

AbbVie Inc.  
Form 10-K  
February 20, 2015

**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, 2014  
Commission file number 001-35565

**AbbVie Inc.**

**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)

**(847) 932-7900**

(telephone number)

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

**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

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

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

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 1,574,311,912 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, 2014), was \$88,854,164,315. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2015: 1,593,886,909

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2015 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Proxy Statement will be filed on or about March 20, 2015.

---

## PART I

## ITEM 1. BUSINESS

## Separation from Abbott Laboratories

AbbVie(1) 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, including rheumatoid arthritis, psoriasis, and Crohn's disease; hepatitis C (HCV); human immunodeficiency virus (HIV); endometriosis; thyroid disease; Parkinson's disease; complications associated with chronic kidney disease and cystic fibrosis; and other health conditions such as low testosterone. AbbVie also has a pipeline of promising new medicines, including more than 30 compounds or indications in Phase 2 or Phase 3 development across such important medical specialties as immunology, virology/liver disease, oncology, renal disease, neurological diseases and women's health.

## 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.

**HUMIRA.** HUMIRA 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
Pediatric enthesitis-related arthritis	European Union

(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 is also approved in over 60 other markets, including Japan, China, Brazil, and Australia. HUMIRA was introduced to the market in January 2003. HUMIRA accounted for 63 percent of AbbVie's total net sales in 2014. 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 April 2018.

AbbVie continues to dedicate substantial research and development efforts to expanding indications for HUMIRA, including in the fields of rheumatology, gastroenterology (pediatric Crohn's disease and pediatric ulcerative colitis), dermatology (pediatric psoriasis and hidradenitis suppurativa), and ophthalmology (uveitis). Phase 3 trials are ongoing in preparation for regulatory applications for uveitis in the United States and the European Union. Regulatory applications for hidradenitis suppurativa have been filed in the United States and the European Union. AbbVie continues to work on HUMIRA formulation and delivery enhancements to improve convenience and the overall patient experience.

**HCV products.** VIEKIRA PAK is an all-oral, short-course, interferon-free therapy, with or without ribavirin, for the treatment of adult patients with genotype 1 chronic hepatitis C (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.

**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 (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 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 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 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 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 (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.

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

**Other products.** AbbVie's other products include the following:

*Duopa and Duodopa.* 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, Trilipix, Niaspan, Simcor and Advicor) address the range of metabolic conditions characterized by high cholesterol and/or high triglycerides.

*Zemlar.* Zemlar 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 \$3.3 billion in 2014, \$2.9 billion in 2013, and \$2.8 billion in 2012 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 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 varies 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 2015 to 2035, 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 European Union patent is expected to expire in the majority of European Union countries in April 2018.

In addition, the following patents, licenses, and trademarks are significant: those related to lopinavir/ritonavir (which is sold under the trademarks Kaletra and Aluvia), 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 lopinavir is expected to expire in 2016. A principal United States non-composition of matter patent covering lopinavir/ritonavir is expected to expire in 2016. The United States composition of matter patents covering ombitasvir, paritaprevir and dasabuvir are expected to expire in 2032, 2031 and 2029, respectively. The principal United States non-composition of matter patent covering AndroGel 1 percent is expected to expire in 2021, including pediatric exclusivity. Agreements that may affect exclusivity are discussed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations."

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.

In 2014, AbbVie's products were sold in over 170 countries. AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty

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

pharmacies, and independent retailers from AbbVie-owned distribution centers and public warehouses. Although there are no significant seasonal aspects to AbbVie's business, AbbVie's product sales 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 2014, 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 42 percent of AbbVie's 2014 gross sales in the United States. Outside the United States, sales are made either directly to customers or through distributors, depending on the market served. These wholesalers purchase product from AbbVie under standard terms and conditions of sale.

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

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

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

### **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 dependent upon it. 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 6, "Acquisitions, Collaborations and Other Arrangements," 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, including in the United States. In addition, certain medical devices and components necessary for the manufacture of our 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 2014 were approximately \$3 million and \$26 million, respectively. Capital and operating expenditures for pollution control in 2015 are estimated to be approximately \$4 million and \$28 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 an indication 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 new law provides that only a biosimilar product that is deemed to be "interchangeable" will be considered by the FDA to be 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 new 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 obtain FDA approval 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 labeling. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive, 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. 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 regulations 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 vary, and the time required to obtain approval may be longer or shorter than that required for FDA

approval. 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 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 foreign 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) 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 must be implemented.

### **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.

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

In addition to regulatory initiatives, AbbVie's business can be affected by ongoing studies of the utilization, safety, efficacy, and outcomes of health care products and their components that are regularly conducted by industry participants, government agencies, and others. These studies can call into question the utilization, safety, and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of, or limitations on, marketing of such products domestically or worldwide, and may give rise to claims for damages from persons who believe they have been injured as a result of their use.

Access to human health care products continues to be a subject of investigation and action by governmental agencies, legislative bodies, and private organizations in the United States and other countries. A major focus is cost containment. Efforts to reduce health care costs are also being made in the private sector, notably by health care payors and providers, which have instituted various cost reduction and containment measures. AbbVie expects insurers and providers to continue attempts to reduce the cost of health care products. Outside the United States, many countries control the price of health care products directly or indirectly, through reimbursement, payment, pricing, coverage limitations, or compulsory licensing. Budgetary pressures in the United States and in other countries may also heighten the scope and severity of pricing pressures on AbbVie's products for the foreseeable future.

**United States.** Specifically, U.S. federal laws require pharmaceuticals 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 pharmaceuticals 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. End stage renal disease treatment is covered through a bundled payment that likewise creates incentives for providers to demand lower pharmaceutical prices. 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 2015 at all government levels worldwide over the marketing, availability, method of delivery, and payment for health care products and services. AbbVie believes that future legislation and regulation in the markets it serves could affect access to health care products and services, increase rebates, reduce prices or the rate of price increases for health care products and services, change health care delivery systems, create new fees and obligations for the pharmaceuticals industry, or require additional reporting and disclosure. It is not possible to predict the extent to which AbbVie or the health care industry in general might be affected by the matters discussed above.

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

**European Union.** The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance, and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the European Union and permits member states to supplement these standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent to launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical products. Differences between national pricing regimes create price differentials within the European Union that can lead to significant parallel trade in pharmaceutical products.

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

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

**Emerging Markets.** Many emerging markets take steps to reduce pharmaceutical product prices, in some cases through direct price controls and in others through the promotion of generic alternatives to branded pharmaceuticals.

Since AbbVie markets its products worldwide, certain products of a local nature and variations of product lines must also meet other local regulatory requirements. Certain additional risks are inherent in conducting business outside the United States, including price and currency exchange controls, changes in

currency exchange rates, limitations on participation in local enterprises, expropriation, nationalization, and other governmental action.

## Employees

AbbVie employed approximately 26,000 persons as of January 31, 2015. 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.

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 selling product and had worldwide net sales of approximately \$12.5 billion in 2014, 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 April 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.

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 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 income will be reduced.

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

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

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

HUMIRA accounted for approximately 63 percent of AbbVie's total net sales in 2014. 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 sales 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 pharmaceuticals and biotechnology companies for a portion of the products in its near-term pharmaceutical pipeline. For example, AbbVie is collaborating with Biogen Idec 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, 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 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. 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 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 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 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, renal disease, 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 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. Product liability claims could have a material adverse effect on AbbVie's business and results of operations.

***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. Recently enacted 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 and agreeing to pay approximately \$700 million in criminal fines and forfeitures and approximately \$900 million to resolve civil claims. Under the plea agreement, Abbott submitted to a term of probation that was initially set at 5 years, but was shortened to 3 years upon the separation of Abbott and AbbVie. The obligations of the plea agreement have transferred to and become fully binding on AbbVie. The conditions of probation include certain reporting requirements, maintenance of certain

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

compliance measures, certifications of AbbVie's CEO and board of directors, and other conditions. If AbbVie violates the terms of its probation, it may face additional monetary sanctions and other such remedies as the court deems appropriate. On October 2, 2012, the court accepted the guilty plea and imposed the agreed-upon sentence.

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. Sales outside of the United States make up approximately 46 percent of AbbVie's total net sales in 2014. The risks associated with AbbVie's operations outside the United States include:

fluctuations in currency exchange rates;

changes in medical reimbursement policies and programs;

multiple legal and regulatory requirements that are subject to change and that could restrict AbbVie's ability to manufacture, market, and sell its products;

differing local product preferences and product requirements;

trade protection measures and import or export licensing requirements;

difficulty in establishing, staffing, and managing operations;

differing labor regulations;

potentially negative consequences from changes in or interpretations of tax laws;

political and economic instability, including sovereign debt issues;

price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization, and other governmental action;

inflation, recession and fluctuations in interest rates;

potential deterioration in the economic position and credit quality of certain non-U.S. countries, including in Europe and Latin America; and

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

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

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

Additionally, changes in AbbVie's structure, operations, revenues, costs, or efficiency resulting from major transactions such as acquisitions, divestitures, mergers, alliances, restructurings or other strategic initiatives, may result in greater than expected costs, may take longer than expected to complete or encounter other difficulties, including the need for regulatory approval where appropriate.

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

In 2014, three wholesale distributors AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation accounted for substantially all of AbbVie's sales 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 that 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 profitability 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; 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 Separation from Abbott**

*AbbVie's historical financial information for fiscal year 2012 and prior periods is not necessarily representative of the results that it would have achieved as a separate, publicly traded company and may not be a reliable indicator of its future results.*

The historical information about AbbVie in this Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and for the periods ending prior to December 31, 2012 refers to AbbVie's business as operated by and integrated with Abbott. AbbVie's historical financial information for these periods was derived from the consolidated financial statements and accounting records of Abbott. Accordingly, the financial information for these periods does not necessarily reflect the financial condition, results of operations or cash flows that AbbVie would have achieved as a separate, publicly traded company during the periods presented or those that AbbVie will achieve in the future.

For additional information about the past financial performance of AbbVie's business and the basis of presentation of the financial statements of AbbVie's business, see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 8, "Financial Statements and Supplementary Data."



***As AbbVie builds its information technology infrastructure and transitions its data to its own systems, AbbVie could incur substantial additional costs and experience temporary business interruptions.***

AbbVie is installing and implementing information technology infrastructure to support its critical business functions, including accounting and reporting, manufacturing process control, customer service, inventory control and distribution. AbbVie may incur temporary interruptions in business operations if it cannot transition effectively from Abbott's existing transactional and operational systems, data centers and the transition services that support these functions as AbbVie replaces these systems. AbbVie may not be successful in implementing its new systems and transitioning its data, and it may incur substantially higher costs for implementation than currently anticipated. AbbVie's failure to avoid operational interruptions as it implements the new systems and replaces Abbott's information technology services, or its failure to implement the new systems and replace Abbott's services successfully, could disrupt its business, adversely affect its ability to collect receivables from customers, and have a material adverse effect on its profitability. In addition, if AbbVie is unable to replicate or transition certain systems, its ability to comply with regulatory requirements could be impaired.

