 shares as of December 31, 2015 and 2014, respectively	17	16
Common stock held in treasury, at cost, 139,134,205 and 18,129,715 shares as of December 31, 2015 and 2014, respectively	(8,839)	(972)
Additional paid-in-capital	13,080	4,194
Retained earnings	2,248	535
Accumulated other comprehensive loss	(2,561)	(2,031)
<b>Total stockholders' equity</b>	<b>3,945</b>	<b>1,742</b>
<b>Total liabilities and equity</b>	<b>\$ 53,050</b>	<b>\$ 27,513</b>

The accompanying notes are an integral part of these consolidated financial statements.

**AbbVie Inc. and Subsidiaries**  
**Consolidated Statements of Equity**

years ended December 31 (in millions)	Common shares outstanding	Common stock	Treasury stock	Additional paid-in capital	Retained earnings	Accumulated other comprehensive loss	Net parent company investment	Total
<b>Balance at December 31, 2012</b>		\$	\$	\$	\$	\$ (350)	\$ 3,713	\$ 3,363
Separation-related adjustments				(1,316)		(662)	707	(1,271)
Reclassification of parent company net investment in connection with separation				4,420			(4,420)	
Issuance of common shares at separation	1,577	16		(16)				
Net earnings					4,128			4,128
Other comprehensive income, net of tax						570		570
Dividends declared					(2,561)			(2,561)
Share repurchases	(4)		(223)					(223)
Stock-based compensation plans and other	14		(97)	583				486
<b>Balance at December 31, 2013</b>	1,587	16	(320)	3,671	1,567	(442)		4,492
Net earnings					1,774			1,774
Other comprehensive loss, net of tax						(1,589)		(1,589)
Dividends declared					(2,806)			(2,806)
Share repurchases	(9)		(550)					(550)
Stock-based compensation plans and other	13		(102)	523				421
<b>Balance at December 31, 2014</b>	1,591	16	(972)	4,194	535	(2,031)		1,742
Net earnings					5,144			5,144
Other comprehensive loss, net of tax						(530)		(530)
Dividends declared					(3,431)			(3,431)
Common shares issued to Pharmacyclics Inc. stockholders	128	1		8,404				8,405
Share repurchases	(119)		(7,774)					(7,774)
Stock-based compensation plans and other	10		(93)	482				389
<b>Balance at December 31, 2015</b>	1,610	\$ 17	\$ (8,839)	\$ 13,080	\$ 2,248	\$ (2,561)		\$ 3,945

Edgar Filing: AbbVie Inc. - Form 10-K

The accompanying notes are an integral part of these consolidated financial statements.

**AbbVie Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**

years ended December 31 (in millions) (brackets denote cash outflows)	2015	2014	2013
<b>Cash flows from operating activities</b>			
Net earnings	\$ 5,144	\$ 1,774	\$ 4,128
Adjustments to reconcile net earnings to net cash from operating activities:			
Depreciation	417	383	388
Amortization of intangible assets	419	403	509
Stock-based compensation	282	241	212
Upfront costs and milestones related to collaborations	280	1,102	338
Other, net	489	434	34
Changes in operating assets and liabilities, net of acquisitions:			
Accounts and other receivables	(1,076)	(172)	681
Inventories	(434)	(203)	(56)
Prepaid expenses and other assets	511	(220)	459
Accounts payable and other liabilities	1,503	(193)	(426)
<b>Cash flows from operating activities</b>	<b>7,535</b>	<b>3,549<sup>(a)</sup></b>	<b>6,267</b>
<b>Cash flows from investing activities</b>			
Acquisition of Pharmacyclics, Inc., net of cash acquired	(11,488)		
Other acquisitions and investments	(964)	(622)	(405)
Acquisitions of property and equipment	(532)	(612)	(491)
Purchases of investment securities	(851)	(1,169)	(930)
Sales and maturities of investment securities	880	1,477	2,705
Other	19		
<b>Cash flows from investing activities</b>	<b>(12,936)</b>	<b>(926)</b>	<b>879</b>
<b>Cash flows from financing activities</b>			
Net change in short-term borrowings	(19)	12	(601)
Proceeds from issuance of long-term debt	20,660		
Repayments of long-term debt and capital leases	(4,018)	(17)	
Debt issuance cost	(182)	(141)	
Dividends paid	(3,294)	(2,661)	(2,555)
Purchases of treasury stock	(7,567)	(652)	(320)
Proceeds from the exercise of stock options	142	225	347
Net transactions with Abbott Laboratories, excluding non-cash items			(247)
Other, net	30	(59)	(66)
<b>Cash flows from financing activities</b>	<b>5,752</b>	<b>(3,293)</b>	<b>(3,442)</b>
Effect of exchange rate changes on cash and equivalents	(300)	(577)	(10)
Net increase (decrease) in cash and equivalents	51	(1,247)	3,694
Cash and equivalents, beginning of year	8,348	9,595	5,901
<b>Cash and equivalents, end of year</b>	<b>\$ 8,399</b>	<b>\$ 8,348</b>	<b>\$ 9,595</b>
<b>Other supplemental information</b>			
Interest paid, net of portion capitalized	\$ 536	\$ 419	\$ 283
Income taxes paid	\$ 1,108	\$ 498	\$ 1,305
<b>Supplemental schedule of non-cash investing and financing activities</b>			

## Edgar Filing: AbbVie Inc. - Form 10-K

Issuance of common shares associated with the acquisition of Pharmacyclics, Inc. \$ 8,405 \$ \$

- (a) Cash flows from operating activities included the impact of transaction and financing-related and other costs incurred in connection with the terminated proposed combination with Shire plc. Refer to Note 5 for additional information.

The accompanying notes are an integral part of these consolidated financial statements.

**AbbVie Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**  
**Note 1 Background and Basis of Presentation**

**Background**

The principal business of AbbVie Inc. (AbbVie or the company) is the discovery, development, manufacture and sale of a broad line of pharmaceutical 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. Substantially all of AbbVie's net revenues in the United States are to three wholesalers. Outside the United States, products are sold primarily to customers or through distributors, depending on the market served.

AbbVie was incorporated in Delaware on April 10, 2012. On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories (Abbott) of 100 percent of the outstanding common stock of AbbVie to Abbott's shareholders. AbbVie's common stock began trading "regular-way" under the ticker symbol "ABBV" on the New York Stock Exchange on January 2, 2013.

During 2013, separation-related adjustments totaling \$1.3 billion were recorded in stockholders' equity. Separation-related adjustments to additional paid-in capital principally reflected dividends to AbbVie shareholders that were declared from pre-separation earnings during the first quarter of 2013 and the transfer of certain pension plan liabilities and assets from Abbott to AbbVie upon the legal split of those plans in 2013. In addition, because AbbVie's historical financial statements prior to January 1, 2013 were derived from Abbott's records, separation-related adjustments also included an adjustment to accumulated other comprehensive loss to reflect the appropriate opening balances associated with currency translation adjustments related to AbbVie's legal entities at the separation date. Refer to Note 11 for further information regarding the separation of the pension plans.

In connection with the separation, AbbVie and Abbott entered into transition services agreements covering certain corporate support and back office services that AbbVie historically received from Abbott. Such services included information technology, accounts payable, payroll, receivables collection, treasury and other financial functions, as well as order entry, warehousing, engineering support, quality assurance support and other administrative services. These agreements facilitated the separation by allowing AbbVie to operate independently prior to establishing stand-alone back office functions across its organization. The transition services agreements had original terms of up to 24 months, with an option for a one-year extension. The majority of these transaction service agreements expired without extension at December 31, 2014. With certain limited exceptions, the remaining transition services agreements terminated on or prior to December 31, 2015.

During the years ended December 31, 2015, 2014, and 2013, AbbVie incurred \$270 million, \$445 million, and \$254 million, respectively, of separation-related expenses, which were principally classified in selling, general and administrative expenses (SG&A) in the consolidated statements of earnings. These charges principally related to information technology, legal and regulatory fees.

**Basis of Historical Presentation**

For a certain portion of AbbVie's operations, the legal transfer of AbbVie's assets (net of liabilities) did not occur with the separation of AbbVie on January 1, 2013 due to the time required to transfer marketing authorizations and satisfy other regulatory requirements in certain countries. Under the terms of the separation agreement with Abbott, AbbVie is responsible for the business activities conducted by Abbott on its behalf, and is subject to the risks and entitled to the benefits generated by these operations and assets.

As a result, the related assets and liabilities and results of operations have been reported in AbbVie's consolidated financial statements as of and for the years ended December 31, 2015, 2014, and 2013. Net revenues related to these operations for 2015, 2014, and 2013 totaled approximately \$213 million, \$282 million, and \$738 million, respectively. With the exception of Venezuela, all of these operations have been transferred to AbbVie as of December 31, 2015.

## Note 2 Summary of Significant Accounting Policies

### Use of Estimates

The financial statements have been prepared in accordance with U.S. GAAP and necessarily include amounts based on estimates and assumptions by management. Actual results could differ from those amounts. Significant estimates include amounts for rebates, pension and post-employment benefits, income taxes, litigation, valuation of intangible assets and goodwill, financial instruments, and inventory and accounts receivable exposures.

### Basis of Consolidation

The consolidated financial statements as of and for the years ended December 31, 2015 and 2014 include the accounts of AbbVie and all of its subsidiaries in which a controlling interest is maintained. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, where AbbVie is determined to be the primary beneficiary. Investments in companies over which AbbVie has a significant influence but not a controlling interest are accounted for using the equity method with AbbVie's share of earnings or losses reported in other expense (income), net in the consolidated statements of earnings. All other investments are generally accounted for using the cost method. Intercompany balances and transactions are eliminated.

Certain reclassifications have been made to conform the prior period consolidated financial statements to the current period presentation.

### 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. Provisions for discounts, rebates and sales incentives to customers and returns and other adjustments are provided for in the period the related revenues are recorded. 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. Sales incentives to customers are not material. Historical data is readily available and reliable, and is used for estimating the amount of the reduction in gross revenues. Revenue from the launch of a new product, from an improved version of an existing product, or for shipments in excess of a customer's normal requirements are recorded when the conditions noted above are met. In those situations, management records a returns reserve for such revenue, if necessary. Sales of product rights for marketable products are recorded as revenue upon disposition of the rights.

### Research and Development Expenses

Internal research and development (R&D) expenses are expensed as incurred. Clinical trial costs incurred by third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development collaborations for pre-commercialization milestones, the milestone payment obligations are expensed when the milestone results are achieved.



## Edgar Filing: AbbVie Inc. - Form 10-K

Payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized to cost of products sold over the remaining useful life of the related product.

### Collaborations and Other Arrangements

The company enters into collaborative agreements with third parties to develop and commercialize drug candidates. Collaborative activities may include joint research and development and commercialization of new products. AbbVie generally receives certain licensing rights under these arrangements. These collaborations often require upfront payments and may include additional milestone, research and development cost sharing, royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development and commercialization. Upfront payments associated with collaborative arrangements during the development stage are expensed to acquired in-process research and development (IPR&D) expenses in the consolidated statements of earnings. Subsequent payments made to the partner for the achievement of milestones during the development stage are expensed to R&D expenses in the consolidated statements of earnings when the milestone is achieved. Milestone payments made to the partner subsequent to regulatory approval are capitalized as intangible assets and amortized to cost of products sold over the estimated useful life of the related asset. Royalties are expensed to cost of products sold in the consolidated statements of earnings when incurred.

### Advertising

Costs associated with advertising are expensed as incurred and are included in SG&A expenses in the consolidated statements of earnings. Advertising expenses were \$704 million, \$665 million, and \$626 million in 2015, 2014, and 2013, respectively.

### Pension and Other Post-Employment Benefits

AbbVie records annual expenses relating to its defined benefit pension and other post-employment plans based on calculations which include various actuarial assumptions, including discount rates, assumed asset rates of return, compensation increases, turnover rates and health care cost trend rates. AbbVie reviews its actuarial assumptions on an annual basis and makes modifications to the assumptions based on current rates and trends. Actuarial losses and gains are amortized over the remaining service attribution periods of the employees under the corridor method, in accordance with the rules for accounting for post-employment benefits. Differences between the expected long-term return on plan assets and the actual annual return are amortized to net periodic benefit cost over a five-year period.

### Income Taxes

Income taxes are accounted for under the asset and liability method. Provisions for federal, state and foreign income taxes are calculated on reported pretax earnings based on current tax laws. Deferred taxes are provided using enacted tax rates on the future tax consequences of temporary differences, which are the differences between the financial statement carrying amount of assets and liabilities and their respective tax bases and the tax benefits of carryforwards. A valuation allowance is established or maintained when, based on currently available information, it is more likely than not that all or a portion of a deferred tax asset will not be realized.

### Cash and Equivalents

Cash and equivalents include time deposits and money market funds with original maturities at the time of purchase of three months or less.

## Investments

Short-term investments consist primarily of time deposits and held-to-maturity debt securities. Investments in marketable equity securities are classified as available-for-sale and are recorded at fair value with any unrealized holding gains or losses, net of tax, included in accumulated other comprehensive loss (AOCI) in AbbVie's consolidated balance sheets. Investments in equity securities that are not traded on public stock exchanges and held-to-maturity debt securities are recorded at cost.

AbbVie reviews the carrying value of investments each quarter to determine whether an other than temporary decline in fair value exists. AbbVie considers factors affecting the investee, factors affecting the industry the investee operates in and general equity market trends. The company considers the length of time an investment's fair value has been below cost and the near-term prospects for recovery. When AbbVie determines that an other than temporary decline has occurred, a cost basis investment is written down with a charge to other expense (income), net in the consolidated statements of earnings and an available-for-sale investment's unrealized loss is reclassified from AOCI to other expense (income), net in the consolidated statements of earnings.

## Accounts Receivable

Accounts receivable are stated at their net realizable value. The allowance against gross accounts receivable reflects the best estimate of probable losses inherent in the receivables portfolio determined on the basis of historical experience, specific allowances for known troubled accounts and other currently available information. Accounts receivable are written off after all reasonable means to collect the full amount (including litigation, where appropriate) have been exhausted. The allowance was \$78 million and \$74 million at December 31, 2015 and 2014, respectively.

## Inventories

Inventories are valued at the lower of cost (first-in, first-out basis) or market. Cost includes material and conversion costs. Inventories, net, consist of the following:

as of December 31 (in millions)	2015	2014
Finished goods	\$ 469	\$ 341
Work-in-process	1,081	629
Raw materials	169	154
Inventories, net	\$ 1,719	\$ 1,124

Inventories, net as of December 31, 2015 included \$356 million acquired through the acquisition of Pharmacyclics, Inc. (Pharmacyclics) on May 26, 2015. Refer to Note 5 for additional information.

## Property and Equipment

as of December 31 (in millions)	2015	2014
Land	\$ 46	\$ 48
Buildings	1,284	1,228
Equipment	5,656	5,324
Construction in progress	348	505
Property and equipment, gross	7,334	7,105
Less accumulated depreciation	(4,769)	(4,620)
Property and equipment, net	\$ 2,565	\$ 2,485



## Edgar Filing: AbbVie Inc. - Form 10-K

Depreciation for property and equipment is recorded on a straight-line basis over the estimated useful lives of the assets. The estimated useful life for buildings ranges from 10 to 50 years and five to 20 years for equipment. Leasehold improvements are amortized over the life of the related facility lease (including any renewal periods, if appropriate) or the asset, whichever is shorter. Depreciation expense was \$417 million, \$383 million, and \$388 million in 2015, 2014, and 2013, respectively. Equipment includes certain computer software and software development costs incurred in connection with developing or obtaining software for internal use and is amortized over three to 10 years. Assets under capital leases included in property and equipment in the consolidated balance sheets are not material.

### Litigation and Contingencies

Loss contingency provisions are recorded when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. When a best estimate cannot be made, the minimum loss contingency amount in a probable range is recorded. Legal fees are expensed as incurred.

AbbVie accrues for product liability claims, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. The liabilities are evaluated quarterly and adjusted if necessary as additional information becomes available. Receivables for insurance recoveries, if any, for product liability claims are recorded as assets, on an undiscounted basis, when it is probable that a recovery will be realized.