***Abbott may fail to perform under various transaction agreements that have been executed as part of the separation or AbbVie may fail to have necessary systems and services in place when certain of the transaction agreements expire.***

In connection with the separation, AbbVie and Abbott entered into a separation and distribution agreement and various other agreements, including transition services agreements, a tax sharing agreement, international commercial operations agreements, finished goods supply agreements, contract manufacturing agreements, an employee matters agreement, a special products master agreement, an information technology agreement, and a transitional trademark license agreement. Certain of these agreements provide for the performance of services by each company for the benefit of the other for a period of time after AbbVie's separation from Abbott. AbbVie relies on Abbott to satisfy its performance and payment obligations under these agreements. If Abbott is unable to satisfy its obligations under these agreements, including its indemnification obligations, AbbVie could incur operational difficulties or losses.

In addition, AbbVie and Abbott entered into long-term arrangements under a special products master agreement relating to certain product rights and into an ex-U.S. transition services agreement for Abbott to provide AbbVie with back office functions and other services in certain markets outside the United States until AbbVie has established sufficient back office infrastructure to conduct operations in such markets. These arrangements could lead to disputes between Abbott and AbbVie over AbbVie's rights to certain intellectual property and territorial commercialization rights and over the allocation of costs and revenues for AbbVie's products and operations outside of the United States.

If AbbVie does not have in place its own systems and services, or if AbbVie does not have agreements with other providers of these services when the transaction or long-term agreements terminate, AbbVie may not be able to operate its business effectively and its profitability may decline. AbbVie is in the process of creating its own, or engaging third parties to provide, systems and services to replace many of the systems and services Abbott currently provides to it. AbbVie may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Abbott's systems to AbbVie's. These systems and services may also be more expensive or less efficient than the systems and services Abbott is expected to provide during the transition period.

AbbVie is developing and implementing its own back office functions, administrative systems, personnel, and processes for markets outside the United States where Abbott will initially provide such functions. There can be no assurance that AbbVie will be able to fully implement such functions effectively and without disrupting its business in those markets.

***Potential indemnification liabilities to Abbott pursuant to the separation agreement could materially adversely affect AbbVie.***

The separation agreement with Abbott provides for, among other things, the principal corporate transactions required to effect the separation, certain conditions to the separation and provisions governing the relationship between AbbVie and Abbott with respect to and resulting from the separation. Among other things, the separation agreement provides for indemnification obligations designed to make AbbVie financially responsible for substantially all liabilities, except certain tax liabilities, that may exist relating to its business activities, whether incurred prior to or after AbbVie's separation from Abbott, as well as those obligations of Abbott assumed by AbbVie pursuant to the separation agreement, including those relating to Depakote. If AbbVie is required to indemnify Abbott under the circumstances set forth in the separation agreement, AbbVie may be subject to substantial liabilities.

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

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

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

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

In the future, a stockholder's percentage ownership in AbbVie may be diluted because of equity issuances for capital market transactions, equity awards that AbbVie will be granting to AbbVie's directors, officers and employees, acquisitions, or other purposes. AbbVie's employees have options to purchase shares of its common stock as a result of conversion of their Abbott stock options (in whole or in part) to AbbVie stock options. AbbVie anticipates its compensation committee will grant additional stock options or other stock-based awards to its employees. Such awards will have a dilutive effect on AbbVie's earnings per share, which could adversely affect the market price of AbbVie's common stock. From time to time, AbbVie will issue additional options or other stock-based awards to its employees under AbbVie's employee benefits plans.

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

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

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

the inability of AbbVie's stockholders to call a special meeting;

the division of AbbVie's board of directors into three classes of directors, with each class serving a staggered three-year term;

a provision that stockholders may only remove directors for cause;

the ability of AbbVie's directors, and not stockholders, to fill vacancies on AbbVie's board of directors; and

the requirement that the affirmative vote of stockholders holding at least 80 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:

<b>United States</b>	<b>Outside the United States</b>
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 United States research and development facilities 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 Shanghai, China and 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	61	Chairman of the Board and Chief Executive Officer
Laura J. Schumacher	51	Executive Vice President, Business Development, External Affairs and General Counsel
William J. Chase	47	Executive Vice President, Chief Financial Officer
Carlos Alban	52	Executive Vice President, Commercial Operations
Michael Severino, M.D.*	49	Executive Vice President, Research and Development, Chief Scientific Officer
Timothy J. Richmond	48	Senior Vice President, Human Resources
Azita Saleki-Gerhardt, Ph.D.	51	Senior Vice President, Operations
Thomas A. Hurwich	54	Vice President, Controller

\*  
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.

Ms. Schumacher is AbbVie's Executive Vice President, Business Development, External Affairs and General Counsel. She served as Abbott's 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. Ms. Schumacher was also responsible for Abbott's licensing and acquisitions function and its Office of Ethics and Compliance. Ms. Schumacher joined Abbott in 1990. She currently serves as a director of General Dynamics Corporation.

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. 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.

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.

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

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). A "when-issued" trading market for AbbVie's common stock began on the NYSE on December 10, 2012, and "regular way" trading of AbbVie's common stock began on January 2, 2013. Prior to December 10, 2012 there was no public market for AbbVie's common stock. 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**

	2014		2013	
	high	low	high	low
First Quarter	\$ 54.73	\$ 46.42	\$ 40.80	\$ 33.33
Second Quarter	56.90	45.50	48.00	39.96
Third Quarter	60.02	51.37	48.42	41.07
Fourth Quarter	70.76	52.06	54.78	44.32

**Stockholders**

There were 56,161 stockholders of record of AbbVie common stock as of January 31, 2015.

**Dividends**

Four quarterly dividends were paid on common stock in 2014. The first quarter cash dividend of \$0.40 per share was payable February 14, 2014 and the second, third and fourth quarter dividends of \$0.42 per share were payable May 15, 2014, August 15, 2014 and November 17, 2014, respectively. On October 20, 2014, AbbVie's board of directors declared an increase in the quarterly cash dividend from \$0.42 per share to \$0.49 per share, payable on February 13, 2015 to stockholders of record as of January 15, 2015. A quarterly dividend of \$0.40 per share was paid on common stock in 2013. 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.

AbbVie Inc. is an Illinois High Impact Business (HIB) and is located in a federal Foreign Trade Sub-Zone (Sub-Zone 22S). Dividends may be eligible for a subtraction from base income for Illinois income tax purposes. If you have questions, please contact your tax advisor.

**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, 2014. This graph assumes \$100 was invested in the stock or the 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 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

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2014 - October 31, 2014	9,410(1)	\$ 39.55		\$ 5,000,000,000(2)
November 1, 2014 - November 30, 2014	34,295(1)	\$ 51.43		\$ 5,000,000,000(2)
December 1, 2014 - December 31, 2014	4,513,139(1)	\$ 67.03	4,475,247	\$ 4,699,938,463(2)
Total	4,556,844(1)	\$ 66.86	4,475,247	\$ 4,699,938,463(2)

(1)

These shares represent:

(i)

the shares deemed surrendered to AbbVie to pay the exercise price in connection with the exercise of employee stock options 9,410 in October; 34,295 in November; and 15,871 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 22,021 in December.

These shares do not include the shares surrendered to AbbVie to satisfy minimum tax withholding obligations in connection with the vesting of restricted stock or restricted stock units. This authorization supersedes the previously-disclosed \$1.5 billion stock repurchase program.

- (2) On October 20, 2014, AbbVie announced that its board of directors authorized the purchase of up to \$5.0 billion of its common stock, from time to 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, 2014 and 2013; and (ii) audited combined financial statements as of and for the years ended December 31, 2012, 2011 and 2010. 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 historical financial statements for periods prior to January 1, 2013 also 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. Refer to "Separation from Abbott Laboratories and Basis of Historical Presentation" and "Transition from Abbott and Cost to Operate as an Independent Company" included under Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information.

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)

	2014	2013	2012	2011	2010
<b>Statement of earnings data</b>					
Net sales	\$ 19,960	\$ 18,790	\$ 18,380	\$ 17,444	\$ 15,638
Net earnings(a)	\$ 1,774	\$ 4,128	\$ 5,275	\$ 3,433	\$ 4,178
Basic earnings per share(a)	\$ 1.11	\$ 2.58	\$ 3.35	\$ 2.18	\$ 2.65
Diluted earnings per share(a)	\$ 1.10	\$ 2.56	\$ 3.35	\$ 2.18	\$ 2.65
Cash dividends declared per share	\$ 1.75	\$ 2.00(b)	n/a	n/a	n/a
Weighted-average basic shares outstanding(c)	1,595	1,589	1,577	1,577	1,577
Weighted-average diluted shares outstanding(c)	1,610	1,604	1,577	1,577	1,577
<b>Balance sheet data</b>					
Total assets	\$ 27,547	\$ 29,198	\$ 27,008	\$ 19,521	\$ 21,135
Long-term debt and lease obligations(d)	\$ 14,586	\$ 14,310	\$ 14,652	\$ 48	\$ 52

(a)

Results for the years ended December 31, 2014 and 2013 included higher expenses associated with operating as an independent, stand-alone publicly traded company than the historically derived financial statements. The increases include the impact of interest expense on debt issued in November 2012, a higher tax rate and other full year incremental costs of operating as an independent company. In addition, results for the year ended December 31, 2014 include after-tax transaction and financing-related costs totaling \$1.8 billion, or \$1.12 per share, incurred in connection with the terminated proposed combination with Shire plc (Shire), a \$750 million after-tax charge related to a research and

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

development collaboration agreement with Calico Life Sciences LLC (Calico), and a \$173 million after-tax charge as a result of entering into a global collaboration with Infinity Pharmaceuticals, Inc. (Infinity). Refer to Notes 4 and 6 to the audited consolidated financial statements included under Item 8, "Financial Statements and Supplementary Data" for further information relating to the termination of the proposed combination with Shire and the collaborations with Calico and Infinity, respectively.

- (b) 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. Refer to Note 12 to the audited consolidated financial statements included under Item 8, "Financial Statements and Supplementary Data" for additional information regarding cash dividends declared in 2013.
- (c) On January 1, 2013, Abbott distributed 1,577 million shares of AbbVie common stock. For periods prior to the separation, the weighted-average basic and diluted shares outstanding was based on the number of shares of AbbVie common stock outstanding on the distribution date. Refer to Note 5 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 the years ended December 31, 2014 and 2013.
- (d) 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) and results of operations as of and for each of the three years in the period ended December 31, 2014. 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. AbbVie develops and markets advanced therapies that address some of the world's most complex and serious diseases. AbbVie products are used to treat chronic autoimmune diseases, including rheumatoid arthritis, psoriasis, and Crohn's disease; hepatitis C (HCV); human immunodeficiency virus (HIV); endometriosis; thyroid disease; Parkinson's disease; complications associated with chronic kidney disease (CKD) and cystic fibrosis; and other health conditions such as low testosterone. AbbVie also has a pipeline of promising new medicines, including more than 30 compounds or indications in Phase 2 or Phase 3 development across such important medical specialties as immunology, virology/liver disease, oncology, renal disease, neurological diseases 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 26,000 employees and its products are sold in over 170 countries. AbbVie operates in one business segment pharmaceutical products.

**Financial Results**

Since becoming an independent company, AbbVie's strategy has focused on delivering strong financial results and returns for shareholders while ensuring a strong sustainable growth business over the longer term. In 2014, AbbVie grew worldwide net sales by 6 percent to \$20.0 billion, driven primarily by the continued strength of HUMIRA and double-digit sales growth from other key products including Creon, Duodopa and Synthroid. Sales growth in 2014 continued to reflect the impact of the loss of exclusivity in the company's lipid franchise, which resulted in the loss of \$748 million of revenue in 2014 over the prior year. Generic competition began in November 2012 for TriCor, July 2013 for Trilipix and September 2013 for Niaspan.

The company's financial performance in 2014 included delivering fully diluted earnings per share of \$1.10, including after-tax transaction and financing-related costs totaling \$1.8 billion incurred in connection with the terminated proposed combination with Shire plc (Shire), a \$750 million after-tax charge related to a research and development collaboration agreement with Calico Life Sciences LLC (Calico) and a \$173 million after-tax charge as a result of entering into a global collaboration with Infinity Pharmaceuticals, Inc. (Infinity). Refer to Note 4 for further information regarding the termination of the company's proposed combination with Shire and Note 6 for further information regarding the company's collaborations with Calico and Infinity. AbbVie's financial performance in 2014 also reflected an improvement in gross margin primarily due to favorable product mix across the product portfolio and operational efficiencies, as well as increased funding in support of AbbVie's emerging mid-and late-stage pipeline assets and additional HUMIRA indications.

In 2014, the company generated cash flows from operations of \$3.5 billion, net of the after-tax transaction and financing-related costs incurred in connection with the terminated proposed combination with Shire. These strong cash flows enabled the company to continue to enhance its pipeline through licensing and collaboration activities, pay cash dividends to shareholders of \$2.7 billion and repurchase approximately 9 million shares for \$550 million. In addition, the board of directors declared an increase in the company's quarterly cash dividend from \$0.42 per share to \$0.49 per share of common stock payable in February 2015, as well as authorized a new \$5.0 billion stock repurchase program that is expected to be executed over the next several years.

In addition to these financial results, AbbVie continued to advance its pipeline during 2014, including securing regulatory approval in the United States for AbbVie's interferon-free HCV treatment, VIEKIRA PAK, as well as submitting its regulatory application in the European Union, which was subsequently approved in January 2015. AbbVie also continued to advance its previously submitted regulatory applications in the United States for Duopa, which were subsequently approved in January 2015, and completed several late-stage clinical trials, including ZINBRYTA (daclizumab) for the treatment of the relapsing/remitting form of multiple sclerosis (MS) and registrational programs for an expanded use of HUMIRA for hidradenitis suppurativa. AbbVie also augmented its pipeline through strategic licensing and partnering activities including in-licensing duvelisib, a dual acting PI3 kinase inhibitor currently under investigation for use in a variety of hematological malignancies, from Infinity and entering into a novel collaboration with Calico to discover, develop, and commercialize new therapies for patients with age-related diseases.

### **2015 Strategic Objectives**

In 2015, AbbVie expects sales performance to be driven by continued strong growth from HUMIRA, the launch of VIEKIRA PAK, and sales growth in certain key products including Creon and Duodopa, partially offset by a decline in several products due to generic competition, including AndroGel 1% and the remainder of the lipid franchise. In addition, AbbVie expects to achieve operating margin improvements while continuing to invest in its pipeline in support of opportunities in oncology, HCV, and immunology, as well as continued investment in key products. AbbVie expects to grow operating cash flows in 2015, which will enable the company to continue to augment its pipeline through concerted focus on strategic licensing, acquisition and partnering activity and returning cash to shareholders via dividends and share repurchases.

AbbVie expects to continue to drive strong HUMIRA sales growth in several ways. AbbVie seeks to expand the HUMIRA patient base by applying for regulatory approval of new indications for HUMIRA, treating conditions such as uveitis and hidradenitis suppurativa. AbbVie will also seek to drive HUMIRA sales growth by expanding its market share and its presence in underserved markets. AbbVie plans to continue making investments in key emerging markets, including Brazil, China, and Russia.

Another key driver of AbbVie's performance in 2015 will be VIEKIRA PAK, which is now approved in the United States, the European Union and a number of other countries around the world. AbbVie expects to support the successful launch of VIEKIRA in the United States by securing payor positions and patient access and focusing commercial efforts on penetration in AbbVie-exclusive and parity accounts. The company has launched VIEKIRAX in several European countries, including Germany, the United Kingdom and Canada, and continues to work with various governments around the world to gain reimbursements approvals.

AbbVie will continue its investment in products with historically stable sales levels, while making adjustments as necessary to increase the value of its product portfolio. AbbVie plans to achieve this objective in a variety of ways depending on product and circumstances by, for example, identifying supply chain efficiencies, pursuing additional indications, and optimizing residual value as products reach the end of exclusivity. AbbVie believes that its approach will allow the company to maintain a strong operating margin.

R&D efforts will continue to focus a significant portion of expenditures on compounds for immunology, virology/liver disease, oncology, renal disease, neurological diseases and women's health. AbbVie's scientists work to advance a pipeline of specialty molecules that demonstrate strong clinical performance for patients and economic value for patients and their healthcare systems. Current R&D projects are described in the "Research and Development" section below. Abbvie will also continue to augment its pipeline through concerted focus on strategic licensing, acquisition and partnering activity in 2015.

## Research and Development

Research and innovation continues to be a key strategic priority for AbbVie. 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 includes more than 40 compounds or indications in clinical development individually or under collaboration or license agreements. Of these programs, approximately 13 are in Phase 3 development or in registration. AbbVie expects multiple Phase 2 programs to transition into Phase 3 programs during 2015. R&D is focused on therapeutic areas that include immunology, virology/liver disease, oncology, renal disease, neurological diseases, and women's health, among others.

### *Immunology*

HUMIRA 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 spondyloarthropathy	United States, European Union
Pediatric Crohn's disease (severe)	United States, European Union
Pediatric enthesitis-related arthritis	European Union

Abbvie continues to dedicate R&D efforts to expanding indications for HUMIRA, including in the fields of gastroenterology, dermatology and ophthalmology. Phase 3 trials are ongoing in preparation for regulatory applications of HUMIRA for uveitis in the United States and the European Union. A regulatory application for hidradenitis suppurativa has been filed in the United States and the European Union.

Abbvie also has a number of next-generation programs underway to address immune-mediated conditions, including the following:

Abbvie's studies of dual variable domain immunoglobulin (DVD-Ig) technology, which represents an approach that can target multiple disease-causing antigens with a single biologic agent, continue to progress. This proprietary technology could lead to next-generation biologic treatments for complex conditions such as cancer or rheumatoid arthritis, where multiple pathways are involved in the disease. ABT-122, a DVD directed against IL-17 and TNF, is currently in Phase 2 investigation in RA, and ABT-981, a DVD targeting IL-1 alpha and beta, is being studied in osteoarthritis in an ongoing Phase 2 program.

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

AbbVie is collaborating with Biotest AG on an anti-CD4 biologic known as tregalizumab. The compound is currently in Phase 2b clinical trials for rheumatoid arthritis and psoriasis.

Filgotinib (GLPG0634), a next-generation, oral Janus Kinase 1 (JAK1) inhibitor, is being developed with Galapagos NV (Galapagos) in a collaboration entered into during the first quarter of 2012. Filgotinib is currently in Phase 2b development to treat rheumatoid arthritis and may be able to address other autoimmune diseases. In January 2014, a Phase 2 study to evaluate Filgotinib to treat Crohn's disease was initiated.

ABT-494, AbbVie's JAK-1 selective inhibitor, is currently in Phase 2b.

In September 2013, AbbVie entered into a global collaboration with Ablynx NV (Ablynx) to develop and commercialize the anti-IL-6R Nanobody, ALX-0061, to treat inflammatory diseases including rheumatoid arthritis and systemic lupus erythematosus. ALX-0061 is currently in Phase 2 development for rheumatoid arthritis.

In May 2013, AbbVie entered into a global collaboration with Alvine Pharmaceuticals, Inc. (Alvine) to develop ALV003, a novel oral treatment for patients with celiac disease. ALV003 is currently in Phase 2b development.

### *Virology/Liver Disease*

On December 19, 2014, the U.S. Food and Drug Administration (FDA) approved AbbVie's VIEKIRA PAK, an all-oral interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with chronic genotype 1 HCV infection, including those with compensated cirrhosis. On January 16, 2015, AbbVie announced that the European Commission granted marketing authorizations for its all-oral, short-course, interferon-free treatment VIEKIRAX (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA (dasabuvir tablets). The treatment has been approved with or without RBV for patients with genotype 1 chronic HCV infection, including those with compensated liver cirrhosis, HIV-1 co-infection, patients on opioid substitution therapy and liver transplant recipients. Additionally, VIEKIRAX has been approved for use with RBV in genotype 4 chronic HCV patients. AbbVie's HCV combination is also in Phase 3 development in Japan. AbbVie submitted its regulatory application in Japan in 2015.

AbbVie is also currently conducting Phase 2 studies of its next-generation HCV program which includes ABT-493, a potent protease inhibitor, and ABT-530, AbbVie's new NS5A inhibitor.

### *Oncology*

AbbVie is focused on the development of targeted treatments that inhibit tumor growth and improve response to common cancer therapies. AbbVie's later-stage oncology pipeline includes the following:

Elotuzumab is an anti-SLAMF7 antibody for the treatment of multiple myeloma under a collaboration with Bristol-Myers Squibb (BMS). Phase 3 development began in June 2011 for multiple myeloma. In 2014, AbbVie and BMS announced that the FDA granted elotuzumab Breakthrough Therapy Designation for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one or more prior therapies. Two Phase 3 studies are ongoing with results expected in 2015.