### Business Combinations

Results of operations of acquired companies are included in AbbVie's results of operations beginning on the respective acquisition dates. Assets acquired and liabilities assumed are recognized at the date of acquisition at their respective fair values. Any excess of the fair value consideration transferred over the estimated fair values of the net assets acquired is recognized as goodwill. Contingent consideration is recognized at the estimated fair value on the acquisition date, which is determined by utilizing a probability weighted discounted cash flow model. Subsequent changes to the fair value of contingent payments are recognized in other expense (income), net in the consolidated statements of earnings. The fair value of assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value. Legal costs, due diligence costs, business valuation costs and all other business acquisition costs are expensed when incurred.

### Goodwill and Intangible Assets

Intangible assets acquired in a business combination are recorded at fair value using a discounted cash flow model. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, risk, the cost of capital, and terminal values of market participants. Definite-lived intangibles are amortized over their estimated useful lives. AbbVie reviews the recoverability of definite-lived intangible assets whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. AbbVie first compares the projected undiscounted cash flows to be generated by the asset to its carrying value. If the undiscounted cash flows of an intangible asset are less than the carrying value of an intangible asset, the intangible asset is written down to its fair value, which is usually the discounted cash flow amount, and a loss is recorded equal to the excess of the asset's net carrying value over its fair value. Where cash flows cannot be identified for an individual asset, the review is applied at the lowest level for which cash flows are largely independent of the cash flows of other assets and liabilities.

Goodwill and indefinite-lived assets are not amortized but are subject to an impairment review annually and more frequently when indicators of impairment exist. An impairment of goodwill would occur if the carrying amount of a reporting unit exceeded the fair value of that reporting unit. Indefinite-lived

intangible assets, which consist of capitalized IPR&D, would occur if the fair value of the IPR&D intangible asset is less than the carrying amount.

The company tests its goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the company concludes it is more likely than not that the fair value of reporting unit is less than its carrying amount, a quantitative impairment test is performed. AbbVie tests indefinite-lived intangible assets using a quantitative impairment test. For its quantitative impairment test, the company uses an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, foreign currency exchange rates, the selection of an appropriate discount rate, asset groupings and other assumptions and estimates. The estimates and assumptions used are consistent with the company's business plans and a market participant's views of a company and similar companies. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the assets, and potentially result in different impacts to the company's results of operations. Actual results may differ from the company's estimates.

Based upon the company's most recent annual impairment test performed in the third quarter of 2015, the company concluded goodwill was not impaired. In 2015 and 2013, no intangible impairment charges were recorded. In 2014, AbbVie recorded an impairment charge of \$37 million related to certain on-market product rights in Japan due to increased generic competition. The charge was included in cost of products sold in the consolidated statements of earnings.

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

The initial costs of rights to IPR&D projects acquired in an asset acquisition are expensed as IPR&D in the consolidated statements of earnings unless the project has an alternative future use. These costs include initial payments incurred prior to regulatory approval in connection with research and development collaboration agreements that provide rights to develop, manufacture, market and/or sell pharmaceutical products. The fair value of IPR&D projects acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a definite-lived intangible asset, or discontinuation, at which point the intangible asset will be written off. Development costs incurred after the acquisition are expensed as incurred. Indefinite- and definite-lived assets are subject to impairment reviews as discussed previously.

#### **Foreign Currency Translation**

Foreign subsidiary earnings are translated into U.S. dollars using average exchange rates. The net assets of foreign subsidiaries are translated into U.S. dollars using period end exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recognized in other comprehensive (loss) income (OCI) in the consolidated statements of comprehensive income. The net assets of subsidiaries in highly inflationary economies are remeasured as if the functional currency were the reporting currency. The remeasurement is recognized in net foreign exchange loss in the consolidated statements of earnings and is immaterial for all years presented.

#### **Derivatives**

All derivative instruments are recognized as either assets or liabilities at fair value in AbbVie's consolidated balance sheets and are classified as current or long-term based on the scheduled maturity of the instrument. The accounting for changes in the fair value of a derivative instrument depends on whether it has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship.

For derivatives formally designated as hedges, the company assesses at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in the fair value or cash flows of the hedged item. The changes in fair value of a derivative designated as a fair value hedge and of the hedged item attributable to the hedge risk are recognized in earnings immediately. Fair value hedges are used to hedge the interest rate risk associated with certain of the company's fixed-rate debt. The effective portions of changes in the fair value of a derivative designated as a cash flow hedge are reported in AOCI and are subsequently recognized in earnings consistent with the underlying hedged item. Cash flow hedges are used to manage exposures from changes in foreign currency exchange rates.

The derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. If it is determined that a derivative is no longer highly effective as a hedge, the company discontinues hedge accounting prospectively. Gains or losses are immediately reclassified from AOCI to earnings relating to hedged forecasted transactions that are no longer probable of occurring. Gains or losses relating to terminations of effective cash flow hedges in which the forecasted transactions are still probable of occurring are deferred and recognized consistent with the income or loss recognition of the underlying hedged items. Terminations of fair value hedges result in fair value adjustments to the hedged items until the date of termination with the new bases being accreted to par value on the date of maturity.

Derivatives, including those that are not designated as a hedge, are principally classified in the operating section of the consolidated statements of cash flows, consistent with the underlying hedged item.

### Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs - Contracts with Customers (Subtopic 340-40)*. The amendments in this standard supersede most current revenue recognition requirements. The core principal of the new guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. AbbVie can apply the amendments using one of the following two methods: (i) retrospectively to each prior reporting period presented, or (ii) modified retrospectively with the cumulative effect of initially applying the amendments recognized at the date of initial application. In July 2015, the FASB issued ASU No. 2015-4, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which deferred the effective date of ASU 2014-09 by one year for all entities. Accordingly, this standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is permitted only for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. AbbVie is currently assessing the timing of its adoption and the impact of adopting this guidance on its consolidated financial statements and the implementation approach to be used.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The standard is effective for annual and interim periods beginning after December 15, 2015, with early adoption permitted on a retrospective basis. AbbVie elected to early adopt this new standard, effective in the three months ended June 30, 2015. As a result, AbbVie reclassified approximately \$7 million and \$27 million of net deferred financing costs as of December 31, 2014 that were previously classified as prepaid expenses and other current assets and other long-term assets, respectively, to long-term debt and lease obligations (current and non-current). Total debt issuance costs classified as a reduction of long-term debt and lease obligations (current and non-current) were \$117 million as of December 31, 2015.

## Edgar Filing: AbbVie Inc. - Form 10-K

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*. This standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. Entities are currently required to retrospectively apply adjustments made to provisional amounts recognized in a business combination. This standard is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The guidance is to be applied prospectively to measurement period adjustments that occur after the effective date of the guidance with earlier application permitted for financial statements that have not been issued. AbbVie elected to early adopt the standard, effective in the year ended December 31, 2015. The impact of this adoption was not material.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. Entities are currently required to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. The amendments, which require non-current presentation only (by jurisdiction), are effective for financial statements issued for annual periods beginning after December 15, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The guidance is to be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. AbbVie elected to early adopt this standard on a prospective basis, effective as of December 31, 2015 in order to simplify the presentation of deferred tax assets and liabilities. Prior periods were not retrospectively adjusted.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The standard requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net income. The new guidance also changes certain disclosure requirements and other aspects of current US GAAP. Amendments are to be applied as a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. This standard is effective for fiscal years starting after December 15, 2017, including interim periods within those fiscal years. The standard does not permit early adoption with the exception of certain targeted provisions. AbbVie is currently assessing the impact and timing of adopting this guidance on its consolidated financial statements.

### Note 3 Supplemental Financial Information

#### Interest Expense, Net

years ended December 31 (in millions)	2015	2014	2013
Interest expense	\$ 719	\$ 429	\$ 299
Interest income	(33)	(38)	(21)
Interest expense, net	\$ 686	\$ 391	\$ 278

Interest expense, net in 2015 included \$86 million of bridge financing-related costs incurred in connection with the acquisition of Pharmacyclics. Refer to Note 5 for additional information. Interest expense, net in 2014 included \$141 million of financing related fees incurred in connection with the terminated proposed combination with Shire plc, a company incorporated in Jersey (Shire).

#### Other Expense (Income), Net

Other expense (income), net, includes income or expense from the resolution of certain contractual agreements, impairments of equity securities, and gains and losses on the sale of equity securities. Other

## Edgar Filing: AbbVie Inc. - Form 10-K

expense, net in 2015 primarily consisted of impairments of certain equity securities. Other income, net in 2014 primarily consisted of income of \$34 million from the resolution of a contractual agreement.

### Accounts Payable and Accrued Liabilities

as of December 31 (in millions)	2015	2014
Sales rebates	\$ 2,355	\$ 1,384
Accounts payable	1,597	1,401
Dividends payable	924	791
Salaries, wages and commissions	632	623
Royalty and license arrangements	411	821
Other	2,544	1,934
<b>Accounts payable and accrued liabilities</b>	<b>\$ 8,463</b>	<b>\$ 6,954</b>

### Other Long-Term Liabilities

as of December 31 (in millions)	2015	2014
Pension and other post-employment benefits	\$ 1,949	\$ 2,220
Liabilities for unrecognized tax benefits	902	471
Other	844	990
<b>Other long-term liabilities</b>	<b>\$ 3,695</b>	<b>\$ 3,681</b>

### Note 4 Earnings Per Share

AbbVie calculates earnings per share (EPS) using the more dilutive of the treasury stock or the two-class method. The two-class method is an earnings allocation formula that determines earnings per share for common stock and participating securities according to dividends declared and participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to common shares and participating securities based on their respective rights to receive dividends. In addition, participating securities may include certain performance-based awards that may otherwise be excluded from the calculation of EPS under the treasury-stock method. AbbVie's forfeitable restricted stock units (RSUs) and restricted stock awards (RSAs), including most performance-based awards, participate in dividends on the same basis as common shares and such dividends are nonforfeitable to the holder once declared. As a result, these forfeitable RSUs and RSAs meet the definition of a participating security.

For all periods presented, the two-class method was more dilutive. As such, the dilutive effect of unvested RSUs and RSAs of approximately 4 million, 4 million, and 5 million shares for 2015, 2014 and 2013, respectively, were excluded from the denominator for the calculation of diluted EPS. These awards otherwise would have been included in the calculation of EPS under the treasury stock method. Additionally, all earnings (distributed and undistributed) allocable to participating securities, including performance-based awards not otherwise included in the calculation of EPS under the treasury stock method, were excluded from the numerator for the calculation of basic and diluted earnings per share under the two-class method. Earnings allocable to participating securities for 2015, 2014, and 2013 were \$26 million, \$9 million, and \$26 million, respectively.

As further described in Note 12, AbbVie entered into and executed a \$5.0 billion accelerated share repurchase agreement (ASR) with Morgan Stanley & Co. LLC (Morgan Stanley) on May 26, 2015, pursuant to which AbbVie paid \$5.0 billion for an initial delivery of 68 million shares of AbbVie's common stock. The initial delivery of shares represented approximately 90 percent of the total shares expected to be delivered under the ASR. Morgan Stanley subsequently delivered an additional 5 million shares of AbbVie's common



stock to AbbVie in final settlement of the ASR in August 2015. For purposes of calculating EPS, AbbVie reflected the ASR as a repurchase of AbbVie common stock.

The number of common shares issuable under stock-based compensation plans that were excluded from the computation of earnings per common share because the effect would have been antidilutive were not material for all periods presented.

## Note 5 Licensing, Acquisitions and Other Arrangements

### Acquisition of Pharmacyclics

On May 26, 2015, AbbVie acquired Pharmacyclics through a tender offer for approximately \$20.8 billion, including cash consideration of \$12.4 billion and equity consideration of \$8.4 billion. Pharmacyclics is a biopharmaceutical company that develops and commercializes novel therapies for people impacted by cancer. Pharmacyclics markets IMBRUVICA® (ibrutinib), a Bruton's tyrosine kinase (BTK) inhibitor, targeting B-cell malignancies. Each outstanding Pharmacyclics share was exchanged for (i) \$152.25 in cash and \$109.00 in fair market value of AbbVie common stock, (ii) \$261.25 in cash, or (iii) \$261.25 in fair market value of AbbVie common stock, at the election of each holder, subject to the election and proration of the consideration at 58 percent cash and 42 percent AbbVie common stock.

The total consideration for the acquisition of Pharmacyclics was approximately \$20.8 billion, consisting of cash and approximately 128 million shares of AbbVie common stock, and is summarized as follows:

(in millions)

Fair value of AbbVie common stock issued to Pharmacyclics stockholders	\$ 8,405
Cash consideration paid to Pharmacyclics stockholders	11,749
Cash consideration paid to Pharmacyclics equity award holders	616
 Total consideration	 \$ 20,770

The acquisition of Pharmacyclics was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be recognized at fair value as of the acquisition date. The valuation of assets acquired and liabilities assumed in the acquisition has not yet been finalized as of December 31, 2015. As a result, AbbVie recorded preliminary estimates for the fair value of assets acquired and liabilities assumed as of the acquisition date. The completion of the valuation will occur no later than one year from the acquisition date and may result in significant changes to the recognized assets and liabilities.

## Edgar Filing: AbbVie Inc. - Form 10-K

The following table summarizes preliminary fair values of assets acquired and liabilities assumed as of the May 26, 2015 acquisition date:

**(in millions)**

<b>Assets acquired and liabilities assumed</b>	
Cash and equivalents	\$ 877
Short-term investments	11
Accounts and other receivables	106
Inventories	492
Other assets	212
<b>Intangible assets</b>	
Definite-lived developed product rights	4,590
Definite-lived license agreements	6,780
Indefinite-lived research and development	7,180
Accounts payable and accrued liabilities	(381)
Deferred income taxes	(6,453)
Other long-term liabilities	(254)
Total identifiable net assets	13,160
Goodwill	7,610
Total assets acquired and liabilities assumed	\$ 20,770

The fair market value step-up adjustment to inventories of \$445 million is being amortized to cost of products sold when the inventory is sold to customers, which is expected to be a period of approximately 18 months from the acquisition date.

Intangible assets relate to the IMBRUVICA developed product rights, IPR&D in the United States related to additional indications for IMBRUVICA, and the contractual rights to IMBRUVICA profits and losses outside the United States as a result of the collaboration agreement with Janssen Biotech, Inc. and its affiliates (Janssen), one of the Janssen Pharmaceutical companies of Johnson & Johnson. Refer to Note 6 for additional information regarding the collaboration with Janssen. The acquired definite-lived intangible assets are being amortized over a weighted-average estimated useful life of 12 years using the estimated pattern of economic benefit. The estimated fair value of the IPR&D and identifiable intangible assets was determined using the "income approach," which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. Some of the more significant assumptions inherent in the development of those asset valuations include the estimated net cash flows for each year for each asset or product (including net revenues, cost of sales, R&D costs, selling and marketing costs, and working capital/contributory asset charges), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream, as well as other factors.

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from the other assets acquired that could not be individually identified and separately recognized. Specifically, the goodwill recognized from the acquisition of Pharmacyclics includes expected synergies, including the ability to leverage the respective strengths of each business, expanding the combined company's product portfolio, acceleration of clinical and commercial presence in oncology and establishment of a strong leadership position in hematological oncology. The goodwill is not deductible for tax purposes.

## Edgar Filing: AbbVie Inc. - Form 10-K

From the acquisition date through December 31, 2015, AbbVie's consolidated statement of earnings for 2015 included net revenues of \$774 million and a pre-tax operating loss of \$519 million associated with the acquisition. The operating loss included \$346 million of acquisition-related compensation expense, \$261 million of inventory step-up and intangible asset amortization, and \$100 million of transaction and integration costs. Of these costs, \$294 million was recorded within SG&A expenses, \$152 million within R&D expenses, and \$261 million within cost of products sold in the consolidated statement of earnings for 2015.