Veliparib (ABT-888), a PARP-inhibitor, is in a Phase 3 study in BRCA-mutated breast cancer being treated with chemotherapy initiated in 2014. Veliparib is also in Phase 2 evaluation for the treatment of a variety of other solid tumors. In 2014, AbbVie announced the initiation of four separate Phase 3 clinical trials evaluating the safety and efficacy of veliparib, in combination with chemotherapy in patients with previously untreated locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) and a separate study in patients with nonsquamous NSCLC, as a neoadjuvant therapy, when added to carboplatin, prior to surgery in women with early-stage, triple



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

negative breast cancer and in patients with human epidermal growth factor receptor 2-(HER2) negative metastatic or locally-advanced breast cancer, containing BRCA1 and/or BRCA2 gene mutations, when added to carboplatin and paclitaxel.

Venetoclax (ABT-199), a next-generation Bcl-2 inhibitor, is in development for patients with relapsed/refractory chronic lymphocytic leukemia. In 2014, two Phase 3 studies in chronic lymphocytic leukemia (CLL) were initiated in collaboration with AbbVie's development partner, Roche Holding AG. AbbVie also completed enrollment in a single arm study evaluating venetoclax in patients with relapsed/refractory CLL harboring the 17p deletion mutation, a negative prognostic factor. AbbVie anticipates results from this study in 2015. Venetoclax is also being explored for use across a number of different hematologic cancers including non-Hodgkin lymphoma, diffuse large B-cell lymphoma and acute myeloid leukemia.

Other molecular targets are being explored with Antibody-Drug Conjugate approaches linking anti-target antibodies with potent cytotoxic agents. In 2014, the European Medicines Agency (EMA) and the FDA granted orphan drug designation to AbbVie's investigational compound ABT-414, an anti-epidermal growth factor receptor antibody drug conjugate, which is being evaluated for safety and efficacy in patients with glioblastoma multiforme, the most common and most aggressive type of malignant primary brain tumor.

In 2014, AbbVie in-licensed duvelisib, a dual acting PI3 kinase inhibitor currently under investigation for use in a variety of hematological malignancies, from Infinity. Duvelisib is also under investigation for use in indolent non-Hodgkins lymphoma and for use in CLL.

### *Renal Disease*

AbbVie's renal care pipeline includes atrasentan, for the prevention of progression of diabetic CKD. In 2013, a Phase 3 study was initiated to assess atrasentan, when added to standard of care, on progression of kidney disease in patients with stage 2 to 4 CKD and type 2 diabetes. This global registrational study is expected to be completed in 2018. Atrasentan will potentially be the first compound launched to treat diabetic nephropathy by specifically targeting albuminuria and slowing the progression of CKD. AbbVie was previously investigating ABT-719, for the treatment of acute kidney injury associated with major cardiac and vascular surgeries. In 2014, AbbVie completed its Phase 2b study and, based on the results of that study, decided not to continue development of ABT-719.

### *Neurological Diseases*

AbbVie has clinical studies underway on multiple compounds that target receptors in the brain that help regulate mood, memory, and other neurological functions and conditions, including the following:

AbbVie is collaborating with Biogen Idec to develop ZINBRYTA (daclizumab) for the treatment of the relapsing/remitting form of MS, which is the most common form, and affects nearly 85 percent of newly diagnosed MS patients. The Phase 3 study for ZINBRYTA (daclizumab), an anti-CD25 monoclonal antibody, was successfully completed in 2014. AbbVie is in the process of working with Biogen Idec to complete its global regulatory applications for ZINBRYTA (daclizumab) which are expected to be submitted in the first half of 2015.

On January 12, 2015, AbbVie announced that the FDA approved Duopa, a levodopa-carbidopa intestinal gel for the treatment of Parkinson's disease. Duopa is administered using a small, portable infusion pump that delivers levodopa and carbidopa 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.

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

In 2014, AbbVie completed two Phase 2b studies of ABT-126, an  $\alpha$ 7-NNR modulator, in both Alzheimer's disease and cognitive impairment associated with schizophrenia. Based on the results of these studies, AbbVie does not plan to advance the molecule in either of these indications.

### *Women's Health*

AbbVie is developing a novel oral gonadotropin-releasing hormone (GnRH) antagonist, elagolix, under a collaboration with Neurocrine Biosciences for the treatment of endometriosis-related pain and uterine fibroids. A Phase 3 study in endometriosis began in mid-2012 and a second Phase 3 trial for endometriosis was initiated in 2013. Positive top-line efficacy results from the initial Phase 3 study were recently announced and additional safety and efficacy data is expected in 2015. A Phase 2a study for uterine fibroids was initiated in November 2011 and transitioned to Phase 2b in 2013.

### *Other*

Given the numerous sources for potential future growth, no individual project is expected to be material to cash flows or results of operations over the next five years. Factors considered included R&D expenses projected to be incurred for the project over the next year relative to AbbVie's total R&D expenses, as well as qualitative factors such as marketplace perceptions and impact of a new product on AbbVie's overall market position. There were no delays in AbbVie's 2014 R&D activities that are expected to have a material impact on operations.

While the aggregate cost to complete the numerous pharmaceutical projects currently in development is expected to be material, the total cost to complete will depend upon AbbVie's ability to successfully complete each project, the rate at which each project advances, the nature and extent of cost-sharing arrangements, and the ultimate timing for completion. Given the potential for significant delays and the high rate of failure inherent in the research and development of new pharmaceutical products, it is not possible to accurately estimate the total cost to complete all projects currently in development.

### **Separation from Abbott Laboratories and Basis of Historical Presentation**

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.

Prior to the separation, the historical financial statements 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 combined financial statements principally represent the historical results of operations and assets and liabilities of Abbott's former research-based pharmaceutical business.

For periods prior to January 1, 2013, the historical combined financial statements also reflected an allocation of expenses related to certain Abbott corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses were allocated to AbbVie based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of revenues, headcount, square footage, number of transactions or other measures. AbbVie considers the expense allocation methodology and results to be reasonable. However, the allocations may not be indicative of the actual expenses that would have been incurred had AbbVie operated as an independent, stand-alone, publicly-traded company for the periods presented. Accordingly, the historical financial information presented for periods prior to January 1, 2013 may not be indicative of the results of operations or financial position that would have been achieved if AbbVie had been an independent, stand-alone, publicly-traded company during the periods shown or of AbbVie's performance for periods subsequent to December 31, 2012.

**RESULTS OF OPERATIONS****Net Sales**

The comparisons presented at constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. This measure provides information on the change in net sales 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 sales at constant currency rates, when used in conjunction with the GAAP measure of change in net sales 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)	2014	2013	2012	Percent change			
				At actual currency rates		At constant currency rates	
				2014	2013	2014	2013
United States	\$ 10,845	\$ 10,181	\$ 10,435	7%	(2)%	7%	(2)%
International	9,115	8,609	7,945	6%	8%	9%	10%
Net sales	\$ 19,960	\$ 18,790	\$ 18,380	6%	2%	8%	3%

Sales growth in 2014 and 2013 was driven by the continued strength of HUMIRA, both in the United States and internationally, as well as sales growth in key products including Synthroid, Creon and Duodopa. Sales increased in 2014 and 2013 despite the loss of exclusivity for AbbVie's consolidated lipid franchise, as well as the unfavorable impact of foreign exchange rates. Generic competition began in November 2012 for TriCor, in July 2013 for Trilipix and in September 2013 for Niaspan.

Edgar Filing: AbbVie Inc. - Form 10-K

The following table details the sales of key products.

years ended December 31 (in millions)	2014	2013	2012	Percent change			
				At actual currency rates		At constant currency rates	
	2014	2013	2012	2014	2013	2014	2013
<b>HUMIRA</b>							
United States	\$ 6,524	\$ 5,236	\$ 4,377	25%	20%	25%	20%
International	6,019	5,423	4,888	11%	11%	13%	12%
Total	\$ 12,543	\$ 10,659	\$ 9,265	18%	15%	19%	15%
<b>AndroGel</b>							
United States	\$ 934	\$ 1,035	\$ 1,152	(10)%	(10)%	(10)%	(10)%
<b>Kaletra</b>							
United States	\$ 213	\$ 244	\$ 279	(13)%	(13)%	(13)%	(13)%
International	657	718	734	(9)%	(2)%	(5)%	(1)%
Total	\$ 870	\$ 962	\$ 1,013	(10)%	(5)%	(7)%	(4)%
<b>Synagis</b>							
International	\$ 835	\$ 827	\$ 825	1%		9%	9%
<b>Lupron</b>							
United States	\$ 580	\$ 566	\$ 569	3%	(1)%	3%	(1)%
International	198	219	231	(10)%	(5)%	(5)%	(3)%
Total	\$ 778	\$ 785	\$ 800	(1)%	(2)%	%	(1)%
<b>Synthroid</b>							
United States	\$ 709	\$ 622	\$ 551	14%	13%	14%	13%
<b>Sevoflurane</b>							
United States	\$ 83	\$ 77	\$ 82	7%	(5)%	7%	(5)%
International	467	491	520	(5)%	(6)%	(1)%	(4)%
Total	\$ 550	\$ 568	\$ 602	(3)%	(6)%	%	(4)%
<b>Creon</b>							
United States	\$ 516	\$ 412	\$ 353	25%	17%	25%	17%
<b>Dyslipidemia products</b>							
United States	\$ 328	\$ 1,076	\$ 2,145	(70)%	(50)%	(70)%	(50)%
<b>Duodopa</b>							
International	\$ 220	\$ 178	\$ 149	24%	20%	25%	16%
<b>VIEKIRA PAK</b>							
United States	\$ 48			100%		100%	
Other	\$ 1,629	\$ 1,666	\$ 1,525	(2)%	9%	(1)%	10%
Total	\$ 19,960	\$ 18,790	\$ 18,380	6%	2%	8%	3%

On a constant currency basis, global HUMIRA sales increased 19 percent in 2014 and 15 percent in 2013, primarily as a result of market growth across therapeutic categories and geographies, approval of new indications, higher market share, and favorable pricing in certain geographies. AbbVie is pursuing several new indications to help further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA.

AndroGel sales decreased 10 percent in both 2014 and 2013 primarily due to a decline in the overall U.S. testosterone replacement market. The company expects this trend will continue. AndroGel sales for 2013 were impacted by rebates implemented during the second half of 2012, certain account losses in early

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

2013, and the moderation of market growth experienced in 2012. AndroGel 1% sales are expected to be impacted by generic competition in early 2015.

Global sales of Kaletra declined in 2014 and 2013 primarily due to lower market share resulting from the impact of increasing competition in the HIV marketplace.

Sales for Synagis increased 9 percent in both 2014 and 2013 primarily due to increased product uptake in 2014 and 2013 compared to 2013 and 2012, respectively.

Synthroid sales increased 14 percent and 13 percent in 2014 and 2013, respectively, due to strong brand loyalty and market leadership, and favorable pricing.

Sales of Sevoflurane, which were relatively flat in 2014 and declined 4 percent in 2013, continued to be impacted by generic competition.

Sales of Creon in 2014 and 2013 grew by 25 percent and 17 percent, respectively, primarily driven by market growth and higher market share. Creon maintains market leadership in the pancreatic enzyme market.

Sales for AbbVie's consolidated lipid franchise, which includes TriCor, Trilipix, Niaspan, Simcor and Advicor, declined 70 percent in 2014 and 50 percent in 2013 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.

Sales of Duodopa, AbbVie's therapy for advanced Parkinson's disease approved in Europe and other international markets, increased 25 percent in 2014 and 16 percent in 2013. Duopa's regulatory submission in the United States was approved by the FDA in January 2015.

AbbVie launched its HCV regimen, VIEKIRA PAK, in the United States following FDA approval in mid-December. Sales of VIEKIRA PAK reflect the shipment of launch quantities into the market to support full commercial launch in January 2015. The European Commission granted marketing authorizations for AbbVie's HCV regimen, VIEKIRAX (ombitasvir/paritaprevir/ritonavir tablets) + Exviera (dasabuvir tablets), in January 2015. AbbVie expects its HCV regimen to be a significant contributor to sales growth in 2015.

### Gross Margin

years ended December 31 (in millions)	2014	2013	2012	Percent change	
				2014	2013
Gross margin	\$ 15,534	\$ 14,209	\$ 13,872	9%	2%
as a % of net sales	78%	76%	75%		

The gross margin for 2014, 2013 and 2012 reflected the favorable impact of product mix across the product portfolio, including HUMIRA, operational efficiencies, price increases, and lower amortization expense for intangible assets, partially offset by the effect of unfavorable foreign exchange rates and, in 2014 and 2013, the loss of exclusivity for the lipid franchise. 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, partially offset by a \$37 million impairment charge for an intangible asset.

### Selling, General and Administrative

years ended December 31 (in millions)	2014	2013	2012	Percent change	
				2014	2013
Selling, general and administrative	\$ 7,724	\$ 5,352	\$ 4,989	44%	7%
as a % of net sales	39%	28%	27%		

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

SG&A expenses in 2014 included transaction-related costs totaling \$1.7 billion incurred in connection with the terminated proposed combination with Shire. Refer to Note 4 of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" for further information regarding the termination of the company's proposed combination with Shire.

Excluding the Shire break fee and transaction-related costs, the increase in SG&A expenses in 2014 and 2013 was due primarily to increased selling and marketing support for new products, including preparations for the expected launch of VIEKIRA PAK, as well as spending relating to new indications and geographic expansion for HUMIRA. These increases were partially offset by the impact of favorable foreign exchange rates in 2014 and 2013. SG&A expenses in 2014, 2013 and 2012 include \$422 million, \$228 million and \$213 million, respectively, of costs associated with the separation of AbbVie from Abbott.

SG&A expenses in 2014 also included a \$129 million charge due to additional expenses related to the Branded Prescription Drug Fee. 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. As a result, an additional expense of \$129 million was recognized in 2014. The final rules and regulations did not change the amount or timing of annual fees to be paid.

SG&A expenses in 2013 included restructuring charges aggregating \$39 million, which principally related to the restructuring of certain commercial operations in conjunction with the loss and expected loss of exclusivity of certain products and, in 2012, included litigation charges of \$100 million related to an investigation of the sales and marketing activities for Depakote which was resolved in May 2012.

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

years ended December 31 (in millions)	2014	2013	2012	Percent change	
				2014	2013
Research and development	\$ 3,297	\$ 2,855	\$ 2,778	15%	3%
as a % of net sales	17%	15%	15%		
Acquired in-process research and development	\$ 352	\$ 338	\$ 288	4%	17%

R&D expense in 2014 and 2013 reflected 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 rate fluctuations in 2014 and 2013. R&D expense included regulatory milestone payments of \$40 million in 2014 and \$50 million in 2012 related to the company's collaboration. R&D expenses also included restructuring charges of \$15 million in 2013 and \$183 million in 2012.

Acquired in-process research and development (IPR&D) expense in 2014 principally 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. Refer to Note 6, "Acquisitions, Collaborations and Other Arrangements," of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data," for additional information related to the company's collaborations and other arrangements.

IPR&D expense in 2013 principally included a charge of \$175 million as a result of entering into a global license agreement with Ablynx to develop and commercialize ALX-0061, a charge of \$70 million as a result of entering into a global collaboration with Alvine to develop ALV003, a charge of \$45 million as a result of

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

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.

IPR&D expense in 2012 included a charge of \$110 million for the acquisition of ABT-719, a charge of \$150 million as a result of entering into a global collaboration to develop and commercialize an oral, next-generation JAK1 inhibitor, and a charge of \$28 million as a result of entering into a two-year collaboration agreement to research, develop, and commercialize up to three compounds with Antibody-Drug Conjugate approaches.

### **Other Expense**

Other expense in 2014 consisted of a \$750 million charge related to an R&D collaboration agreement with Calico to discover, develop, and commercialize new therapies for patients with age-related diseases.

### **Interest Expense, Net**

Interest expense, net of \$391 million in 2014, \$278 million in 2013, and \$84 million in 2012 was comprised primarily of interest expense on outstanding debt. In November 2012, AbbVie issued \$14.7 billion of long-term debt with maturities ranging from three to 30 years and entered into interest rate swaps with various financial institutions, which converted \$8.0 billion of its fixed rate interest rate debt to floating interest rate debt. Commercial paper outstanding at December 31, 2014, 2013 and 2012 was \$416 million, \$400 million and \$1.0 billion, respectively.

Interest expense, net in 2014 also included \$141 million of financing related fees incurred in connection with the terminated proposed combination with Shire and, in 2012, bridge facility fees related to the separation from Abbott.

### **Other Income, Net**

Other income, net, includes income from the resolution of certain contractual agreements, fair value adjustments to contingent consideration, and impairments of equity securities. Other 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 25 percent in 2014, 23 percent in 2013, and 8 percent in 2012. 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 increase in the effective income tax rate in 2014 was principally driven by state valuation allowances of \$129 million and additional expenses of \$129 million related to the Branded Prescription Drug Fee, which is non-deductible. The increase in the effective tax rate in 2013 over 2012 is principally due to income tax expense related to certain 2013 earnings outside the United States that are not expected to be indefinitely reinvested, as well as the absence of \$195 million of tax benefits recorded in 2012 as a result of the favorable resolution of various tax positions pertaining to a prior year.

### **Transition from Abbott and Cost to Operate as an Independent Company**

AbbVie has and will continue to incur additional ongoing operating expenses to operate as an independent company, including the cost of various corporate headquarters functions, incremental information technology-related costs, and incremental costs to operate a stand-alone back office infrastructure outside the United States.

AbbVie's transition services agreements with Abbott in the United States cover certain corporate support services that AbbVie has historically received from Abbott. Such services include information technology, accounts payable, payroll, and other financial functions, as well as engineering support for various facilities,



quality assurance support, and other administrative services. The terms of the services under the agreements vary by activity. These agreements facilitate the separation by allowing AbbVie to operate independently prior to establishing stand-alone back office functions across its organization.

As of the date of the separation, AbbVie did not have sufficient back office infrastructure to operate in markets outside the United States. As a result, AbbVie entered into transition services agreements with Abbott to provide services outside the United States, including back office services in certain countries, for up to three years after separation. These back office services include information technology, accounts payable, payroll, receivables collection, treasury, and other financial functions, as well as order entry, warehousing, and other administrative services. These transition services agreements have allowed AbbVie to operate its international pharmaceuticals business independently prior to establishing a stand-alone back office infrastructure for all countries. During the transition from Abbott, AbbVie has and will continue to incur non-recurring expenses to expand its international infrastructure. In addition, in certain international markets as of the date of the separation and as of December 31, 2014, certain marketing authorizations to sell AbbVie's products continued to be held by Abbott until such authorizations could be transferred through the applicable regulatory channels.

It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical financial statements for the functions described above. Actual costs that would have been incurred if AbbVie operated as a stand-alone company during these periods would have depended on various factors including organizational design, outsourcing, and other strategic decisions related to corporate functions, information technology, and international back office infrastructure. Refer to Note 1 entitled "Background and Basis of Presentation" of the Notes to Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" for further description of transactions between AbbVie and Abbott.

#### FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

years ended December 31 (in millions)	2014	2013	2012
Cash flows provided by/(used in):			
Operating activities	\$ 3,549	\$ 6,267	\$ 6,345
Investing activities	(926)	879	(2,418)
Financing activities	(3,293)	(3,442)	1,931

Cash flows provided by operations in 2014 was \$3.5 billion compared to \$6.3 billion in 2013. The decrease was primarily due to 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 outflows and the exit of certain foreign currency positions. The decrease was also due to the timing of U.S. wholesaler collections and an investment in inventory in preparation for the launch of AbbVie's interferon-free HCV combination in the United States starting in mid-December 2014 and in the European Union in January 2015. The decrease was also due to an increase in AbbVie's voluntary contribution to its main domestic defined benefit pension plan, which was \$370 million in 2014 and \$145 million in 2013. AbbVie also made a voluntary contribution of \$150 million to this plan subsequent to December 31, 2014.

In 2014, cash outflows related to collaborations, acquisitions, and other arrangements 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. AbbVie accrued an additional \$500 million payment to Calico in 2014 due to the satisfaction of certain conditions under the R&D collaboration, which was subsequently paid in 2015. In 2013, cash outflows related to collaborations, acquisitions, and other arrangements totaled \$405 million, including \$175 million related to the global collaboration with Ablynx NV and \$70 million related to a global collaboration with Alvine. Cash flows from investing activities

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

in 2014 also reflected capital expenditures, including the purchase of a small molecule active pharmaceutical ingredient manufacturing facility in Singapore, and net sales (purchases) of short-term investments.

In 2014 and 2013, the company issued and redeemed commercial paper. The balance of commercial paper outstanding was \$416 million and \$400 million at December 31, 2014 and 2013, respectively. AbbVie may issue additional commercial paper or retire commercial paper to meet liquidity requirements as needed.

Cash dividend payments totaled \$2.7 billion in 2014 and \$2.6 billion in 2013. On October 20, 2014, the board of directors declared a quarterly cash dividend of \$0.49 per share for stockholders of record at the close of business on January 15, 2015, payable on February 13, 2015. The timing, declaration, amount of, and payment of any dividends is within the discretion of AbbVie's 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 February 2013, AbbVie's board of directors authorized a \$1.5 billion common stock repurchase program, which was effective immediately. In October 2014, AbbVie's board of directors authorized a new \$5.0 billion stock repurchase program, which was effective immediately and superseded the prior authorization. Under these programs, the company repurchased approximately 9 million shares for \$550 million in the open market in 2014 and approximately 4 million shares for \$223 million in the open market in 2013. Purchases of AbbVie shares 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 share repurchase authorization was \$4.7 billion as of December 31, 2014.