### *Pro Forma Financial Information*

The following table presents the unaudited pro forma combined results of operations of AbbVie and Pharmacyclics for 2015 and 2014 as if the acquisition of Pharmacyclics had occurred on January 1, 2014:

<b>years ended December 31 (in millions, except per share data)</b>	<b>2015</b>	<b>2014</b>
Net revenues	\$ 23,215	\$ 20,690
Net earnings	\$ 5,345	\$ 812
Basic earnings per share	\$ 3.18	\$ 0.47
Diluted earnings per share	\$ 3.16	\$ 0.47

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of AbbVie and Pharmacyclics. In order to reflect the occurrence of the acquisition on January 1, 2014 as required, the unaudited pro forma financial information includes adjustments to reflect the incremental amortization expense to be incurred based on the current preliminary fair values of the identifiable intangible assets acquired; the incremental cost of products sold related to the fair value adjustments associated with acquisition-date inventory; the additional interest expense associated with the issuance of debt to finance the acquisition; and the reclassification of acquisition, integration and financing-related costs incurred during the year ended December 31, 2015 to the year ended December 31, 2014. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been had the acquisition been completed on January 1, 2014. In addition, the unaudited pro forma financial information is not a projection of the future results of operations of the combined company nor does it reflect the expected realization of any cost savings or synergies associated with the acquisition.

### **Other Licensing & Acquisitions Activity**

Excluding the acquisition of Pharmacyclics, cash outflows related to other acquisitions and investments totaled \$964 million, \$622 million, and \$405 million in 2015, 2014, and 2013, respectively. AbbVie recorded IPR&D charges of \$150 million, \$352 million, and \$338 million in 2015, 2014, and 2013, respectively. In 2014, AbbVie also recorded other operating expenses of \$750 million related to the collaboration with Calico Life Sciences LLC (Calico). Significant arrangements impacting 2015, 2014, and 2013, some of which require contingent milestone payments, are summarized below.

In addition to the significant arrangements described below, AbbVie entered into several other arrangements resulting in charges to IPR&D of \$50 million in 2015, \$77 million in 2014, and \$48 million in 2013. In connection with the other individually insignificant arrangements entered into in 2015, AbbVie could make additional payments of up to \$1.2 billion upon the achievement of certain development, regulatory and commercial milestones.

### *C<sub>2</sub>N Diagnostics*

In March 2015, AbbVie entered into an exclusive worldwide license agreement with C<sub>2</sub>N Diagnostics (C<sub>2</sub>N) to develop and commercialize anti-tau antibodies for the treatment of Alzheimer's disease and other neurological disorders. As part of the agreement, AbbVie made an initial upfront payment of \$100 million,

## Edgar Filing: AbbVie Inc. - Form 10-K

which was expensed to IPR&D in 2015. Upon the achievement of certain development, regulatory, and commercial milestones, AbbVie could make additional payments of up to \$685 million, as well as royalties on net sales.

### *Calico Life Sciences LLC*

In September 2014, AbbVie and Calico entered into a novel R&D collaboration agreement to discover, develop and commercialize new therapies for patients with age-related diseases, including neurodegeneration and cancer. In 2014, AbbVie recorded \$750 million in other operating expense in the consolidated statement of earnings related to its commitments under the agreement of which \$250 million was paid in 2014 and \$500 million was paid in early 2015. Calico is responsible for research and early development during the first five years and will continue to advance collaboration projects through Phase 2a for a ten year period. AbbVie will have the option to exclusively license collaboration compounds after completion of Phase 2a. AbbVie will support Calico in its early R&D efforts and, upon option exercise, would be responsible for all late-stage development and commercial activities. Collaboration costs and profits will be shared equally by both companies post option exercise.

### *Infinity Pharmaceuticals, Inc.*

In September 2014, AbbVie entered into a global collaboration agreement with Infinity Pharmaceuticals, Inc. (Infinity) to develop and commercialize duvelisib (IPI-145) for the treatment of patients with cancer. As part of the agreement, AbbVie made an initial upfront payment of \$275 million, which was expensed to IPR&D in the third quarter of 2014. In 2015, AbbVie made an additional payment of \$130 million, which was recorded in R&D expense in the consolidated statement of earnings, due to the achievement of a development milestone under the collaboration agreement. Upon the achievement of certain development, regulatory and commercial milestones, AbbVie could make additional payments of up to \$400 million. In the United States, the companies will jointly commercialize duvelisib and will share equally in any potential profits. Outside the United States, AbbVie will be responsible for the commercialization of duvelisib, and Infinity is eligible to receive tiered double-digit royalties on net product sales.

### *Ablynx NV*

In September 2013, AbbVie entered into a global collaboration agreement with Ablynx NV to develop and commercialize the anti-IL-6R Nanobody, ALX-0061, for the treatment of inflammatory diseases including rheumatoid arthritis and systemic lupus erythematosus, resulting in a charge to IPR&D of \$175 million. Upon the achievement of certain development, regulatory and commercial milestones, AbbVie could make additional payments of up to \$665 million, as well as royalties on net sales.

### *Galapagos NV*

In September 2013, AbbVie recorded a charge to IPR&D of \$45 million as a result of entering into a global collaboration with Galapagos NV (Galapagos) to discover, develop and commercialize cystic fibrosis therapies. Upon the achievement of certain development, regulatory and commercial milestones, AbbVie could make additional payments of up to \$360 million, as well as royalties on net sales.

### *Alvine Pharmaceuticals, Inc.*

In May 2013, AbbVie entered into a global collaboration with Alvine Pharmaceuticals, Inc. to develop ALV003, a novel oral treatment for patients with celiac disease. As part of the agreement, AbbVie made an initial upfront payment of \$70 million, which was expensed to IPR&D in the second quarter of 2013. As of December 31, 2015, AbbVie will not make any additional payments pursuant to this arrangement.

**Other Activity***United Therapeutics Corporation*

In August 2015, AbbVie entered into an agreement to purchase a rare pediatric disease priority review voucher (PRV) from United Therapeutics Corporation. The PRV entitles AbbVie to receive an FDA priority review of a single New Drug Application or Biologics License Application, which reduces the target review time and could lead to an expedited approval. In exchange for the PRV, AbbVie made a payment of \$350 million, which was recorded in R&D expenses in the consolidated statement of earnings and as an operating cash outflow in the consolidated statement of cash flows for 2015. AbbVie intends to use the PRV for an existing R&D project.

*Termination of Proposed Combination with Shire*

On October 15, 2014, AbbVie's board of directors withdrew its previous recommendation to AbbVie stockholders in favor of a proposed combination with Shire, and recommended stockholders vote against the proposed combination. On October 20, 2014, AbbVie and Shire mutually agreed to terminate the proposed combination. In 2014, the company incurred transaction and financing-related costs totaling \$1.8 billion, of which \$1.7 billion was recorded in SG&A expenses and \$141 million was recorded in interest expense, net in the consolidated statement of earnings. Included in SG&A expenses was a break fee of \$1.6 billion, which was tax deductible, paid by AbbVie to Shire in October 2014 as a result of the termination of the proposed combination. In addition, the company recorded \$666 million of net foreign exchange losses primarily due to undesignated forward contracts that were entered into to hedge anticipated foreign currency cash outflows associated with the terminated proposed combination with Shire and the exit of certain foreign currency positions. The forward contracts were settled in 2014. In the first quarter of 2015, AbbVie recorded additional foreign exchange losses of \$170 million to reflect the completed liquidation of its remaining foreign currency positions. Refer to Note 10 for further information regarding these forward contracts entered into in anticipation of the proposed combination with Shire.

**Note 6 Collaboration with Janssen Biotech, Inc.**

In December 2011, Pharmacyclics entered into a worldwide collaboration and license agreement with Janssen for the joint development and commercialization of IMBRUVICA, a novel, orally active, selective covalent inhibitor of BTK, and certain compounds structurally related to IMBRUVICA, for oncology and other indications, excluding all immune and inflammatory mediated diseases or conditions and all psychiatric or psychological diseases or conditions, in the United States and outside the United States.

The collaboration provides Janssen with an exclusive license to commercialize IMBRUVICA outside of the United States and co-exclusively with AbbVie in the United States. Both parties are responsible for the development, manufacturing and marketing of any products generated as a result of the collaboration. The collaboration has no set duration or specific expiration date and provides for potential future development, regulatory and approval milestone payments of up to \$200 million to AbbVie.

The collaboration includes a cost sharing arrangement for associated collaboration activities. Except in certain cases, in general, Janssen is responsible for approximately 60 percent of collaboration development costs and AbbVie is responsible for the remaining 40 percent of collaboration development costs. AbbVie and Janssen share pre-tax profits and losses equally from the commercialization of products. Janssen is responsible for and has exclusive rights to commercialize IMBRUVICA outside the United States. While both parties have co-exclusive rights to commercialize the products in the United States, AbbVie is the principal in the end customer product sales. Operating expenses for costs incurred under the collaboration are reported in their respective expense line items, net of any payments due or reimbursements due from Janssen. Revenues and profit share costs related to sales of IMBRUVICA in the United States are included in net revenues and cost of products sold, respectively. Amounts payable to AbbVie by Janssen for IMBRUVICA sales outside the United States are included in net revenues.

## Edgar Filing: AbbVie Inc. - Form 10-K

Janssen's share of the pre-tax profits in the United States under the collaboration was \$306 million for 2015 and was recorded within cost of products sold in the consolidated statement of earnings. For 2015, AbbVie's share of pre-tax profits outside the United States and cost sharing expenses under the collaboration were \$95 million and \$159 million, respectively.

At December 31, 2015, AbbVie's receivable from Janssen was \$45 million and AbbVie's payable to Janssen was \$134 million, which were classified in accounts and other receivables, net and accounts payable and accrued liabilities, respectively, in AbbVie's consolidated balance sheet.

### Note 7 Goodwill and Intangible Assets

#### Goodwill

The following table summarizes the changes in the carrying amount of AbbVie's goodwill:

(in millions)

Balance as of December 31, 2013	\$ 6,277
Additions	
Foreign currency translation and other adjustments	(415)
Balance as of December 31, 2014	5,862
Additions	7,610
Foreign currency translation and other adjustments	(304)
Balance as of December 31, 2015	\$ 13,168

Goodwill additions in 2015 related to the acquisition of Pharmacyclics. Refer to Note 5 for additional information regarding this acquisition. The latest impairment assessment of goodwill was completed in the third quarter of 2015. As of December 31, 2015, there were no accumulated goodwill impairment losses. Future impairment tests for goodwill will be performed annually in the third quarter, or earlier if indicators of impairment exist.

#### Intangible Assets, Net

The following table summarizes AbbVie's intangible assets:

as of December 31 (in millions)	2015			2014		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
<b>Definite-lived intangible assets</b>						
Developed product rights	\$ 9,103	\$ (3,944)	\$ 5,159	\$ 4,546	\$ (3,706)	\$ 840
License agreements	8,000	(1,023)	6,977	1,097	(869)	228
Total definite-lived intangible assets	17,103	(4,967)	12,136	5,643	(4,575)	1,068
Indefinite-lived research and development	7,573		7,573	445		445
Total intangible assets, net	\$ 24,676	\$ (4,967)	\$ 19,709	\$ 6,088	\$ (4,575)	\$ 1,513

Intangible assets with finite useful lives are amortized over their estimated useful lives, which range between 3 to 16 years with an average of 12 years and 11 years for developed product rights and license agreements, respectively. Additions in 2015 were primarily due to the

## Edgar Filing: AbbVie Inc. - Form 10-K

acquisition of Pharmacyclics and those amounts will be amortized using the estimated pattern of economic benefit. Refer to Note 5 for additional information regarding this acquisition. Additions in 2014 are primarily related to the acquisition of \$80 million of amortizable intangible assets under license agreements for on-market product rights in the United States with an average amortization period of 10 years.

## Edgar Filing: AbbVie Inc. - Form 10-K

Amortization expense for 2015, 2014, and 2013 was \$419 million, \$403 million, and \$509 million, respectively, and is included in cost of products sold in the consolidated statements of earnings. The anticipated annual amortization expense for definite lived intangible assets recorded as of December 31, 2015 is \$655 million in 2016, \$740 million in 2017, \$894 million in 2018, \$1.0 billion in 2019 and \$1.1 billion in 2020. In the third quarter of 2014, an impairment charge of \$37 million was recorded related to certain on-market product rights in Japan due to increased generic competition. The charge was based on a discounted cash flow analysis and was included in cost of products sold in the consolidated statement of earnings.

The indefinite-lived intangible assets represent acquired IPR&D associated with products that have not yet received regulatory approval. The indefinite-lived intangible assets as of December 31, 2014 relate to IPR&D acquired in a business combination. The increase in 2015 was primarily due to the acquisition of Pharmacyclics. The latest impairment assessment of intangible assets not subject to amortization was completed in the third quarter of 2015. No impairment charges were recorded in 2015. Impairment charges recorded in 2014 related to indefinite-lived intangible assets were not material. Future impairment tests for indefinite-lived intangible assets will be performed annually in the third quarter, or earlier if indicators of impairment exist.

### Note 8 Restructuring Plans

AbbVie continuously evaluates its operations to identify opportunities to optimize its manufacturing and R&D operations, commercial infrastructure, and administrative costs and to respond to changes in its business environment, for example, in conjunction with the loss and expected loss of exclusivity of certain products. As a result, AbbVie management periodically approves individual restructuring plans to achieve these objectives. In 2015, 2014 and 2013, no such plans were individually material. Restructuring charges recorded in 2015, 2014 and 2013 were \$138 million, \$23 million, \$83 million, respectively, and were primarily related to employee severance and contractual obligations. These charges were recorded in cost of products sold, R&D expenses, and SG&A expenses in the consolidated statements of earnings based on classification of the affected employees or operations.

The following summarizes the cash activity in the restructuring reserve for 2015, 2014 and 2013:

(in millions)

Accrued balance at December 31, 2012	\$	233
2013 restructuring charges		76
Payments and other adjustments		(118)
Accrued balance at December 31, 2013		191
2014 restructuring charges		16
Payments and other adjustments		(85)
Accrued balance at December 31, 2014		122
2015 restructuring charges		126
Payments and other adjustments		(100)
Accrued balance at December 31, 2015	\$	148

Payments and other adjustments for 2013 included a \$23 million reversal of a previously recorded restructuring reserve due to the company's re-evaluation of a prior year decision to exit a manufacturing facility.



**Note 9 Debt, Credit Facilities, and Commitments and Contingencies**

The following is a summary of AbbVie's long-term debt:

as of December 31 (in millions)	Effective interest rate in 2015(a)	2015	Effective interest rate in 2014(a)	2014
<b>Senior notes issued in 2012:</b>				
Floating rate notes due 2015	1.13%	\$	1.09%	\$ 500
1.2% notes due 2015	1.29%		1.31%	3,500
1.75% notes due 2017	1.86%	4,000	1.86%	4,000
2.0% notes due 2018	2.15%	1,000	2.15%	1,000
2.9% notes due 2022	2.97%	3,100	2.97%	3,100
4.4% notes due 2042	4.46%	2,600	4.46%	2,600
<b>Senior notes issued in 2015:</b>				
1.8% notes due 2018	1.92%	3,000		
2.5% notes due 2020	2.65%	3,750		
3.2% notes due 2022	3.28%	1,000		
3.6% notes due 2025	3.66%	3,750		
4.5% notes due 2035	4.58%	2,500		
4.7% notes due 2045	4.73%	2,700		
<b>Term loan facilities:</b>				
Floating rate notes due 2016	1.23%	2,000		
Floating rate notes due 2018	1.38%	2,000		
Other		139		115
Fair value hedges		(72)		(180)
Unamortized bond discounts		(85)		(49)
Unamortized deferred financing costs		(117)		(34)
Total long-term debt and lease obligations		31,265		14,552
Current portion		2,025		4,014
Noncurrent portion		\$ 29,240		\$ 10,538

(a)

Excludes the effect of any related interest rate swaps.

On September 25, 2015, AbbVie entered into a \$2 billion three-year term loan credit agreement and a \$2 billion 364-day term loan credit agreement (collectively, the term loan facilities). In November 2015, AbbVie drew on these term loan facilities and used the proceeds to refinance its \$4 billion of senior notes that matured in November 2015. The borrowings under the term loan facilities bear interest at variable rates which will adjust based on AbbVie's public debt ratings. The term loan facilities may be prepaid without penalty upon prior notice and contain customary covenants, all of which the company was in compliance with as of December 31, 2015.

In May 2015, the company issued \$16.7 billion aggregate principal amount of unsecured senior notes. The senior notes rank equally with all other unsecured and unsubordinated indebtedness of the company. AbbVie may redeem the senior notes prior to maturity at a redemption price equal to the principal amount of the senior notes redeemed plus a make-whole premium and, except for the 1.8% notes due 2018, AbbVie may redeem the senior notes at par between one and six months prior to maturity. Debt issuance costs incurred in connection with the offering totaled \$93 million and are being amortized over the respective terms of the senior notes to interest expense, net in the consolidated statements of earnings. The senior notes contain customary covenants, all of which the company was in compliance with as of December 31, 2015.

## Edgar Filing: AbbVie Inc. - Form 10-K

Approximately \$11.5 billion of the net proceeds from the issuance of the senior notes were used to finance the acquisition of Pharmacyclics and approximately \$5.0 billion of the net proceeds were used to finance the ASR with Morgan Stanley. Refer to Notes 5 and 12 for additional information related to the acquisition of Pharmacyclics and the ASR, respectively.

In March 2015, AbbVie entered into an \$18 billion, 364-Day Bridge Term Loan Credit Agreement (the bridge loan) in support of the then planned acquisition of Pharmacyclics. No amounts were drawn under the bridge loan, which was terminated as a result of the company's May 2015 issuance of the senior notes. Interest expense, net in 2015 include \$86 million of costs related to the bridge loan.

AbbVie has outstanding \$10.7 billion aggregate principal amount of unsecured senior notes which were issued in 2012. AbbVie may redeem all of the senior notes of each series, at any time, and some of the senior notes of each series, from time to time, at a redemption price equal to the principal amount of the senior notes redeemed plus a make-whole premium. At December 31, 2015, the company was in compliance with its senior note covenants.

### Short-Term Borrowings

At December 31, 2015 and 2014, short-term borrowings included \$400 million and \$416 million, respectively, of commercial paper borrowings. The weighted-average interest rate on short-term borrowings was 0.3 percent and 0.2 percent for 2015 and 2014, respectively.

In October 2014, AbbVie entered into a \$3.0 billion five-year revolving credit facility, which matures in October 2019 and replaced a \$2.0 billion five-year revolving credit facility. 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, 2015, the company was in compliance with all its credit facility covenants. Commitment fees under AbbVie's revolving credit facilities were not material in 2015, 2014 and 2013. No amounts were outstanding under the credit facility as of December 31, 2015 and December 31, 2014.

### Maturities of Long-Term Debt and Capital Lease Obligations

The following table summarizes AbbVie's future minimum lease payments under non-cancelable operating leases and debt maturities and future minimum lease payments for capital lease obligations as of December 31, 2015:

as of and for the years ended December 31 (in millions)	Operating leases	Debt maturities and capital leases
2016	\$ 119	\$ 2,025
2017	111	4,024
2018	97	6,025
2019	86	18
2020	78	3,760
Thereafter	519	15,687
Total obligations and commitments	1,010	31,539
Fair value hedges and unamortized bond discounts and deferred financing costs		(274)
Total debt and lease obligations	\$ 1,010	\$ 31,265

Lease expense was \$146 million in 2015, \$115 million in 2014, and \$107 million in 2013. AbbVie's operating leases generally include renewal options and provide for the company to pay taxes, maintenance, insurance and other operating costs of the leased property. As of December 31, 2015, annual future minimum lease payments for capital lease obligations are not material.

Debt maturities and capital leases in 2016 include the \$2.0 billion floating rate notes due in 2016 drawn under the 364-day term loan credit agreement.

### Contingencies and Guarantees

In connection with the separation, AbbVie has indemnified Abbott for all liabilities resulting from the operation of AbbVie's business other than income tax liabilities with respect to periods prior to the distribution date and other liabilities as agreed to by AbbVie and Abbott. AbbVie has no material exposures to off-balance sheet arrangements, no special-purpose entities and no activities that included non-exchange-traded contracts accounted for at fair value. In the ordinary course of business, AbbVie has periodically entered into third-party agreements, such as the assignment of product rights, which have resulted in AbbVie becoming secondarily liable for obligations for which AbbVie had previously been primarily liable. Based upon past experience, the likelihood of payments under these agreements is remote. AbbVie periodically acquires a business or product rights in which AbbVie agrees to pay contingent consideration based on attaining certain thresholds or based on the occurrence of certain future events.

## Note 10 Financial Instruments and Fair Value Measures

### Risk Management Policy

The company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. The company's hedging policy attempts to manage these risks to an acceptable level based on the company's judgment of the appropriate trade-off between risk, opportunity and costs. The company uses derivative instruments to reduce its exposure to foreign currency exchange rates. The company is also exposed to the risk that its earnings and cash flows could be adversely impacted by fluctuations in interest rates. The company periodically enters into interest rate swaps, based on judgment, to manage interest costs in which the company agrees to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional amount. Derivative instruments are not used for trading purposes or to manage exposure to changes in interest rates for investment securities, and none of the company's outstanding derivative instruments contain credit risk related contingent features; collateral is generally not required.

### Financial Instruments

Various AbbVie foreign subsidiaries enter into foreign currency forward exchange contracts to manage exposures to changes in foreign exchange rates for anticipated intercompany transactions denominated in a currency other than the functional currency of the local entity. These contracts, with notional amounts totaling \$1.5 billion and \$1.4 billion at December 31, 2015 and December 31, 2014, respectively, are designated as cash flow hedges and are recorded at fair value. Resulting gains or losses are reflected in OCI. Accumulated gains and losses as of December 31, 2015 will be reclassified from AOCI and included in cost of products sold at the time the products are sold, generally not exceeding twelve months.

The company also enters into foreign currency forward exchange contracts to manage its exposure to foreign currency denominated trade payables and receivables and intercompany loans. These contracts are not designated as hedges and are recorded at fair value. Resulting gains or losses are reflected in net foreign exchange loss in the consolidated statements of earnings and are generally offset by losses or gains on the foreign currency exposure being managed. At December 31, 2015 and December 31, 2014, AbbVie held notional amounts of \$6.8 billion and \$6.8 billion, respectively, of such undesignated foreign currency forward exchange contracts.

In 2014, the company entered into undesignated forward exchange contracts with a total notional amount of \$16.9 billion to hedge anticipated foreign currency cash outflows associated with the terminated proposed combination with Shire. A large portion of these contracts were originally due to mature in the

Edgar Filing: AbbVie Inc. - Form 10-K

first quarter of 2015 but were net settled in the fourth quarter of 2014. In 2014, the company realized \$490 million in net foreign exchange losses associated with the Shire-related forward exchange contracts.

AbbVie is a party to interest rate hedge contracts, designated as fair value hedges, totaling \$11.0 billion and \$8.0 billion at December 31, 2015 and December 31, 2014, respectively. The effect of the hedge is to change a fixed-rate interest obligation to a floating rate for that portion of the debt. AbbVie recorded the contracts at fair value and adjusted the carrying amount of the fixed-rate debt by an offsetting amount.

The following table summarizes the amounts and location of AbbVie's derivative instruments in the consolidated balance sheets:

as of December 31 (in millions)	Fair value		Derivatives in asset position	Fair value		Derivatives in liability position
	2015	2014	Balance sheet caption	2015	2014	Balance sheet caption
Foreign currency forward exchange contracts						
Hedging instruments			Prepaid expenses and other	\$	\$	Accounts payable and accrued liabilities
	\$ 33	\$ 141				
Others not designated as hedges			Prepaid expenses and other	21	63	Accounts payable and accrued liabilities
	28	70				
Interest rate swaps designated as fair value hedges			Prepaid expenses and other	81	180	Other long-term liabilities
	9					
<b>Total derivatives</b>	<b>\$ 70</b>	<b>\$ 211</b>		<b>\$ 102</b>	<b>\$ 243</b>	

While certain derivatives are subject to netting arrangements with the company's counterparties, the company does not offset derivative assets and liabilities within the consolidated balance sheets.

The unrealized gains/(losses) for the effective portions of the derivative instruments designated as cash flow hedges recognized in OCI were \$122 million, \$193 million and (\$77) million for 2015, 2014, and 2013, respectively. The amount of hedge ineffectiveness was not significant for any of the years presented.

The following table summarizes the pre-tax amounts and location in the consolidated statements of earnings of net gains/(losses) recognized in the consolidated statements of earnings for derivative instruments, including the effective portions of the net gains/(losses) reclassified out of AOCI into net earnings for 2015, 2014, and 2013, respectively. See Note 12 for the amount of net gains/(losses) reclassified out of AOCI.

years ended December 31 (in millions)				Statement of earnings caption
	2015	2014	2013	
Foreign currency forward exchange contracts				
Designated as cash flow hedges	\$ 265	\$ (79)	\$	Cost of products sold
Not designated as hedges	(155)	(523)	81	Net foreign exchange loss
Interest rate swaps designated as fair value hedges	108	252	(351)	Interest expense, net
<b>Total</b>	<b>\$ 218</b>	<b>\$ (350)</b>	<b>\$ (270)</b>	

The gain/(loss) related to fair value hedges is recognized in interest expense, net in the consolidated statements of earnings and directly offsets the (loss)/gain on the underlying hedged item, the fixed-rate debt, resulting in no net impact to interest expense, net for all periods

presented.

**Fair Value Measures**

The fair value hierarchy under the accounting standard for fair value measurements consists of the following three levels:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets that the company has the ability to access;

Level 2 Valuations based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuations in which all significant inputs are observable in the market; and

Level 3 Valuations using significant inputs that are unobservable in the market and include the use of judgment by the company's management about the assumptions market participants would use in pricing the asset or liability.

The following table summarizes the bases used to measure certain assets and liabilities that are carried at fair value on a recurring basis in the consolidated balance sheet as of December 31, 2015:

(in millions)	Total	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable Inputs (Level 3)
<b>Assets</b>				
Cash and equivalents	\$ 8,399	\$ 798	\$ 7,601	\$
Time deposits	8		8	
Equity securities	111	111		
Interest rate hedges	9		9	
Foreign currency contracts	61		61	
Total assets	\$ 8,588	\$ 909	\$ 7,679	\$
<b>Liabilities</b>				
Interest rate hedges	\$ 81		\$ 81	\$
Foreign currency contracts	21		21	
Total liabilities	\$ 102		\$ 102	\$

Edgar Filing: AbbVie Inc. - Form 10-K

The following table summarizes the bases used to measure certain assets and liabilities that are carried at fair value on a recurring basis in the consolidated balance sheet as of December 31, 2014:

(in millions)	Total	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable Inputs (Level 3)
<b>Assets</b>				
Cash and equivalents	\$ 8,348	\$ 1,214	\$ 7,134	\$
Time deposits	9		9	
Equity securities	13	13		
Foreign currency contracts	211		211	
Total assets	\$ 8,581	\$ 1,227	\$ 7,354	\$
<b>Liabilities</b>				
Interest rate hedges	\$ 180		\$ 180	\$
Foreign currency contracts	63		63	
Total liabilities	\$ 243		\$ 243	\$

The fair values for time deposits included in cash and equivalents and short-term investments are determined based on a discounted cash flow analysis reflecting quoted market rates for the same or similar instruments. The fair values of time deposits approximate their amortized cost due to the short maturities of these instruments. Available-for-sale equity securities consists of investments for which the fair values are determined by using the published market price per unit multiplied by the number of units held, without consideration of transaction costs. The derivatives entered into by the company are valued using publicized spot curves for interest rate hedges and publicized forward curves for foreign currency contracts.

Cumulative net unrealized holding gains on available-for-sale equity securities totaled \$47 million and \$3 million at December 31, 2015 and December 31, 2014, respectively.

There have been no transfers of assets or liabilities between the fair value measurement levels.

In addition to the financial instruments that the company is required to recognize at fair value on the consolidated balance sheets, the company has certain financial instruments that are recognized at historical cost or some basis other than fair value. The carrying values and fair values of certain financial instruments are summarized in the table below:

as of December 31 (in millions)	Book values		Approximate fair values	
	2015	2014	2015	2014
<b>Assets</b>				
Investments	\$ 34	\$ 95	\$ 37	\$ 145
<b>Liabilities</b>				
Short-term borrowings	\$ 406	\$ 425	\$ 406	\$ 425
Current portion of long-term debt and lease obligations	\$ 2,025	\$ 4,014	\$ 2,016	\$ 4,026
Long-term debt and lease obligations, excluding fair value hedges	\$ 29,312	\$ 10,718	\$ 29,143	\$ 10,803





Edgar Filing: AbbVie Inc. - Form 10-K

The following table summarizes the bases used to measure the approximate fair values of the financial instruments as of December 31, 2015:

(in millions)	Total	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable Inputs (Level 3)
<b>Assets</b>				
Investments	\$ 37	\$	\$	\$ 37
Total assets	\$ 37	\$	\$	\$ 37
<b>Liabilities</b>				
Short-term borrowings	\$ 406	\$	\$ 406	\$
Current portion of long-term debt and lease obligations	2,016		2,016	
Long-term debt and lease obligations, excluding fair value hedges	29,143	27,061	2,082	
Total liabilities	\$ 31,565	\$ 27,061	\$ 4,504	\$

The following table summarizes the bases used to measure the approximate fair values of the financial instruments as of December 31, 2014:

(in millions)	Total	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable Inputs (Level 3)
<b>Assets</b>				
Investments	\$ 145	\$ 68	\$ 13	\$ 64
Total assets	\$ 145	\$ 68	\$ 13	\$ 64
<b>Liabilities</b>				
Short-term borrowings	\$ 425	\$	\$ 425	\$
Current portion of long-term debt and lease obligations	4,026	4,005	21	
Long-term debt and lease obligations, excluding fair value hedges	10,803	10,710	93	
Total liabilities	\$ 15,254	\$ 14,715	\$ 539	\$

Investments consist of cost method investments and held-to-maturity debt securities. To determine the fair values of other cost method investments, the company takes into consideration recent transactions, as well as the financial information of the investee, which represents a Level 3 basis of fair value measurement. The fair value of held-to-maturity debt securities was estimated based upon the quoted market prices for the same or similar debt instruments. The fair values of short-term and current borrowings approximate the carrying values due to the short maturities of these instruments.

The fair values of long-term debt, excluding fair value hedges and the term loans, were determined by using the published market price for the debt instruments, without consideration of transaction costs, which represents a Level 1 basis of fair value measurement. The fair values of the term loans were determined based on a discounted cash flow analysis using quoted market rates, which represents a Level 2 basis of fair value measurement. The counterparties to financial instruments consist of select major international financial institutions.

## Concentrations of Risk

The company invests excess cash in time deposits and money market funds and diversifies the concentration of cash among different financial institutions. The company monitors concentrations of credit risk associated with deposits with financial institutions. Credit exposure limits have been established to limit a concentration with any single issuer or institution.

The functional currency of the company's Venezuela operations is the U.S. dollar due to the hyperinflationary status of the Venezuelan economy. Currency restrictions enacted in Venezuela require approval from the Venezuelan government to exchange Venezuelan bolivars (VEF) for U.S. dollars and require such exchange to be made at the official exchange rate established by the government. In the first quarter of 2014, the Venezuelan government expanded the number of exchange mechanisms to three rates of exchange. As of December 31, 2015, these were the official rate of 6.3; the Supplementary System for the Administration of Foreign Currency (SICAD) rate of approximately 13.5; and the Foreign Exchange Marginal System (SIMADI) rate of approximately 200. In the consolidated financial statements as of and for the year ended December 31, 2015, the company used the official rate of 6.3 VEF per U.S. dollar, and reported \$317 million of net monetary assets and \$210 million of net revenues denominated in the Venezuelan bolivar.