Cash and equivalents in 2014 was also impacted by net unfavorable exchange rate changes totaling \$577 million principally due to the impact of the substantial weakening of the Euro in 2014 on the translation of the company's Euro-denominated assets, and 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. While a significant portion of cash and equivalents at December 31, 2014 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, 2014 has been reinvested indefinitely.

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, 2014 and 2013 were as follows:

(in millions)	Net receivables		Net receivables over one year past due	
	2014	2013	2014	2013
Greece	\$ 30	\$ 37	\$	\$
Portugal	27	59	7	3
Italy	176	245	16	22
Spain	213	440	10	135
<b>Total</b>	<b>\$ 446</b>	<b>\$ 781</b>	<b>\$ 33</b>	<b>\$ 160</b>

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. Currently, AbbVie does not believe the economic conditions in Southern Europe 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, 2014.

### **Credit Facility, Access to Capital and Credit Ratings**

#### *Credit Facility*

Prior to October 2014, AbbVie was party to a \$2.0 billion unsecured five-year revolving credit facility from a syndicate of lenders, which also supported commercial paper borrowings. The credit facility enabled the company to borrow funds at floating interest rates. In October 2014, AbbVie replaced its existing revolving credit facility with a new \$3.0 billion five-year revolving credit facility. The new revolving credit facility enables the company to borrow funds on an unsecured basis at variable interest rates and contains various covenants.

At December 31, 2014, the company was in compliance with 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, 2014 and 2013.

#### *Access to Capital*

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

#### *Credit Ratings*

On July 18, 2014, following the announcement of the proposed combination with Shire, Moody's Investor Service affirmed its Baa1 senior unsecured long-term rating and Prime-2 short-term rating and revised its ratings outlook to "stable" from "positive". In addition, Standard & Poor's Ratings Services (S&P) placed its "A" corporate credit rating and senior unsecured debt rating on AbbVie on CreditWatch with negative implications. On October 21, 2014, S&P affirmed AbbVie's "A" corporate credit rating and senior unsecured debt rating and removed the negative credit watch. S&P affirmed its "A-1" commercial paper rating and did not place it on CreditWatch. There were no other changes in the company's credit ratings in 2014.

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, 2014.

(in millions)	Total	Less than one year	One to three years	Three to five years	More than five years
Short-term borrowings	\$ 425	\$ 425	\$	\$	\$
Research and development collaborations(a)	500	500			
Long-term debt and capital lease obligations, including current portion	14,815	4,021	4,037	1,020	5,737
Interest on long-term debt(b)	4,604	303	685	517	3,099
Future minimum non-cancelable operating lease commitments	562	114	195	155	98
Purchase obligations and other(c)	863	818	38	5	2
Other long-term liabilities(d)	930	174	193	154	409
<b>Total</b>	<b>\$ 22,699</b>	<b>\$ 6,355</b>	<b>\$ 5,148</b>	<b>\$ 1,851</b>	<b>\$ 9,345</b>

- (a) Accounts payable and accrued liabilities includes a \$500 million accrual for a payment to Calico due to the satisfaction of certain conditions under the R&D collaboration, which was paid in the first quarter of 2015.
- (b) 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 2014. 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, 2014. Refer to Notes 9 and 10 for further discussion regarding the company's debt instruments and related interest rate agreements outstanding at December 31, 2014. Annual interest on capital lease obligations is not material.
- (c) 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.
- (d) 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, 2014. 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 6 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 U.S. generally accepted accounting principles 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 management companies, state agencies that administer the federal Medicaid program, insurance companies that administer Medicare drug plans, wholesalers, group purchasing organizations, and other government agencies and private entities. Rebate amounts are usually based upon the volume of purchases using contractual or statutory prices for a product. For each type of rebate, the factors used in the calculations of the accrual for that rebate include the identification of which products have been sold subject to the rebate, which customer or government agency price terms apply for that rebate, and the estimated lag time between sale and payment of the rebate. Using historical trends for that rebate, adjusted for current changes, AbbVie estimates the amount of the rebate that will be paid, and records the liability as a reduction of gross sales when AbbVie records its sale of the product. Settlement of the rebate generally occurs from two to eight months after sale. AbbVie regularly analyzes the historical rebate trends and makes adjustments to reserves for changes in trends and terms of rebate programs.

Rebate and chargeback accruals are recorded in the same period as the related sales, and are reflected as a reduction of sales. Rebates and chargebacks in 2014, 2013 and 2012 totaled \$5.9 billion, \$4.9 billion, and \$4.3 billion, respectively, or 29 percent, 30 percent, and 28 percent, respectively, of the gross sales subject to rebate. A one-percentage point increase in the percentage of rebates to related annual gross sales would decrease net sales by \$201 million in 2014. AbbVie considers a one-percentage point increase to be a reasonably likely increase in the percentage of rebates to related gross sales. Other allowances for cash discounts and returns charged against gross sales were \$610 million, \$748 million, and \$667 million in 2014, 2013 and 2012, respectively.

Management analyzes the adequacy of ending rebate accrual balances each quarter. In the United States, the most significant charges against gross sales are for Medicaid and Medicare rebates, managed care rebates, and wholesaler chargebacks. Medicaid rebates relate to the Federal Medicaid program, which is administered by state agencies, whereby rebates are provided to participating state and local government entities under various laws and regulations and in some cases supplemental rebates are also provided to the states under contractual agreements. Medicare rebates are negotiated with managed care organizations that manage prescription drug plans covering the Medicare Part D drug benefit. Pharmacy benefit manager rebates arise from contractual agreements with private health care plans that seek to reduce costs by negotiating discounts with pharmaceuticals manufacturers. Under wholesaler chargeback programs, the wholesaler charges AbbVie back for the difference between the price paid by the wholesaler to AbbVie and the price paid by the end customer to the wholesaler under contractual discount agreements negotiated between AbbVie and the end customer. In order to evaluate the adequacy of the ending accrual balances,

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

for each type of rebate, management uses both internal and external data to estimate the level of inventory in the distribution channel and the rebate claims processing lag time for that rebate. External data sources used to estimate the inventory in the distribution channel include inventory levels periodically reported by wholesalers. Management estimates the processing lag time based on periodic sampling of claims data. To estimate the rebate percentage or net price, systems and calculations are used to track sales by product and by customer or payer and to estimate the contractual or statutory rebate or net price. AbbVie believes its systems and calculations are reliable.

The following table is an analysis of the three largest rebate accruals and chargeback allowances, which comprise approximately 82 percent of the total consolidated rebate provisions charged against revenues in 2014. Remaining rebate provisions charged against gross sales 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, 2011	\$ 720	\$ 506	\$ 171
Provisions	1,077	830	1,645
Payments	(990)	(840)	(1,592)
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

Historically, adjustments to prior years' rebate accruals have not been material to net income. AbbVie employs various techniques to verify the accuracy of claims submitted to it, and where possible, works with the organizations submitting claims to gain insight into changes that might affect the rebate amounts. For Medicaid, Medicare, and other government agency programs, the calculation of a rebate involves interpretations of relevant regulations, which are subject to challenge or change in interpretation.

### *Cash Discounts and Returns*

Cash discounts can be reliably estimated. Product returns can be reliably estimated because AbbVie's historical returns are low, and because sales return terms and other sales terms have remained relatively unchanged for several periods.

### **Pension and 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 discount rate is the single rate that equates the discounted cash flows to the rates utilizing the yield curve. As a result, the yield-curve

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

approach reflects the specific cash flows for plans (i.e. duration) in calculating the discount rate. 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 post-employment plans as of December 31, 2014, and will be used in the calculation of net periodic benefit cost in 2015. A 50 basis point change in the assumed discount rate would have had the following effects on AbbVie's calculation of net periodic benefit costs in 2015 and projected benefit obligations as of December 31, 2014:

(in millions)	50 basis point	
	Increase	Decrease
<b>Defined benefit plans</b>		
Service cost and interest cost	\$ (53)	\$ 59
Projected benefit obligation	(466)	540
<b>Other post-employment plans</b>		
Service cost and interest cost	\$ (6)	\$ 7
Projected benefit obligation	(50)	58

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, 2014 and will be used in the calculation of net periodic benefit cost in 2015. As of December 31, 2014, 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 2015 by \$42 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, 2014 and will be used in the calculation of net periodic benefit cost in 2015. 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 2015 and projected benefit obligation as of December 31, 2014:

(in millions)	One percentage point	
	Increase	Decrease
Service cost and interest cost	\$ 21	\$ (16)
Projected benefit obligation	121	(92)

### 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 legal proceedings and claims, 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. There were no significant litigation reserves at December 31, 2014.

## 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 that could result in an impairment occurs. 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.

At December 31, 2014 and 2013, goodwill and intangible assets, net of amortization totaled \$7.4 billion and \$8.2 billion, respectively, and amortization expense for intangible assets was \$403 million, \$509 million, and \$625 million in 2014, 2013 and 2012, respectively. There were no impairments of goodwill in 2014, 2013 or



2012. 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 2012, AbbVie recorded impairment charges of \$13 million for certain projects under development. These charges were included in R&D expense. There were no impairment charges recorded in 2013.

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board 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 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. This guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. AbbVie can apply the amendments using one of the following two methods: (i) retrospectively to each prior reporting period presented, or (ii) retrospectively with the cumulative effect of initially applying the amendments recognized at the date of initial application. AbbVie is currently assessing the impact 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, British pound, and Japanese yen. 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 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, 2014 and 2013, AbbVie held \$1.4 billion and \$1.5 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, 2014 and 2013, AbbVie held notional amounts of \$6.8 billion and \$5.3 billion, respectively, of such foreign currency forward exchange contracts.

The following table reflects the total foreign currency forward contracts outstanding at December 31, 2014 and 2013.

(in millions)	2014			2013		
	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	\$ 6,342	1.263	\$ 114	\$ 4,650	1.359	\$ (56)
British pound	563	1.618	21	492	1.638	(3)
Japanese yen	333	116.9	6	401	103.2	7
All other currencies	930	N/A	7	1,308	N/A	(4)
Total	\$ 8,168		\$ 148	\$ 6,851		\$ (56)

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 \$790 million at December 31, 2014. If realized, this appreciation would negatively affect earnings over the remaining life of the contracts. 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 company estimates that a 10 percent depreciation of AbbVie's most significant foreign currency positions against the U.S. dollar would cause a foreign exchange loss on cash and short-term investments of \$611 million at December 31, 2014. A 10 percent depreciation is believed to be a reasonably possible near-term change in these currencies.