On February 17, 2016, the Venezuelan government announced that it plans to devalue the official rate of 6.3 to 10 VEF to U.S. dollars, and eliminate the SICAD rate of 13.5 VEF to U.S. dollars. The devaluation of the Venezuelan bolivar will result in a charge to AbbVie's results of operations in the first quarter of 2016. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at a rate of 10 VEF to U.S. dollars at December 31, 2015, the company would have reported a devaluation loss of \$117 million in 2015. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at the SIMADI rate of 200 at December 31, 2015, the company would have reported a devaluation loss of \$307 million in 2015.

The company cannot predict whether there will be further devaluations of the Venezuelan currency or whether the use of the official rate will continue to be supported by evolving facts and circumstances, which could result in a significant charge to AbbVie's results of operations at that time.

The company also continues to do business with foreign governments in certain oil-exporting countries, including Venezuela and Saudi Arabia, which have experienced a deterioration in economic conditions. Due to the decline in the price of oil, liquidity issues in certain countries may result in delays in the collection of receivables.

Three U.S. wholesalers accounted for 51 percent and 49 percent of total net accounts receivable as of December 31, 2015 and December 31, 2014, respectively, and substantially all of AbbVie's net revenues in the United States are to these three wholesalers. In addition, net governmental receivables outstanding in Greece, Portugal, Italy and Spain totaled \$525 million at December 31, 2015 and \$446 million at December 31, 2014.

HUMIRA (adalimumab) is AbbVie's single largest product and accounted for approximately 61 percent, 63 percent, and 57 percent of AbbVie's total net revenues in 2015, 2014, and 2013, respectively.

## Note 11 Post-Employment Benefits

AbbVie sponsors various pension and other post-employment benefit plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. In addition, AbbVie provides medical benefits, primarily to eligible retirees in the United States and Puerto Rico, through other post-retirement benefit plans. Net obligations for these plans have been reflected in the consolidated balance sheets as of December 31, 2015 and 2014.

AbbVie's principal domestic defined benefit plan is the AbbVie Pension Plan. AbbVie employees who were eligible to participate in the Abbott pension plan on December 31, 2012 automatically became eligible for the AbbVie Pension Plan. During the first quarter of 2013, the AbbVie Pension Plan assumed the obligations and related assets for AbbVie employees from Abbott. AbbVie made voluntary contributions of

Edgar Filing: AbbVie Inc. - Form 10-K

\$150 million, \$370 million, and \$145 million in 2015, 2014, and 2013 respectively, to this plan. AbbVie also made a voluntary contribution of \$150 million to this plan subsequent to December 31, 2015.

The benefit plan information in the table below pertains to the global AbbVie-sponsored defined benefit and other post-employment plans:

as of and for the years ended December 31 (in millions)	Defined benefit plans		Other post-employment plans	
	2015	2014	2015	2014
<b>Projected benefit obligations</b>				
Beginning of period	\$ 5,681	\$ 4,484	\$ 538	\$ 403
Service cost	227	173	25	22
Interest cost	219	217	23	22
Employee contributions	2	1		
Plan amendments		1		(13)
Actuarial (gain) loss	(467)	1,108	(17)	111
Benefits paid	(158)	(163)	(11)	(8)
Other, primarily foreign currency translation adjustments	(117)	(140)	(1)	1
End of period	5,387	5,681	557	538
<b>Fair value of plan assets</b>				
Beginning of period	4,173	3,666		
Actual (loss) return on plan assets	(25)	282		
Company contributions	217	430	11	8
Employee contributions	2	1		
Benefits paid	(158)	(163)	(11)	(8)
Other, primarily foreign currency translation adjustments	(35)	(43)		
End of period	4,174	4,173		
Funded status end of period	\$ (1,213)	\$ (1,508)	\$ (557)	\$ (538)
<b>Amounts recognized in the consolidated balance sheets</b>				
Other non-current assets	\$ 214	\$ 210	\$	\$
Accounts payable and accrued liabilities	(24)	(26)	(11)	(10)
Other long-term liabilities	(1,403)	(1,692)	(546)	(528)
Net obligation	\$ (1,213)	\$ (1,508)	\$ (557)	\$ (538)
Actuarial losses, net	\$ 1,939	\$ 2,216	\$ 154	\$ 181
Prior service cost	16	19	(45)	(53)
Accumulated other comprehensive loss at December 31	\$ 1,955	\$ 2,235	\$ 109	\$ 128

The projected benefit obligations (PBO) in the table above included \$1.5 billion and \$1.4 billion at December 31, 2015 and 2014, respectively, related to international defined benefit plans, a number of which generally are not funded as permitted by local regulations. Benefit payments under those plans are funded from company assets. AbbVie considered the release of the new mortality tables and projection scales by the Society of Actuaries in 2014 and determined they were an improvement of the estimate of future mortality and opted to change to the new tables in determining the funded status as of December 31, 2014. In 2015, the Society of Actuaries released an improvement scale that adjusted

## Edgar Filing: AbbVie Inc. - Form 10-K

the previously issued 2014 scale which AbbVie determined was appropriate to utilize in determining the funded status as of December 31, 2015.

For plans reflected in the table above, the accumulated benefit obligations (ABO) were \$4.8 billion and \$5.0 billion at December 31, 2015 and 2014, respectively. For those plans reflected in the table above in which the ABO exceeded plan assets at December 31, 2015, the ABO, PBO and aggregate plan assets were \$3.1 billion, \$3.6 billion and \$2.2 billion, respectively.

## Edgar Filing: AbbVie Inc. - Form 10-K

### *Amounts Recognized in Accumulated Other Comprehensive Loss and Other Comprehensive (Loss) Income*

The defined benefit and other post-employment plans' actuarial (gains) or losses and prior service costs or (credits) not yet recognized in net periodic benefit cost are included in AOCI, net of tax, and will be amortized to net periodic benefit cost in future periods. The following table summarizes the pre-tax gains and losses included in other comprehensive (loss) income:

years ended December 31 (in millions)	2015	2014	2013
<b>Defined benefit plans</b>			
Actuarial (gain) loss	\$ (117)	\$ 1,127	\$ (715)
Prior service cost		1	15
Amortization of actuarial losses and prior service costs	(127)	(68)	(114)
Foreign exchange (gain) loss	(37)	(41)	2
<b>Total pre-tax (gain) loss recognized in other comprehensive (income) loss</b>	<b>\$ (281)</b>	<b>\$ 1,019</b>	<b>\$ (812)</b>
<b>Other post-employment plans</b>			
Actuarial (gain) loss	\$ (17)	\$ 111	\$ (42)
Prior service cost		(13)	(53)
Amortization of actuarial losses and prior service costs	(2)	3	
<b>Total pre-tax (gain) loss recognized in other comprehensive (income) loss</b>	<b>\$ (19)</b>	<b>\$ 101</b>	<b>\$ (95)</b>

The pre-tax amount of actuarial loss and prior service cost included in AOCI at December 31, 2015 that is expected to be recognized in net periodic benefit cost in 2016 is \$87 million for defined benefit plans and \$1 million for other post-employment plans.

### *Net Periodic Benefit Cost*

years ended December 31 (in millions)	2015	2014	2013
<b>Defined benefit plans</b>			
Service cost	\$ 227	\$ 173	\$ 184
Interest cost	219	217	196
Expected return on plan assets	(325)	(302)	(259)
Amortization of actuarial losses and prior service costs	127	68	114
<b>Net periodic benefit cost</b>	<b>\$ 248</b>	<b>\$ 156</b>	<b>\$ 235</b>
<b>Other post-employment plans</b>			
Service cost	\$ 25	\$ 22	\$ 23
Interest cost	23	22	19
Amortization of actuarial (gain) loss and prior service costs	2	(2)	(1)
<b>Net periodic benefit cost</b>	<b>\$ 50</b>	<b>\$ 42</b>	<b>\$ 41</b>

### *Weighted-Average Assumptions Used in Determining Benefit Obligations at the Measurement Date*

as of December 31	2015	2014
-------------------	------	------

<b>Defined benefit plans</b>		
Discount rate	4.4%	3.9%
Rate of compensation increases	4.4%	4.4%
<b>Other post-employment plans</b>		
Discount rate	4.9%	4.5%

The assumptions used in calculating the December 31, 2015 measurement date benefit obligations will be used in the calculation of net periodic benefit cost in 2016.

*Weighted-Average Assumptions Used in Determining Net Periodic Benefit Cost*

<b>years ended December 31</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
<b>Defined benefit plans</b>			
Discount rate	3.9%	4.9%	4.3%
Expected long-term rate of return on plan assets	7.8%	7.9%	8.2%
Expected rate of change in compensation	4.4%	5.0%	5.0%
<b>Other post-employment plans</b>			
Discount rate	4.5%	5.3%	4.5%

Effective December 31, 2015, AbbVie elected to change the method it uses to estimate the service and interest cost components of net periodic benefit costs for the AbbVie Pension Plan and its primary other post-employment benefit plan in the United States as well as certain international defined benefit plans and other post-employment benefit plans. Historically, AbbVie estimated these service and interest cost components of this expense utilizing a single weighted-average discount rate derived from the yield curve used to measure the benefit obligation at the beginning of the period. In late 2015, AbbVie elected to utilize a full yield curve approach in the estimation of these components by applying the specific spot rates along the yield curve used in the determination of the benefit obligation to the relevant projected cash flows. AbbVie elected to make this change to provide a more precise measurement of service and interest costs by improving the correlation between projected benefit cash flows to the corresponding spot yield curve rates. AbbVie has accounted for this change prospectively as a change in accounting estimate that is inseparable from a change in accounting principle. Based on current economic conditions, this change is expected to reduce AbbVie's net periodic benefit cost by approximately \$41 million in 2016. This change had no effect on the 2015 expense and will not affect the measurement of AbbVie's total benefit obligations as the change in service cost and interest cost will be completely offset in the actuarial (gain) loss reported.

For 2015, for purposes of measuring post-retirement health care obligations as of the measurement date, the company assumed a 7.3 percent pre-65 (8.3 percent post-65) annual rate of increase in the per capita cost of covered health care benefits. The rate was assumed to decrease gradually to 4.5 percent in 2064 and remain at that level thereafter. For purposes of measuring post-retirement health care costs, the company assumed a 7.5 percent pre-65 (7.3 percent post-65) annual rate of increase in the per capita cost of covered health care benefits. The rate was assumed to decrease gradually to 4.5 percent for 2064 and remain at that level thereafter.

Assumed health care cost trend rates have a significant effect on the amounts reported for health care plans. As of December 31, 2015, a 1 percentage point change in assumed health care cost trend rates would have the following effects:

<b>year ended December 31, 2015 (in millions) (brackets denote a reduction)</b>	<b>One percentage point</b>	
	<b>Increase</b>	<b>Decrease</b>
Service cost and interest cost	\$ 12	\$(9)
Projected benefit obligation	\$ 116	\$(90)



## Defined Benefit Pension Plan Assets

as of December 31 (in millions)	2015	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Equities</b>				
U.S. large cap <sup>(a)</sup>	\$ 1,041	\$ 542	\$ 499	\$
U.S. mid cap <sup>(b)</sup>	260	35	225	
International <sup>(c)</sup>	688	100	588	
<b>Fixed income securities</b>				
U.S. government securities <sup>(d)</sup>	178	15	163	
Corporate debt instruments <sup>(d)</sup>	440	124	297	19
Non-U.S. government securities <sup>(d)</sup>	182	33	149	
Other <sup>(d)</sup>	156	122	34	
Absolute return funds <sup>(e)</sup>	1,097	2	498	597
Real assets	39	8	7	24
Other <sup>(f)</sup>	93	93		
Fair value of plan assets	\$ 4,174	\$ 1,074	\$ 2,460	\$ 640

as of December 31 (in millions)	2014	Basis of fair value measurement		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Equities</b>				
U.S. large cap <sup>(a)</sup>	\$ 1,314	\$ 588	\$ 726	\$
U.S. mid cap <sup>(b)</sup>	267	67	200	
International <sup>(c)</sup>	608	137	471	
<b>Fixed income securities</b>				
U.S. government securities <sup>(d)</sup>	216		216	
Corporate debt instruments <sup>(d)</sup>	326	101	225	
Non-U.S. government securities <sup>(d)</sup>	425	201	224	
Other <sup>(d)</sup>	37	29	8	
Absolute return funds <sup>(e)</sup>	848	3	371	474
Real assets	53	7	46	
Other <sup>(f)</sup>	79	79		
Fair value of plan assets	\$ 4,173	\$ 1,212	\$ 2,487	\$ 474

(a)

## Edgar Filing: AbbVie Inc. - Form 10-K

A mix of pooled index funds and actively managed equity accounts that are benchmarked to various large cap indices.

(b) A mix of pooled index funds and actively managed equity accounts that are benchmarked to various mid cap indices.

(c) A mix of pooled index funds and actively managed equity accounts that are benchmarked to various non-US equity indices in both developed and emerging markets.

(d) Securities held by actively managed accounts, pooled index funds, and mutual funds.

(e) Funds having global mandates with the flexibility to allocate capital broadly across a wide range of asset classes and strategies, including but not limited to equities, fixed income, commodities, financial futures, currencies, and other securities, with objectives to outperform agreed upon benchmarks of specific return and volatility targets.

(f) Investments in cash and cash equivalents.

## Edgar Filing: AbbVie Inc. - Form 10-K

Equities that are valued using quoted prices are valued at the published market prices. Equities in a common collective trust or a registered investment company that are valued using significant other observable inputs are valued at the net asset value (NAV) provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund minus its liabilities. Fixed income securities that are valued using significant other observable inputs are valued at prices obtained from independent financial service industry-recognized vendors. Absolute return funds and commodities are valued at the NAV provided by the fund administrator.

The following table summarizes the change in the value of plan assets that are measured using significant unobservable inputs (Level 3):

<b>as of and for the years ended December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>
Beginning of period	\$ 474	\$ 411
Actual return on plan assets on hand at end of period	5	21
Purchases, sales and settlements, net	161	42
End of period	\$ 640	\$ 474

The investment mix of equity securities, fixed income and other asset allocation strategies is based upon achieving a desired return, balancing higher return, more volatile equity securities, and lower return, less volatile fixed income securities. Investment allocations are established for each plan and are generally made across a range of markets, industry sectors, capitalization sizes, and in the case of fixed income securities, maturities and credit quality. The target investment allocations for the AbbVie Pension Plan is 35 percent in equity securities, 20 percent in fixed income securities and 45 percent in asset allocation strategies and other holdings. There are no known significant concentrations of risk in the plan assets of the AbbVie Pension Plan or any other plans' assets.

The plans' expected return on plan assets assumption, as shown above, is based on management's expectations of long-term average rates of return to be achieved by the underlying investment portfolios. In establishing this assumption, management considers historical and expected returns for the asset classes in which the plans are invested, as well as current economic and capital market conditions.

### *Expected Defined Benefit and Other Post-Employment Plan Payments*

<b>years ended December 31 (in millions)</b>	<b>Defined benefit plans</b>	<b>Other post-employment plans</b>
2016	\$ 168	\$ 11
2017	\$ 177	\$ 14
2018	\$ 188	\$ 17
2019	\$ 199	\$ 20
2020	\$ 212	\$ 19
2021 to 2025	\$ 1,295	\$ 133

The above table reflects total benefit payments expected to be paid to participants, which includes payments funded from company assets as well as paid from the plans.

### **Other**

AbbVie's principal defined contribution plan is the AbbVie Savings Plan. AbbVie recorded expense of \$73 million in 2015, \$67 million in 2014, and \$62 million in 2013 related to this plan. AbbVie provides certain other post-employment benefits, primarily salary continuation arrangements, to qualifying employees and accrues for the related cost over the service lives of the employees.

## Note 12 Equity

### Stock-Based Compensation

Stock-based compensation expense was \$282 million, \$241 million, and \$212 million in 2015, 2014, and 2013, respectively, and is principally classified in SG&A for all periods presented, with the remainder classified in R&D expenses and cost of products sold. The related tax benefit recognized in 2015, 2014, and 2013 was \$89 million, \$73 million, and \$68 million, respectively.