The company's Venezuelan operations continue to report with the U.S. dollar as the functional currency due to the hyperinflationary status of the Venezuelan economy. Currency restrictions enacted in Venezuela require AbbVie to obtain approval from the Venezuelan government to exchange Venezuelan bolivars for U.S. dollars and require such exchange to be made at the official exchange rate established by the government. Effective February 8, 2013, the Venezuelan government devalued the official exchange rate from 4.3 to 6.3, which resulted in a loss of \$11 million in 2013 that was recorded in net foreign exchange loss on the consolidated statement of earnings.

In the first quarter of 2014, the Venezuelan government expanded the number of exchange mechanisms to three rates of exchange. As of December 31, 2014, these were the CENCOEX rate of 6.3 (the official rate); the SICAD I rate at approximately 12; and the SICAD II rate at approximately 50. In February 2015, the Venezuelan government confirmed the official exchange rate of 6.3 Venezuelan bolivars per U.S. dollar will be used for settlement of food and medicine purchases. The company continues to use the official rate of 6.3 Venezuelan bolivars per U.S. dollar to report its Venezuela financial position, results of operations and cash flows, since the company believes that the nature of AbbVie's business operations qualify for the official rate as permitted by law. The company cannot predict whether there will be further devaluations of the Venezuelan currency or whether the use of the official rate of 6.3 will continue to be supported by evolving facts and circumstances. If circumstances change such that the company concludes it would be appropriate to use a different rate, or if a devaluation of the official rate occurs, it could result in a significant change to AbbVie's results of operations. At December 31, 2014, AbbVie had approximately \$240 million of net monetary assets denominated in the Venezuelan bolivar (converted at a rate of 6.3 VEF/USD) in its Venezuelan entity, which had net sales of \$240 million in 2014. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at a rate of 12 VEF/USD at December 31, 2014, it would have resulted in a devaluation loss of \$114 million in 2014.

### **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. AbbVie does not use derivative instruments, such as interest rate swaps, to manage its exposure to changes in interest rates for investment securities. At both December 31, 2014 and 2013, AbbVie had interest rate hedge contracts totaling \$8.0 billion. 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 \$348 million at December 31, 2014. 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 \$758 million at December 31, 2014. 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 from strategic technology acquisitions that are traded on public stock exchanges. The fair value of these investments was approximately \$82 million and \$49 million as of December 31, 2014 and 2013, respectively. AbbVie monitors these investments for other than temporary declines in market value, and charges impairment losses to income when an other than temporary decline in value occurs. A hypothetical 20 percent decrease in the share prices of these investments would have had an immaterial decrease to their fair value at December 31, 2014. 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 from strategic technology acquisitions that are not traded on public stock exchanges. The carrying value of these investments was approximately \$63 million and \$58 million as of December 31, 2014 and 2013, respectively. AbbVie monitors these investments for other than temporary declines in market value, and charges impairment losses to income when an other than temporary decline in estimated value occurs.

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

	<b>Page</b>
<b>Consolidated Financial Statements</b>	
<u>Consolidated Statements of Earnings</u>	<u>57</u>
<u>Consolidated Statements of Comprehensive Income</u>	<u>58</u>
<u>Consolidated Balance Sheets</u>	<u>59</u>
<u>Consolidated Statements of Equity</u>	<u>60</u>
<u>Consolidated Statements of Cash Flows</u>	<u>61</u>
<u>Notes to Consolidated Financial Statements</u>	<u>62</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>100</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>101</u>

## AbbVie Inc. and Subsidiaries

## Consolidated Statements of Earnings

years ended December 31 (in millions, except per share data)	2014	2013	2012
<b>Net sales</b>	\$ 19,960	\$ 18,790	\$ 18,380
Cost of products sold	4,426	4,581	4,508
Selling, general and administrative	7,724	5,352	4,989
Research and development	3,297	2,855	2,778
Acquired in-process research and development	352	338	288
Other expense	750		
<b>Total operating costs and expenses</b>	<b>16,549</b>	<b>13,126</b>	<b>12,563</b>
Operating earnings	3,411	5,664	5,817
Interest expense, net	391	278	84
Net foreign exchange loss	678	55	17
Other income, net	(27)	(1)	(9)
Earnings before income tax expense	2,369	5,332	5,725
Income tax expense	595	1,204	450
<b>Net earnings</b>	<b>\$ 1,774</b>	<b>\$ 4,128</b>	<b>\$ 5,275</b>

## Per share data

Basic earnings per share	\$ 1.11	\$ 2.58	\$ 3.35
Diluted earnings per share	\$ 1.10	\$ 2.56	\$ 3.35
Cash dividends declared per common share	\$ 1.75	\$ 2.00(a)	n/a
Weighted-average basic shares outstanding	1,595	1,589	1,577(b)
Weighted-average diluted shares outstanding	1,610	1,604	1,577(b)

(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. Refer to Note 12 for additional information regarding cash dividends declared in 2013.

(b) On January 1, 2013, Abbott Laboratories distributed 1,577 million shares of AbbVie common stock. For periods prior to the separation, the weighted-average basic and diluted shares outstanding was based on the number of shares of AbbVie common stock outstanding on the distribution date. Refer to Note 5 for information regarding the calculation of basic and diluted earnings per common share for the years ended December 31, 2014 and 2013.

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

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

years ended December 31 (in millions)	2014	2013	2012
<b>Net earnings</b>	\$ 1,774	\$ 4,128	\$ 5,275
Foreign currency translation adjustments, net of tax (benefit) expense of \$(158) in 2014 and \$71 in 2013	(1,073)	48	173
Pension and post-employment benefits, net of tax (benefit) expense of \$(351) in 2014, \$309 in 2013, and \$(24) in 2012	(781)	598	(150)
Unrealized (losses) gains on marketable equity securities, net of tax expense (benefit) of \$1 in 2014, \$ in 2013, and \$(15) in 2012	1	1	(25)
Hedging activities, net of tax expense (benefit) of \$8 in 2014, \$ in 2013, and \$(8) in 2012	264	(77)	(27)
Other comprehensive (loss) income	(1,589)	570	(29)
<b>Comprehensive income</b>	\$ 185	\$ 4,698	\$ 5,246

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

## AbbVie Inc. and Subsidiaries

## Consolidated Balance Sheets

as of December 31 (in millions, except share data)	2014	2013
<b>Assets</b>		
<b>Current assets</b>		
Cash and equivalents	\$ 8,348	\$ 9,595
Short-term investments	26	300
Accounts and other receivables, net	3,735	3,854
Inventories, net	1,124	1,150
Income tax receivable	556	949
Deferred income taxes	896	766
Prepaid expenses and other	1,403	1,234
<b>Total current assets</b>	<b>16,088</b>	<b>17,848</b>
Investments	92	118
Property and equipment, net	2,485	2,298
Intangible assets, net of amortization	1,513	1,890
Goodwill	5,862	6,277
Other assets	1,507	767
<b>Total assets</b>	<b>\$ 27,547</b>	<b>\$ 29,198</b>
<b>Liabilities and Equity</b>		
<b>Current liabilities</b>		
Short-term borrowings	\$ 425	\$ 413
Current portion of long-term debt and lease obligations	4,021	18
Accounts payable and accrued liabilities	6,954	6,448
<b>Total current liabilities</b>	<b>11,400</b>	<b>6,879</b>
Long-term liabilities	3,840	3,535
Long-term debt and lease obligations	10,565	14,292
Commitments and contingencies		
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value, authorized 4,000,000,000 shares, issued 1,609,519,046 and 1,594,260,996 shares as of December 31, 2014 and 2013, respectively	16	16
Common stock held in treasury, at cost, 18,129,715 and 6,900,434 shares as of December 31, 2014 and 2013, respectively	(972)	(320)
Additional paid-in-capital	4,194	3,671
Retained earnings	535	1,567
Accumulated other comprehensive loss	(2,031)	(442)
<b>Total stockholders' equity</b>	<b>1,742</b>	<b>4,492</b>
<b>Total liabilities and equity</b>	<b>\$ 27,547</b>	<b>\$ 29,198</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		Treasury stock	Additional		Retained earnings	Net parent company investment	Total
	shares outstanding	Common stock		paid-in capital	other comprehensive loss			
<b>Balance at December 31, 2011</b>		\$	\$	\$	\$	(25)	\$ 11,957	\$ 11,932
Net earnings							5,275	5,275
Net transactions with Abbott Laboratories							(13,519)	(13,519)
Assumption of accumulated unrealized losses on pension and other post-employment benefits, net of tax benefit of \$36						(296)		(296)
Other comprehensive loss, net of tax						(29)		(29)
<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 stock 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		(442)	1,567	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	\$	(2,031)	\$ 535	\$ 1,742

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)	2014	2013	2012
<b>Cash flows from operating activities</b>			
Net earnings	\$ 1,774	\$ 4,128	\$ 5,275
Adjustments to reconcile net earnings to net cash from operating activities:			
Depreciation	383	388	525
Amortization of intangible assets	403	509	625
Stock-based compensation	241	212	187
Upfront costs related to collaborations and acquired in-process research and development	1,102	338	288
Other, net	434	34	66
Changes in operating assets and liabilities, net of acquisitions:			
Accounts and other receivables	(172)	681	223
Inventories	(203)	(56)	(203)
Prepaid expenses and other assets	(220)	459	90
Accounts payable and other liabilities	(193)	(426)	(731)
<b>Cash flows from operating activities</b>	<b>3,549(a)</b>	<b>6,267</b>	<b>6,345</b>
<b>Cash flows from investing activities</b>			
Acquisitions and investments, net of cash acquired	(622)	(405)	(688)
Acquisitions of property and equipment	(612)	(491)	(333)
Purchases of investment securities	(1,169)	(930)	(2,550)
Sales and maturities of investment securities	1,477	2,705	1,153
<b>Cash flows from investing activities</b>	<b>(926)</b>	<b>879</b>	<b>(2,418)</b>
<b>Cash flows from financing activities</b>			
Net change in short-term borrowings	12	(601)	1,000
Dividends paid	(2,661)	(2,555)	
Purchases of treasury stock	(652)	(320)	
Proceeds from the exercise of stock options	225	347	
Proceeds from issuance of long-term debt			14,586
Net transactions with Abbott Laboratories, excluding noncash items		(247)	(13,504)
Other, net	(217)	(66)	(151)
<b>Cash flows from financing activities</b>	<b>(3,293)</b>	<b>(3,442)</b>	<b>1,931</b>
Effect of exchange rate changes on cash and equivalents	(577)	(10)	16
Net (decrease) increase in cash and equivalents	(1,247)	3,694	5,874
Cash and equivalents, beginning of year	9,595	5,901	27
<b>Cash and equivalents, end of year</b>	<b>\$ 8,348</b>	<b>\$ 9,595</b>	<b>\$ 5,901</b>
<b>Other supplemental information</b>			
Interest paid, net of portion capitalized	\$ 419	\$ 283	\$ 61
Income taxes paid	\$ 498	\$ 1,305	\$

(a)

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

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. Refer to Note 4 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 sales 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 (the separation). On January 1, 2013, Abbott's shareholders of record as of the close of business on December 12, 2012, received one share of AbbVie common stock for every one share of Abbott common stock held as of the record date. AbbVie's common stock began trading "regular-way" under the ticker symbol "ABBV" on the New York Stock Exchange on January 2, 2013.