Compensation expense for stock-based awards is measured based on the fair value of the awards, as of the date the stock-based awards are granted and adjusted to the estimated number of awards that are expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. Compensation cost for stock-based awards is amortized over their service period, which could be shorter than the vesting period if an employee is retirement eligible, with a charge to compensation expense. For stock-based awards granted to retirement-eligible employees, compensation expense is recognized immediately at the grant date because the employee is able to retain the award without continuing to provide service. Retirement eligible employees are generally those that are age 55 and have at least ten years of service.

Prior to separation, AbbVie employees participated in Abbott's incentive stock program. The AbbVie 2013 Incentive Stock Program, adopted at the time of separation, facilitated the assumption of certain awards granted under Abbott's incentive stock program and authorizes the post-separation grant of several different forms of benefits, including nonqualified stock options, RSAs, RSUs, and performance-based RSAs and RSUs. Under the AbbVie 2013 Incentive Stock Program, 100 million shares of common stock were reserved for issuance with respect to post-separation awards for participants.

In connection with the separation, outstanding Abbott employee stock options, RSAs and RSUs previously issued under Abbott's incentive stock program were adjusted and converted into new Abbott and AbbVie stock-based awards using a formula designed to preserve the intrinsic value and fair value of the awards immediately prior to the separation. Upon the separation on January 1, 2013, holders of Abbott stock options, RSAs and RSUs generally received one AbbVie stock-based award for each Abbott stock-based award outstanding. These adjusted awards retained the vesting schedule and expiration date of the original awards. No AbbVie awards have been granted to Abbott employees other than in connection with the separation.

In 2015, 2014, and 2013, realized excess tax benefits associated with stock-based compensation and recorded in additional paid-in capital totaled \$61 million, \$56 million, and \$38 million, respectively, and were presented in the consolidated statements of cash flows as an outflow in operating activities and an inflow in financing activities.

### *Stock Options*

The exercise price for options granted is at least equal to 100 percent of the fair value on the date of grant. Stock options typically have a contractual term of 10 years and generally vest in one-third increments over a three-year period.

## Edgar Filing: AbbVie Inc. - Form 10-K

The fair value of stock options is determined using the Black-Scholes model. The weighted-average grant-date fair values of stock options granted were \$9.96, \$9.83, and \$6.87 in 2015, 2014, and 2013, respectively. Stock-based compensation expense attributable to options during each of the years presented was not material.

The following table summarizes AbbVie stock option activity in 2015:

<b>year ended December 31</b> <b>(options in thousands, aggregate intrinsic value in millions)</b>	<b>Options</b>	<b>Weighted- average exercise price</b>	<b>Weighted- average remaining life (in years)</b>	<b>Aggregate intrinsic value</b>
Outstanding at beginning of period	28,280	\$ 28.53	3.3	\$ 1,044
Granted	1,207	58.83		
Exercised	(5,871)	26.31		
Lapsed	(47)	27.50		
Outstanding at end of period	23,569	\$ 30.64	3.0	\$ 674
Exercisable at end of period	21,091	\$ 28.16	2.4	\$ 656

The aggregate intrinsic value in the table above represents the difference between the exercise price and the company's closing share price on the last day of trading in 2015. The total intrinsic value of options exercised in 2015, 2014 and 2013 was \$216 million, \$253 million, and \$229 million respectively. The total fair value of options vested during 2015 was \$10 million.

### **RSAs & RSUs**

RSAs and RSUs generally vest in one-third increments over three years. Upon vesting, the recipient receives one share of common stock for each vested award. AbbVie grants performance-based RSAs and RSUs to selected executives and other key employees with vesting primarily contingent upon AbbVie achieving a minimum return on equity. The fair value of RSAs and RSUs (including performance-based awards) is determined based on the number of shares granted and the quoted price of AbbVie's common stock on the date of grant. For purposes of determining compensation expense, AbbVie periodically evaluates whether the performance goals will be achieved. If such goals are not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

The following table summarizes AbbVie RSA and RSU activity (including performance-based awards) for both AbbVie and Abbott employees for 2015:

<b>year ended December 31 (share units in thousands)</b>	<b>Share units</b>	<b>Weighted-average grant date fair value</b>
Outstanding at beginning of period	12,815	\$ 40.98
Granted	6,052	60.85
Vested	(5,702)	37.46
Lapsed	(675)	51.11
Outstanding at end of period	12,490	\$ 51.66

The fair market value of RSAs and RSUs vested in 2015, 2014 and 2013 was \$335 million, \$338 million and \$285 million, respectively.

## Edgar Filing: AbbVie Inc. - Form 10-K

As of December 31, 2015, \$239 million of unrecognized compensation cost related to RSAs and RSUs is expected to be recognized as expense over approximately the next two years.

## Cash Dividends

On February 13, May 15, August 14 and November 16, 2015, AbbVie paid quarterly cash dividends of \$0.49, \$0.51, \$0.51 and \$0.51 per share of common stock, respectively, which were declared by the board of directors on October 20, 2014 and February 19, June 18, and September 11, 2015 respectively. The dividends declared on October 20, 2014 and February 19, 2015, represented an increase of nearly 17 percent and approximately 4 percent, respectively, over the previous quarterly rates of \$0.42 per share and \$0.49 per share, respectively. On October 30, 2015, the company announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.51 per share to \$0.57 per share beginning with the dividend payable on February 16, 2016 to stockholders of record as of January 15, 2016. This reflects an increase of approximately 12 percent over the previous quarterly rate.

On February 14, May 15, August 15, and November 17, 2014, AbbVie paid quarterly cash dividends of \$0.40, \$0.42, \$0.42 and \$0.42 per share of common stock, respectively, which were declared by the board of directors on December 12, 2013 and February 20, June 19, and September 19, 2014, respectively.

## Stock Repurchase Program

On February 15, 2013, AbbVie's board of directors authorized a \$1.5 billion stock repurchase program. On October 20, 2014, AbbVie's board of directors authorized a new \$5.0 billion stock repurchase program, which was effective immediately and superseded the previous authorization. The current stock repurchase authorization permits purchases of AbbVie shares from time to time in open market or private transactions at management's discretion depending on the company's cash flows, net debt level and market conditions. The program has no time limit and can be discontinued at any time.

In March 2015, the board of directors authorized a \$5.0 billion increase to the existing stock repurchase program in anticipation of executing an accelerated share repurchase agreement in connection with the acquisition of Pharmacyclics. On May 26, 2015, AbbVie entered into and executed the \$5.0 billion ASR with Morgan Stanley. Pursuant to the terms of ASR, Morgan Stanley made an initial delivery of approximately 68 million shares of AbbVie's common stock on May 27, 2015, which represented approximately 90 percent of the total shares expected to be delivered under the ASR. Morgan Stanley subsequently delivered an additional 5 million shares of AbbVie's common stock to AbbVie in final settlement of the ASR in 2015. AbbVie recorded the aggregate \$5.0 billion purchase price as a reduction to common stock held in treasury in the consolidated balance sheet as of December 31, 2015.

In addition to the ASR, AbbVie repurchased approximately 46 million shares, 9 million shares, and 4 million shares for \$2.8 billion, \$550 million, and \$223 million in 2015, 2014 and 2013, respectively, in the open market. AbbVie settled \$300 million of its 2015 open market purchases in 2016. Shares repurchased under these programs are recorded at acquisition cost, including related expenses, and are available for general corporate purposes. AbbVie's remaining share repurchase authorization was \$1.9 billion as of December 31, 2015.

Edgar Filing: AbbVie Inc. - Form 10-K

Accumulated Other Comprehensive Loss

The following table summarizes the changes in each component of AOCI, net of tax, for 2015, 2014 and 2013:

(in millions) (brackets denote losses)	Foreign currency translation adjustments	Pension and post- employment benefits	Unrealized gains (losses) on marketable equity securities	Hedging activities	Total
Balance as of December 31, 2012	\$ 181	\$ (511)	\$ 1	\$ (21)	\$ (350)
Other comprehensive income (loss) before reclassifications	48	519	1	(77)	491
Net losses reclassified from accumulated other comprehensive loss		79			79
Net current-period other comprehensive income (loss)	48	598	1	(77)	570
Separation-related adjustments	241	(914)		11	(662)
Balance as of December 31, 2013	470	(827)	2	(87)	(442)
Other comprehensive (loss) income before reclassifications	(1,073)	(827)	1	187	(1,712)
Net losses reclassified from accumulated other comprehensive loss		46		77	123
Net current-period other comprehensive (loss) income	(1,073)	(781)	1	264	(1,589)
Balance as of December 31, 2014	(603)	(1,608)	3	177	(2,031)
Other comprehensive income before reclassifications	(667)	147	48	122	(350)
Net losses (gains) reclassified from accumulated other comprehensive loss		83	(4)	(259)	(180)
Net current-period other comprehensive (loss) income	(667)	230	44	(137)	(530)
Balance as of December 31, 2015	\$ (1,270)	\$ (1,378)	\$ 47	\$ 40	\$ (2,561)

Other comprehensive loss in 2014 includes foreign currency translation adjustments totaling a loss of \$1.1 billion, which was principally driven by (i) the impact of the substantial weakening of the Euro in 2014 on the translation of the company's Euro-denominated assets, and (ii) the weakening of foreign currencies in combination with an increased concentration of cash denominated in foreign currencies accumulated in anticipation of the terminated proposed combination with Shire plc. Other comprehensive loss in 2015 includes foreign currency translation adjustments totaling a loss of \$667 million, which was principally driven by the impact of the continued weakening of the Euro on the translation of the company's Euro-denominated assets.



## Edgar Filing: AbbVie Inc. - Form 10-K

The table below presents the impact on AbbVie's consolidated statements of earnings for significant amounts reclassified out of each component of accumulated other comprehensive loss:

years ended December 31 (in millions) (brackets denote gains)	2015	2014	2013
<b>Pension and post-employment benefits</b>			
Amortization of actuarial losses and other <sup>(a)</sup>	\$ 129	\$ 66	\$ 114
Less tax benefit	(46)	(20)	(35)
Total reclassifications, net of tax	\$ 83	\$ 46	\$ 79
<b>Hedging activities</b>			
(Gains) losses on designated cash flow hedges <sup>(b)</sup>	\$ (265)	\$ 79	\$
Less tax expense (benefit)	6	(2)	\$
Total reclassifications, net of tax	\$ (259)	\$ 77	\$

(a) Amounts are included in the computation of net periodic benefit cost (see Note 11).

(b) Amounts are included in cost of products sold (see Note 10).

### Other

In addition to common stock, AbbVie's authorized capital includes 200 million shares of preferred stock, par value \$0.01. As of December 31, 2015, no shares of preferred stock were issued or outstanding.

## Note 13 Income Taxes

### Earnings Before Income Tax Expense

years ended December 31 (in millions)	2015	2014	2013
Domestic	\$ (1,038)	\$ (3,245)	\$ (581)
Foreign	7,683	5,614	5,913
Total earnings before income tax expense	\$ 6,645	\$ 2,369	\$ 5,332

The domestic loss before income taxes in 2014 was driven by transaction and financing-related costs associated with the terminated proposed combination with Shire. Refer to Note 5 for further information.

### Income Tax Expense

years ended December 31 (in millions)	2015	2014	2013
<b>Current</b>			
Domestic	\$ 1,036	\$ 634	\$ 226

Edgar Filing: AbbVie Inc. - Form 10-K

Foreign	313	341	354
Total current taxes	\$ 1,349	\$ 975	\$ 580
<b>Deferred</b>			
Domestic	\$ 141	\$ (301)	\$ 678
Foreign	11	(79)	(54)
Total deferred taxes	\$ 152	\$ (380)	\$ 624
Total income tax expense	\$ 1,501	\$ 595	\$ 1,204

**Effective Tax Rate Reconciliation**

<b>years ended December 31</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Statutory tax rate	35.0%	35.0%	35.0%
State taxes, net of federal benefit	0.1		0.3
Effect of foreign operations	(9.4)	(11.3)	(11.5)
U.S. tax credits	(4.5)	(8.9)	(2.7)
Branded prescription drug fee	0.7	3.7	0.4
Valuation allowances	(1.6)	3.6	0.1
All other, net	2.3	3.0	1.0
Effective tax rate	22.6%	25.1%	22.6%

The effective tax rate fluctuates year to year due to the allocation of the company's taxable earnings among jurisdictions, as well as certain discrete factors and events in each year, including acquisitions and collaborations. The effective tax rates in 2015, 2014 and 2013 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, and business development activities together with the cost of repatriation decisions. The effective tax rates for these periods also reflected the benefit from U.S. tax credits principally related to research and development credits, the orphan drug tax credit and Puerto Rico excise tax credits. The research and development credits for 2015 and 2014 were due to legislation enacted in the fourth quarter of each year that retroactively extended the credit. The Puerto Rico excise tax credits relate to legislation enacted by Puerto Rico that assesses an excise tax beginning in 2011 on certain products manufactured in Puerto Rico. The tax is levied on gross inventory purchases from entities in Puerto Rico and is included in cost of products sold in the consolidated statements of earnings. The majority of the tax is creditable for U.S. income tax purposes. The effective income tax rate in 2015 included a tax benefit of \$103 million from a reduction of state valuation allowances.

The effective tax rate in 2014 included additional expenses of \$129 million related to the Branded Prescription Drug Fee, which is non-deductible, and state valuation allowances of \$129 million. On July 28, 2014, the Internal Revenue Service issued final rules and regulations for the Branded Prescription Drug Fee, an annual non-tax-deductible fee payable to the federal government under the Affordable Care Act based on an allocation of a company's market share for branded prescription drugs sold to certain government programs in the prior year. The final rules accelerated the expense recognition criteria for the fee obligation from the year in which the fee is paid, to the year in which the market share used to allocate the fee is determined. This change required AbbVie and other industry participants to recognize an additional year of expense in 2014.

The effective income tax rate in 2015, 2014 and 2013 reflects income tax expenses relating to current earnings outside the United States that are not deemed indefinitely reinvested.

**Deferred Tax Assets and Liabilities**

<b>as of December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>
<b>Deferred tax assets</b>		
Compensation and employee benefits	\$ 584	\$ 627
Accruals and reserves	368	376
Chargebacks and rebates	472	297
Deferred revenue	372	382
Depreciation	45	53
Net operating losses and other credit carryforwards	282	125
Other	316	292
<b>Total deferred tax assets</b>	<b>2,439</b>	<b>2,152</b>
Valuation allowances	(70)	(172)
<b>Total net deferred tax assets</b>	<b>2,369</b>	<b>1,980</b>
<b>Deferred tax liabilities</b>		
Excess of book basis over tax basis of intangible assets	(4,459)	(331)
Excess of book basis over tax basis in investments	(2,958)	(326)
<b>Total deferred tax liabilities</b>	<b>(7,417)</b>	<b>(657)</b>
<b>Net deferred tax (liabilities) assets</b>	<b>\$ (5,048)</b>	<b>\$ 1,323</b>

The increases in the deferred tax liabilities are primarily due to the acquisition of Pharmacyclics in which AbbVie recorded the excess of book basis over tax basis of intangible assets and investments.

Gross federal net operating loss and tax credit carryforwards as of December 31, 2015 were \$293 million and \$147 million, respectively, and are available for use through 2035. Gross state net operating loss and tax credit carryforwards as of December 31, 2015 were \$1.3 billion and \$152 million, respectively. The state tax carryforwards expire between 2017 and 2035. As of December 31, 2015, foreign net operating loss carryforwards were \$232 million. Foreign net operating loss carryforwards of \$177 million expire between 2018 and 2023, and the remaining do not have an expiration period.

As of December 31, 2015 and 2014, the company had valuation allowances of \$70 million and \$172 million, respectively, principally related to state net operating losses and credit carryforwards that are not expected to be realized.

Deferred income taxes have not been provided on approximately \$25 billion of the undistributed earnings of foreign subsidiaries as these earnings have been indefinitely reinvested for continued use in foreign operations. Due to the complexities in tax laws and assumptions that would have to be made, it is not practicable to estimate the amount of income taxes that would be due if these earnings were distributed.

**Unrecognized Tax Benefits**

<b>years ended December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Balance as of January 1	\$ 421	\$ 247	\$ 1,140
Increase due to current year tax positions	187	115	195
Increase due to prior year tax positions	369	67	
Decrease due to prior year tax positions	(15)	(6)	
Lapse of statutes of limitations	(8)	(2)	
Separation-related adjustments			(1,088)
<b>Balance as of December 31</b>	<b>\$ 954</b>	<b>\$ 421</b>	<b>\$ 247</b>



## Edgar Filing: AbbVie Inc. - Form 10-K

AbbVie and Abbott entered into a tax sharing agreement, effective on the date of separation, which provides that Abbott is liable for and has indemnified AbbVie against all income tax liabilities for periods prior to the separation. AbbVie will be responsible for unrecognized tax benefits and related interest and penalties for periods after separation or in instances where an existing entity was transferred to AbbVie upon separation.

The table above reflects the 2013 reduction of \$1.1 billion relating to tax periods prior to the separation for which Abbott is the primary obligor. However, under U.S. Treasury Regulations, each member of a consolidated group is severally liable for the U.S. federal income tax liability of each other member of the consolidated group. Accordingly, with respect to periods in which AbbVie was included in Abbott's consolidated group, AbbVie could be liable to the U.S. government for any U.S. federal income tax liability incurred by the consolidated group, to the extent not discharged by any other member. However, if any such liability were imposed, AbbVie would be entitled to be indemnified by Abbott pursuant to the tax sharing agreement.

If recognized, the net amount of potential tax benefits that would impact the company's effective tax rate is \$901 million and \$389 million in 2015 and 2014, respectively. Of the unrecognized tax benefits recorded in the table above as of December 31, 2015, AbbVie would be indemnified for approximately \$107 million. The "Increase due to prior year tax positions" in the table above includes amounts relating to federal, state, and international items as well as prior positions acquired through business development activities during the year. Uncertain tax positions are generally included as a long-term liability on the consolidated balance sheets.

AbbVie recognizes interest and penalties related to income tax matters in income tax expense. In 2015, 2014, and 2013, AbbVie recognized gross income tax expense of \$13 million, \$10 million, and \$3 million, respectively, for interest and penalties related to income tax matters. At December 31, 2015, 2014, and 2013, AbbVie had \$83 million, \$25 million, and \$15 million accrued for the payment of gross interest and penalties.

The company is routinely audited by the tax authorities in significant jurisdictions, and a number of audits are currently underway. It is reasonably possible during the next twelve months that uncertain tax positions may be settled, which could result in a decrease in the gross amount of unrecognized tax benefits. Due to the potential for resolution of federal, state, and foreign examinations, and the expiration of various statutes of limitation, the company's gross unrecognized tax benefits balance may change within the next twelve months up to \$15 million. All significant federal, state, local, and international matters have been concluded for years through 2005. The company believes adequate provision has been made for all income tax uncertainties.

### Note 14 Legal Proceedings and Contingencies

AbbVie is subject to contingencies, such as various claims, legal proceedings and investigations regarding product liability, intellectual property, commercial, securities and other matters that arise in the normal course of business. Loss contingency provisions are recorded for probable losses at management's best estimate of a loss, or when a best estimate cannot be made, a minimum loss contingency amount within a probable range is recorded. The recorded accrual balance for litigation at December 31, 2015 was \$166 million and at December 31, 2014 was not significant. Initiation of new legal proceedings or a change in the status of existing proceedings may result in a change in the estimated loss accrued by AbbVie. While it is not feasible to predict the outcome of all proceedings and exposures with certainty, management believes that their ultimate disposition should not have a material adverse effect on AbbVie's consolidated financial position, results of operations or cash flows.

Subject to certain exceptions specified in the separation agreement by and between Abbott and AbbVie, AbbVie assumed the liability for, and control of, all pending and threatened legal matters related to its business, including liabilities for any claims or legal proceedings related to products that had been part

of its business but were discontinued prior to the distribution, as well as assumed or retained liabilities, and will indemnify Abbott for any liability arising out of or resulting from such assumed legal matters.

Several pending lawsuits filed against Unimed Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc. (a company Abbott acquired in February 2010 and now known as AbbVie Products LLC) and others are consolidated for pre-trial purposes in the United States District Court for the Northern District of Georgia under the Multi-District Litigation (MDL) Rules as *In re: AndroGel Antitrust Litigation*, MDL No. 2084. These cases, brought by private plaintiffs and the Federal Trade Commission (FTC), generally allege Solvay's 2006 patent litigation involving AndroGel was sham litigation and the patent litigation settlement agreement and related agreements with three generic companies violate federal and state antitrust laws and state consumer protection and unjust enrichment laws. Plaintiffs generally seek monetary damages and/or injunctive relief and attorneys' fees. MDL No. 2084 includes: (a) four individual plaintiff lawsuits; (b) six purported class actions; and (c) *Federal Trade Commission v. Watson Pharmaceuticals, Inc. et al.* Following the district court's dismissal of all plaintiffs' claims, appellate proceedings led to the reinstatement of the claims regarding the patent litigation settlement, which are proceeding in discovery in the district court. The Attorney General of the State of Alaska has served AbbVie with a Civil Investigative Demand, primarily seeking documents that AbbVie produced in these lawsuits.

In November 2007, GlaxoSmithKline plc (GSK) filed a lawsuit against Abbott in the United States District Court for the Northern District of California alleging that Abbott violated federal antitrust and various state laws in connection with the 2003 Norvir re-pricing. In March 2011, a jury found that Abbott did not violate antitrust laws, but breached its license agreement with GSK. In January 2014, the United States Court of Appeals for the Ninth Circuit reversed this verdict and remanded the case for a new trial due to the alleged improper exclusion of a potential juror. The case was returned to the district court in California, but after GSK dismissed its federal antitrust claims, the case was transferred in April 2015 to the United States District Court for the Middle District of North Carolina, where pre-trial proceedings are pending. AbbVie assumed the liability for and control of this proceeding in connection with its separation from Abbott.

Lawsuits are pending against AbbVie and others generally alleging that the 2005 patent litigation settlement involving Niaspan entered into between Kos Pharmaceuticals, Inc. (a company acquired by Abbott in 2006 and presently a subsidiary of AbbVie) and a generic company violates federal and state antitrust laws and state unfair and deceptive trade practices and unjust enrichment laws. Plaintiffs generally seek monetary damages and/or injunctive relief and attorneys' fees. The lawsuits consist of three individual plaintiff lawsuits and two consolidated purported class actions: one brought by three named direct purchasers of Niaspan and the other brought by ten named end-payor purchasers of Niaspan. The cases are consolidated for pre-trial proceedings in the United States District Court for the Eastern District of Pennsylvania under the MDL Rules as *In re: Niaspan Antitrust Litigation*, MDL No. 2460. The office of the Attorney General of the State of Alaska has served AbbVie with a Civil Investigative Demand, primarily seeking documents that AbbVie produced in this lawsuit.

In September 2014, the FTC filed suit in the United States District Court for the Eastern District of Pennsylvania against AbbVie and others, alleging that the 2011 patent litigation with two generic companies regarding AndroGel was sham litigation and the patent litigation settlement with one of those generic companies violates federal antitrust laws. The FTC's complaint seeks monetary damages and injunctive relief. In May 2015, the court dismissed the FTC's claim regarding the patent litigation settlement. The office of the Attorney General of the State of Alaska has served AbbVie with a Civil Investigative Demand, primarily seeking documents that AbbVie produced in this lawsuit.

In March 2015, the State of Louisiana filed a lawsuit, *State of Louisiana v. Fournier Industrie et Sante, et al.*, against AbbVie, Abbott and affiliated Abbott entities in Louisiana state court. Plaintiff alleges that patent applications and patent litigation filed and other alleged conduct from the early 2000's and before related to the drug TriCor violated Louisiana state antitrust and unfair trade practices laws. The lawsuit

## Edgar Filing: AbbVie Inc. - Form 10-K

seeks monetary damages and attorneys' fees. In August 2015, the court dismissed the case as time-barred. The state's appeal of that dismissal is pending.

In August 2013, a putative class action lawsuit, *Sidney Hillman Health Center of Rochester, et al. v. AbbVie Inc., et al.*, was filed against AbbVie in the United States District Court for the Northern District of Illinois by three healthcare benefit providers alleging violations of Federal Racketeer Influenced and Corrupt Organizations (RICO) statutes and state deceptive business practice and unjust enrichment laws in connection with reimbursements for certain uses of Depakote from 1998 to 2012. Plaintiffs seek monetary damages and/or equitable relief and attorneys' fees.

In November 2014, a putative class action lawsuit, *Medical Mutual of Ohio v. AbbVie Inc., et al.*, was filed against several manufacturers of testosterone replacement therapies (TRTs), including AbbVie, in the United States District Court for the Northern District of Illinois on behalf of all insurance companies, health benefit providers, and other third party payors who paid for TRTs, including AndroGel. The claims asserted include violations of the federal RICO Act and state consumer fraud and deceptive trade practices laws. The complaint seeks monetary damages and injunctive relief. A similar lawsuit, *Allied Services Division Welfare Fund v. AbbVie Inc., et al.*, was filed in the same court in October 2015 on behalf of the same putative class members and a putative class of consumers.

Product liability cases are pending in which plaintiffs generally allege that AbbVie and other manufacturers of TRTs did not adequately warn about risks of certain injuries, primarily heart attacks, strokes and blood clots. Approximately 2,500 claims are consolidated for pre-trial purposes in the United States District Court for the Northern District of Illinois under the MDL Rules as *In re: Testosterone Replacement Therapy Products Liability Litigation*, MDL No. 2545. Approximately 170 claims are pending in various state courts. Plaintiffs seek compensatory and punitive damages.

Product liability cases are pending in which plaintiffs generally allege that AbbVie did not adequately warn about risk of certain injuries, primarily various birth defects, arising from use of Depakote. Over ninety percent of the approximately 715 claims are pending in the United States District Court for the Southern District of Illinois, and the rest are pending in various other federal and state courts. Plaintiffs seek compensatory and punitive damages.

In November 2014, five individuals filed a putative class action lawsuit on behalf of purchasers and sellers of certain Shire securities between June 20 and October 14, 2014, against AbbVie and its chief executive officer in the United States District Court for the Northern District of Illinois alleging that the defendants made and/or are responsible for material misstatements in violation of federal securities laws in connection with AbbVie's proposed transaction with Shire. The complaint seeks monetary damages and injunctive relief.

In December 2014, a shareholder derivative lawsuit, *Plumbers & Steamfitters Local 60 Pension Plans v. J.P. Morgan Securities LLC, et al.*, was filed in Delaware Chancery Court, alleging that AbbVie's directors breached their fiduciary duties in connection with the approval and termination of AbbVie's proposed transaction with Shire. The lawsuit seeks monetary damages for AbbVie, among other relief.



**Note 15 Segment and Geographic Area Information**

AbbVie operates in one business segment pharmaceutical products. Substantially all of AbbVie's net revenues in the United States are to three wholesalers. Outside the United States, products are sold primarily to health care providers or through distributors, depending on the market served. The following tables detail AbbVie's worldwide net revenues:

<b>years ended December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
HUMIRA	\$ 14,012	\$ 12,543	\$ 10,659
IMBRUVICA	754		
VIEKIRA	1,639	48	
Creon	632	516	412
Synagis	740	835	827
Lupron	826	778	785
Synthroid	755	709	622
Kaletra	700	870	962
AndroGel	694	934	1,035
Sevoflurane	474	550	568
Duodopa	231	220	178
Dyslipidemia products	179	328	1,076
All other	1,223	1,629	1,666
Total net revenues	\$ 22,859	\$ 19,960	\$ 18,790

Net revenues to external customers by geographic area, based on product shipment destination, were as follows:

<b>years ended December 31 (in millions)</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
United States	\$ 13,561	\$ 10,845	\$ 10,181
Germany	1,082	1,035	911
United Kingdom	688	722	606
Spain	618	534	543
Japan	599	581	625
France	597	584	540
Canada	551	551	538
Italy	452	432	404
Brazil	376	435	439
The Netherlands	334	345	332
All other countries	4,001	3,896	3,671
Total net revenues	\$ 22,859	\$ 19,960	\$ 18,790

Long-lived assets include net property and equipment of \$2.6 billion and \$2.5 billion as of December 31, 2015 and 2014, of which \$1.9 billion and \$1.8 billion, respectively, was located in the United States and Puerto Rico and \$513 million and \$551 million, respectively, was located in Europe.

## Note 16 Quarterly Financial Data (unaudited)

(in millions except per share data)	2015	2014
<b>First Quarter</b>		
Net revenues	\$ 5,040	\$ 4,563
Gross margin	\$ 4,098	\$ 3,463
Net earnings <sup>(a)</sup>	\$ 1,022	\$ 980
Basic earnings per share	\$ 0.64	\$ 0.61
Diluted earnings per share	\$ 0.63	\$ 0.61
Cash dividends declared per common share	\$ 0.51	\$ 0.42
<b>Second Quarter</b>		
Net revenues	\$ 5,475	\$ 4,926
Gross margin	\$ 4,559	\$ 3,813
Net earnings <sup>(b)</sup>	\$ 1,366	\$ 1,098
Basic earnings per share	\$ 0.84	\$ 0.69
Diluted earnings per share	\$ 0.83	\$ 0.68
Cash dividends declared per common share	\$ 0.51	\$ 0.42
<b>Third Quarter</b>		
Net revenues	\$ 5,944	\$ 5,019
Gross margin	\$ 4,777	\$ 3,925
Net earnings <sup>(c)</sup>	\$ 1,239	\$ 506
Basic earnings per share	\$ 0.75	\$ 0.32
Diluted earnings per share	\$ 0.74	\$ 0.31
Cash dividends declared per common share	\$ 0.51	\$ 0.42
<b>Fourth Quarter</b>		
Net revenues <sup>(d)</sup>	\$ 6,400	\$ 5,452
Gross margin <sup>(d)</sup>	\$ 4,925	\$ 4,333
Net earnings (loss) <sup>(e)</sup>	\$ 1,517	\$ (810)
Basic earnings (loss) per share	\$ 0.93	\$ (0.51) <sup>(f)</sup>
Diluted earnings (loss) per share	\$ 0.92	\$ (0.51) <sup>(f)</sup>
Cash dividends declared per common share	\$ 0.57	\$ 0.49

- (a) Results for the first quarter of 2015 included after-tax foreign exchange losses of \$170 million related to the liquidation in 2015 of remaining foreign currency positions related to the terminated proposed combination with Shire in 2014, a \$100 million after-tax charge as a result of entering into an exclusive worldwide license agreement with C<sub>2</sub>N and after-tax costs of \$41 million incurred in connection with the with the acquisition of Pharmacyclics.
- (b) Second quarter results for 2015 included after-tax costs totaling \$215 million incurred in connection with the acquisition and integration of Pharmacyclics. In 2014, second quarter results included an after-tax charge of \$40 million related to a regulatory milestone made to a collaboration partner for regulatory milestones related to the company's HCV program.
- (c) Results for the third quarter of 2015 included a \$350 million after-tax charge related to the purchase of a rare pediatric disease PRV from United Therapeutics Corporation, after after-tax costs totaling \$85 million incurred in connection with the acquisition and integration of Pharmacyclics, and an \$83 million after-tax charge due to the achievement of a development milestone under the global collaboration with Infinity. In 2014, third quarter results included a \$173 million after-tax charge as a result of entering into a global collaboration with Infinity, a \$250 million after-tax charge related to a research and development collaboration agreement with Calico, and transaction and financing-related

## Edgar Filing: AbbVie Inc. - Form 10-K

and other costs aggregating \$172 million after-tax that were incurred in connection with the terminated proposed combination with Shire. Refer to Note 5 for further information relating to the termination of the proposed combination with Shire and the collaborations with Calico and Infinity.

- (d) Net revenues and gross margin in 2015 included milestone revenue of \$40 million from a collaboration partner related the company's oncology program. Net revenues and gross margin in 2014 include royalty income of \$81 million relating to prior periods as a result of the settlement of a licensing arrangement.
- (e) Fourth quarter results for 2015 included after-tax costs totaling \$68 million incurred in connection with the acquisition and integration of Pharmacyclics and after-tax charges of \$101 million to increase the company's litigation reserves. For 2014, results for the fourth quarter included after-tax transaction and financing-related and other costs incurred in connection with the terminated proposed combination with Shire aggregating \$1.6 billion and a \$500 million after-tax charge related to the research and development collaboration agreement with Calico.
- (f) Basic loss per share for the fourth quarter of 2014 was calculated under the treasury-stock method as it was more dilutive. Approximately 36 million common shares were excluded from the computation of diluted (loss) per share assuming dilution because the effect would have been anti-dilutive.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of AbbVie Inc.

We have audited the accompanying consolidated balance sheets of AbbVie Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of earnings, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of AbbVie Inc. and subsidiaries at December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), AbbVie Inc. and subsidiaries' internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 19, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Chicago, Illinois  
February 19, 2016

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### *Disclosure Controls and Procedures*

**Evaluation of disclosure controls and procedures.** The Chief Executive Officer, Richard A. Gonzalez, and the Chief Financial Officer, William J. Chase, evaluated the effectiveness of AbbVie's disclosure controls and procedures as of the end of the period covered by this report, and concluded that AbbVie's disclosure controls and procedures were effective to ensure that information AbbVie is required to disclose in the reports that it files or submits with the Securities and Exchange Commission under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and to ensure that information required to be disclosed by AbbVie in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to AbbVie's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### *Internal Control Over Financial Reporting*

**Management's annual report on internal control over financial reporting.** Management's report on internal control over financial reporting is included on page 105 hereof. The report of AbbVie's independent registered public accounting firm related to its assessment of the effectiveness of internal control over financial reporting is included on page 106 hereof.

**Changes in internal control over financial reporting.** As part of its separation from Abbott, in 2014 AbbVie began a phased global implementation of a new enterprise resource planning system, related technology infrastructure and transaction processing services to replace the information technology infrastructure and transactional services provided to AbbVie by Abbott under various transition services agreements. These initiatives, which were completed in 2015, included modifications to the design and operation of controls over financial reporting. AbbVie reviewed these controls for design effectiveness prior to the implementation of each phase.

There were no other changes in AbbVie's internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) that have materially affected, or are reasonably likely to materially affect, AbbVie's internal control over financial reporting during the quarter ended December 31, 2015.

**Inherent Limitations on Effectiveness of Controls.** AbbVie's management, including its Chief Executive Officer and its Chief Financial Officer, do not expect that AbbVie's disclosure controls or internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

## ITEM 9B. OTHER INFORMATION

None.

## Management's Report on Internal Control Over Financial Reporting

Management of AbbVie is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. AbbVie's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of AbbVie's internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework* (2013 framework). Based on that assessment, management concluded that AbbVie maintained effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

On May 26, 2015, AbbVie acquired Pharmacyclics, Inc. (Pharmacyclics), which represents a material change in the internal control over financial reporting since management's last assessment of effectiveness. Management has excluded Pharmacyclics from its assessment of and conclusion on the effectiveness of internal control over financial reporting as of December 31, 2015. AbbVie's consolidated balance sheet as of December 31, 2015 included \$1 billion of total assets (excluding goodwill and other intangible assets which were included in management's assessment of internal controls over financial reporting) related to Pharmacyclics. In addition, AbbVie's consolidated statement of net earnings for 2015 included \$774 million of net revenues and reflected a net loss of \$331 million related to Pharmacyclics.

The effectiveness of AbbVie's internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing on page 106 hereof, which expresses an unqualified opinion on the effectiveness of AbbVie's internal control over financial reporting as of December 31, 2015.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of AbbVie Inc.

We have audited AbbVie Inc. and subsidiaries' internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). AbbVie Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include internal controls of Pharmacyclics, Inc., which was acquired on May 26, 2015 and is included in the 2015 consolidated financial statements of AbbVie Inc. and subsidiaries and constituted \$1 billion of total assets (excluding goodwill and other intangible assets which were included in management's assessment of and conclusions on the effectiveness of internal control over financial reporting) as of December 31, 2015 and \$774 million and \$331 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of AbbVie Inc. and subsidiaries also did not include an evaluation of the internal control over financial reporting of Pharmacyclics, Inc.

In our opinion, AbbVie Inc. and subsidiaries' maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2015 and 2014, and the related consolidated statements of earnings, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2015 of AbbVie Inc. and subsidiaries and our report dated February 19, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Chicago, Illinois  
February 19, 2016

## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Incorporated herein by reference are "Information Concerning Director Nominees," "The Board of Directors and its Committees Committees of the Board of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Procedure for Recommendation and Nomination of Directors and Transaction of Business at Annual Meeting" to be included in the 2016 AbbVie Inc. Proxy Statement. The 2016 Definitive Proxy Statement will be filed on or about March 21, 2016. Also incorporated herein by reference is the text found under the caption, "Executive Officers of the Registrant" on pages 26 and 27 hereof.

AbbVie's code of business conduct requires all its business activities to be conducted in compliance with all applicable laws, regulations, and ethical principles and values. All directors, officers, and employees of AbbVie are required to read, understand, and abide by the requirements of the code of business conduct applicable to them. AbbVie's code of business conduct is available in the corporate governance section of AbbVie's investor relations website at [www.abbvieinvestor.com](http://www.abbvieinvestor.com).

Any waiver of the code of business conduct for directors or executive officers may be made only by AbbVie's audit committee. AbbVie will disclose any amendment to, or waiver from, a provision of the code of conduct for the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on its website within four business days following the date of the amendment or waiver. In addition, AbbVie will disclose any waiver from the code of business conduct for the other executive officers and for directors on the website.

AbbVie has a chief ethics and compliance officer who reports to the chief executive officer and to the public policy committee. The chief ethics and compliance officer is responsible for overseeing, administering, and monitoring AbbVie's compliance program.

## ITEM 11. EXECUTIVE COMPENSATION

The material to be included in the 2016 Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Compensation Committee Report" is incorporated herein by reference. The 2016 Definitive Proxy Statement will be filed on or about March 21, 2016.

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

(a) *Equity Compensation Plan Information.*

The following table presents information as of December 31, 2015 about AbbVie's equity compensation plans under which AbbVie common stock has been authorized for issuance:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)	(b) Weighted- average exercise price of outstanding options, warrants and rights(2)	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	34,485,674	\$ 30.64	86,286,146



Edgar Filing: AbbVie Inc. - Form 10-K

Equity compensation plans not approved by security holders

Total	34,485,674	\$	30.64	86,286,146
-------	------------	----	-------	------------

- (1) Includes 20,061,746 shares issuable under AbbVie's Incentive Stock Program pursuant to awards granted by Abbott and adjusted into AbbVie awards in connection with AbbVie's separation from Abbott.
- (2) The weighted-average exercise price does not include outstanding restricted stock units and restricted stock awards that have no exercise price.
- (b) *Information Concerning Security Ownership.* Incorporated herein by reference is the material under the heading "Securities Ownership Securities Ownership of Executive Officers and Directors" in the 2016 Proxy Statement. The 2016 Definitive Proxy Statement will be filed on or about March 21, 2016.

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

The material to be included in the 2016 Proxy Statement under the headings "The Board of Directors and its Committees," "Corporate Governance Materials," and "Procedures for Approval of Related Person Transactions" is incorporated herein by reference. The 2016 Definitive Proxy Statement will be filed on or about March 21, 2016.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The material to be included in the 2016 Proxy Statement under the headings "Audit Fees and Non-Audit Fees" and "Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of the Independent Registered Public Accounting Firm" is incorporated herein by reference. The 2016 Definitive Proxy Statement will be filed on or about March 21, 2016.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

- (a) *Documents filed as part of this Form 10-K.*
- (1) *Financial Statements:* See Item 8, "Financial Statements and Supplementary Data," on page 47 hereof, for a list of financial statements.
- (2) *Financial Statement Schedules:* All schedules omitted are inapplicable or the information required is shown in the consolidated financial statements or notes thereto.
- (3) *Exhibits Required by Item 601 of Regulation S-K:* The information called for by this paragraph is incorporated herein by reference to the Exhibit Index on pages 111 through 113 of this Form 10-K.
- (b) *Exhibits filed:* See Exhibit Index on pages 111 through 113.
- (c) *Financial Statement Schedules:* None applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, AbbVie Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AbbVie Inc.

By: /s/ RICHARD A. GONZALEZ

Name: Richard A. Gonzalez  
Title: Chairman of the Board and  
Chief Executive Officer

Date: February 19, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of AbbVie Inc. on February 19, 2016 in the capacities indicated below.

/s/ RICHARD A. GONZALEZ

Richard A. Gonzalez  
Chairman of the Board and  
Chief Executive Officer  
(Principal Executive Officer)

/s/ WILLIAM J. CHASE

William J. Chase  
Executive Vice President,  
Chief Financial Officer  
(Principal Financial Officer)

/s/ THOMAS A. HURWICH

Thomas A. Hurwich  
Vice President, Controller  
(Principal Accounting Officer)

/s/ ROBERT J. ALPERN, M.D.

Robert J. Alpern, M.D.  
Director of AbbVie Inc.

/s/ ROXANNE S. AUSTIN

Roxanne S. Austin  
Director of AbbVie Inc.

/s/ WILLIAM H.L. BURNSIDE

William H.L. Burnside  
Director of AbbVie Inc.

/s/ EDWARD M. LIDDY

Edward M. Liddy  
Director of AbbVie Inc.

/s/ EDWARD J. RAPP

Edward J. Rapp  
Director of AbbVie Inc.

/s/ ROY S. ROBERTS

Roy S. Roberts  
Director of AbbVie Inc.

/s/ GLENN F. TILTON

Glenn F. Tilton  
Director of AbbVie Inc.

/s/ FREDERICK H. WADDELL

Frederick H. Waddell  
Director of AbbVie Inc.

**EXHIBIT INDEX  
ABBVIE INC.  
ANNUAL REPORT  
FORM 10-K  
2015**

Exhibits 32.1 and 32.2 are furnished herewith and should not be deemed to be "filed" under the Securities Exchange Act of 1934.

<b>Exhibit Number</b>	<b>Exhibit Description</b>
2.1	*Agreement and Plan of Reorganization by and among AbbVie Inc., Oxford Amherst Corporation, Oxford Amherst LLC and Pharmacyclics, Inc. dated as of March 4, 2015 (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed on March 6, 2015).
2.2	*Amendment No. 1 to Agreement and Plan of Reorganization by and among AbbVie Inc., Oxford Amherst Corporation, Oxford Amherst LLC and Pharmacyclics, Inc. dated as of March 22, 2015 (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed on March 23, 2015).
3.1	*Amended and Restated Certificate of Incorporation of AbbVie Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on January 2, 2013).
3.2	*Amended and Restated By-Laws of AbbVie Inc. (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on January 2, 2013).
4.1	*Indenture dated as of November 8, 2012 between AbbVie Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 4.1 of Amendment No. 5 to the Company's Registration Statement on Form 10 filed on November 16, 2012).
4.2	*Supplemental Indenture No. 1 dated as of November 8, 2012 among AbbVie Inc. and U.S. Bank National Association, including forms of notes (incorporated by reference to Exhibit 4.2 of Amendment No. 5 to the Company's Registration Statement on Form 10 filed on November 16, 2012).
4.3	*Supplemental Indenture No. 2 dated May 14, 2015, between AbbVie Inc. and U.S. Bank National Association, as trustee, including forms of notes (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 14, 2015).
4.4	*Support Agreement by and among AbbVie Inc., Oxford Amherst Corporation and Robert W. Duggan dated as of March 4, 2015 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on March 6, 2015).
10.1	*Form of Agreement Regarding Change in Control by and between AbbVie Inc. and its named executive officers (incorporated by reference to Exhibit 10.13 of Amendment No. 5 to the Company's Registration Statement on Form 10 filed on November 16, 2012).**
10.2	*AbbVie 2013 Incentive Stock Program (incorporated by reference to Exhibit A to the AbbVie Inc. Definitive Proxy Statement on Schedule 14A dated March 15, 2013).**
10.3	*AbbVie 2013 Management Incentive Plan (incorporated by reference to Exhibit 10.14 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.4	AbbVie Performance Incentive Plan, as amended and restated.**
10.5	AbbVie Deferred Compensation Plan, as amended and restated.**
10.6	AbbVie Non-Employee Directors' Fee Plan, as amended and restated.**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.7	*AbbVie Supplemental Pension Plan (incorporated by reference to Exhibit 10.18 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.8	AbbVie Supplemental Savings Plan, as amended and restated. **
10.9	*Form of AbbVie Inc. Non-Employee Director Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.10	*Form of AbbVie Inc. Performance Restricted Stock Agreement (CEO/Chairman) (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.11	*Form of AbbVie Inc. Performance Restricted Stock Agreement (Annual) (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.12	*Form of AbbVie Inc. Performance Restricted Stock Agreement (Interim) (incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.13	*Form of AbbVie Inc. Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.14	*Pharmacyclics, Inc. 2014 Equity Incentive Award Plan (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-8 filed on May 27, 2015).**
10.15	*Revolving Credit Agreement, dated as of August 18, 2014, among AbbVie Inc., AbbVie Private Limited, AbbVie Holdings Private Limited, JPMorgan Chase Bank, N.A. and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on August 21, 2014).
10.16	*Amendment No. 1 to Revolving Credit Agreement, dated as of March 16, 2015, by and among AbbVie Inc., JPMorgan Chase Bank, N.A., as Administrative Agent, and the lenders party thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on March 20, 2015).
10.17	*Three-Year Term Loan Agreement, dated as of September 25, 2015, among AbbVie, Bank of America, N.A. and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on September 29, 2015).
10.18	*364-Day Term Loan Credit Agreement, dated as of September 25, 2015, among AbbVie, Bank of America, N.A. and the lenders and other parties party thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on September 29, 2015).
10.19	*364-Day Bridge Term Loan Credit Agreement, dated as of March 27, 2015, among the Company, as borrower, the various financial institutions party thereto, as lenders, and Morgan Stanley Senior Funding, Inc., as administrative agent (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on March 30, 2015).
10.20	*Underwriting Agreement, dated as of May 5, 2015, by and among AbbVie Inc., and Morgan Stanley & Co. LLC, Barclays Capital Inc., Deutsche Bank Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representatives of the several other underwriters named therein (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed on May 7, 2015).

<b>Exhibit Number</b>	<b>Exhibit Description</b>
12	Ratio of Earnings to Fixed Charges
21	Subsidiaries of AbbVie Inc.
23	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer Required by Rule 13a-14(a) (17 CFR 240.13a-14(a)).
31.2	Certification of Chief Financial Officer Required by Rule 13a-14(a) (17 CFR 240.13a-14(a)).
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements and notes from the AbbVie Inc. Annual Report on Form 10-K for the year ended December 31, 2015 filed on February 19, 2016, formatted in XBRL: (i) Consolidated Statements of Earnings; (ii) Consolidated Statements of Comprehensive Income; (iii) Consolidated Balance Sheets; (iv) Consolidated Statements of Equity; (v) Consolidated Statements of Cash Flows; and (vi) the Notes to Consolidated Financial Statements.

The AbbVie Inc. 2016 Definitive Proxy Statement will be filed with the Securities and Exchange Commission under separate cover on or about March 21, 2016.

---

\*  
Incorporated herein by reference. Commission file number 001-35565.

\*\*  
Denotes management contract or compensatory plan or arrangement required to be filed as an exhibit hereto.

AbbVie will furnish copies of any of the above exhibits to a stockholder upon written request to the Secretary, AbbVie Inc., 1 North Waukegan Road, North Chicago, Illinois 60064.