During the year ended 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 the historical financial statements 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 include 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 facilitate the separation by allowing AbbVie to operate independently prior to establishing stand-alone back office functions across its organization. Transition services may be provided for 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.

During the years ended December 31, 2014, 2013 and 2012, AbbVie incurred \$445 million, \$254 million, and \$288 million, respectively, of separation-related expenses including legal, information technology and regulatory fees, which were principally classified in selling, general and administrative expenses (SG&A) in the consolidated statements of earnings.

**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.

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

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, 2014 and 2013. Net sales related to these operations for the years ended December 31, 2014 and 2013 totaled approximately \$282 million and \$738 million, respectively. At December 31, 2014, the assets and liabilities consisted primarily of accounts receivable of \$27 million, inventories of \$16 million, other assets of \$33 million and accounts payable and other accrued liabilities of \$50 million. At December 31, 2013, the assets and liabilities consisted primarily of accounts receivable of \$62 million, inventories of \$190 million, other assets of \$93 million and accounts payable and other accrued liabilities of \$212 million. The majority of these operations are expected to be transferred to AbbVie by the end of 2015.

Prior to the separation on January 1, 2013, the historical financial statements of AbbVie 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 herein 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 U.S. generally accepted accounting principles (GAAP).

The historical combined financial statements included the allocation of certain assets and liabilities that were historically held at the Abbott corporate level but which were specifically identifiable or allocable to AbbVie. Prior to 2012, cash and equivalents, short-term investments and restricted funds held by Abbott were not allocated to AbbVie unless those assets were held by an entity that was transferred to AbbVie. As of December 31, 2012, AbbVie's combined balance sheet reflected the direct holdings of AbbVie legal entities. Prior to November 2012, long-term debt and short-term borrowings were not allocated to AbbVie as none of the debt recorded by Abbott was directly attributable to or guaranteed by AbbVie. In November 2012, AbbVie issued \$14.7 billion of long-term debt with maturities ranging from three to 30 years and \$1.0 billion of commercial paper, which was reflected on AbbVie's combined balance sheet as of December 31, 2012. All AbbVie intracompany transactions and accounts were eliminated. Prior to 2012, all intercompany transactions between AbbVie and Abbott were considered to be effectively settled in the historical combined financial statements at the time the transactions were recorded. As a result, the total net effect of the settlement of these intercompany transactions was reflected in the combined statement of cash flows for the year ended December 31, 2012 as a financing activity and in the combined balance sheet as of December 31, 2012 as net parent company investment in AbbVie. As of December 31, 2012, outstanding transactions between AbbVie and Abbott were reflected in the combined balance sheet outside of net parent company investment in AbbVie Inc. As of December 31, 2014 and 2013, the aggregate amount due from Abbott totaled \$526 million and \$738 million, respectively, and was primarily classified in accounts and other receivables, net in AbbVie's consolidated balance sheets. The aggregate amount due to Abbott totaled \$536 million and \$876 million as of December 31, 2014 and 2013, respectively, and was classified in accounts payable and accrued liabilities in AbbVie's consolidated balance sheets.

Prior to the separation on January 1, 2013, Abbott provided AbbVie certain services, which included administration of treasury, payroll, employee compensation and benefits, travel and meeting services, public and investor relations, real estate services, internal audit, telecommunications, information technology, corporate income tax and selected legal services. Some of these services continue to be provided to AbbVie on a temporary basis after the separation pursuant to certain transition services agreements. AbbVie's historical combined financial statements for periods prior to January 1, 2013 reflect an allocation of expenses related to these services. 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, publicly-traded company for the

periods prior to January 1, 2013. These allocations totaled \$838 million for the year ended December 31, 2012.

Prior to the separation on January 1, 2013, AbbVie employees participated in various benefits and stock-based compensation programs maintained by Abbott. A portion of the cost of those programs was included in AbbVie's historical combined financial statements. See Note 11 and Note 12 for a further description of the accounting for post-employment benefits and stock-based compensation, respectively.

## **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 sales 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, 2014 and 2013 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 income, net. 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 sales are recorded. 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 sales. 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 Costs**

Internal research and development (R&D) costs 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. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in intangible assets, net of accumulated amortization.

### **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). Subsequent payments made to the partner for the achievement of milestones during the development stage are expensed to R&D 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 as cost of products sold when incurred.

### **Advertising**

Costs associated with advertising are expensed as incurred and are included in SG&A in AbbVie's consolidated statements of earnings. Advertising expenses were \$665 million, \$626 million, and \$506 million in 2014, 2013 and 2012, respectively.

### **Pension and 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 period benefit cost over a five-year period.

Prior to separation, AbbVie employees participated in certain defined benefit pension and other post-employment plans sponsored by Abbott, which included participants of Abbott's other businesses. Such plans were accounted for as multiemployer plans in AbbVie's historical combined financial statements as of and for the year ended December 31, 2012. As a result, no asset or liability was recorded by AbbVie in the historical combined balance sheets to recognize the funded status of these plans. In 2013, subsequent to the separation from Abbott, AbbVie's portion of the defined benefit pension plans was separated from the Abbott defined benefit pension plans using a December 31, 2012 measurement date. As a result, the funded status for each plan is reflected in AbbVie's consolidated balance sheets as of December 31, 2014 and 2013. AbbVie is the sole sponsor for certain defined benefit pension and other post-employment plans. The funded status of these plans was recorded in AbbVie's combined balance sheet at December 31, 2012 and the consolidated balance sheets at December 31, 2014 and 2013.

Refer to Note 11 for information regarding AbbVie's pension and post-employment plans.

### **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



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

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.

In AbbVie's financial statements for periods prior to 2013, income tax expense and tax balances were calculated as if AbbVie was a separate taxpayer, although AbbVie's operations were historically included in tax returns filed by Abbott. After separation, AbbVie's income tax expense and income tax balances represent AbbVie's federal, state and foreign income taxes as an independent company. As a result, its effective tax rate and income tax balances are not necessarily comparable to those for periods prior to the separation.

### Cash and Equivalents

Cash and equivalents include time deposits, money market funds, and treasury securities 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. 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 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, the cost basis investment is written down with a charge to other income, net and the available-for-sale securities' unrealized loss is recognized as a charge to income and removed from accumulated other comprehensive loss (AOCI).

### 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 \$74 million at December 31, 2014 and \$88 million at December 31, 2013.

### 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)	2014	2013
Finished goods	\$ 341	\$ 485
Work-in-process	629	404
Materials	154	261
Inventories, net	\$ 1,124	\$ 1,150

**Property and Equipment**

as of December 31 (in millions)	2014	2013
Land	\$ 48	\$ 50
Buildings	1,228	1,263
Equipment	5,324	5,214
Construction in progress	505	382
Property and equipment, gross	7,105	6,909
Less accumulated depreciation	(4,620)	(4,611)
Property and equipment, net	\$ 2,485	\$ 2,298

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 for the years ended December 31, 2014, 2013 and 2012 was \$383 million, \$388 million and \$525 million, 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**

Loss contingency provisions are recorded for probable losses 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.

**Product Liability**

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 adjusted quarterly as additional information becomes available. Recoveries 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 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 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.

Based upon the company's most recent annual impairment test performed in the third quarter of 2014, the company concluded goodwill was not impaired. 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 2012, AbbVie recorded impairment charges of \$13 million for certain projects under development. These charges were included in R&D expense. There were no impairment charges recorded in 2013.

#### **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 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. 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 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 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 accumulated other comprehensive loss 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 accumulated other comprehensive loss 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 a 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.

Refer to Note 10 for information regarding AbbVie's derivative and hedging activities.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board 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 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. This guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. AbbVie can apply the amendments using one of the following two methods: (i) retrospectively to each prior reporting period presented, or (ii) retrospectively with the cumulative effect of initially applying the amendments recognized at the date of initial application. AbbVie is currently assessing the impact of adopting this guidance to its consolidated financial statements.

**Note 3 Supplemental Financial Information****Interest Expense, Net**

years ended December 31 (in millions)	2014	2013	2012
Interest expense	\$ 429	\$ 299	\$ 104
Interest and dividend income	(38)	(21)	(20)
Interest expense, net	\$ 391	\$ 278	\$ 84

Interest expense, net in 2014 included \$141 million of financing related fees incurred in connection with the terminated proposed combination with Shire.

**Other Income, Net**

Other income, net, includes income from the resolution of certain contractual agreements, fair value adjustments to contingent consideration, and impairments of 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)	2014	2013
Sales rebates	\$ 1,384	\$ 1,401
Accounts payable	881	933
Due to Abbott Laboratories	536	876
Dividends payable	791	643
Salaries, wages and commissions	623	621
Royalty license arrangements	821	443
Other	1,918	1,531
Accounts payable and accrued liabilities	\$ 6,954	\$ 6,448

**Long-Term Liabilities**

as of December 31 (in millions)	2014	2013
Deferred income taxes	\$ 630	\$ 570
Pension and other post-employment benefits	2,220	1,628
Other	990	1,337
Long-term liabilities	\$ 3,840	\$ 3,535

**Note 4 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 plc, a company incorporated in Jersey (Shire), and recommended stockholders vote against the proposed combination. On October 20, 2014, AbbVie and Shire mutually agreed to terminate the proposed combination. During the year-ended December 31, 2014, the company incurred transaction and financing-related costs totaling \$1.8 billion, of which \$1.7 billion was recorded in SG&A expense and

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

\$141 million was recorded in interest expense. Included in SG&A expense was a break fee of \$1.6 billion, which is 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. AbbVie expects to record additional foreign exchange losses of \$170 million in the first quarter of 2015 to reflect the completed liquidation of its remaining foreign currency positions. Refer to Note 10 for further information regarding these forward contracts and to Note 9 for further information regarding certain credit facilities entered into in anticipation of the proposed combination with Shire.

#### **Note 5 Earnings Per Share**

---

For periods subsequent to the separation, AbbVie calculated basic earnings per share (EPS) pursuant to 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 have been 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.

The dilutive effect of participating securities is calculated using the more dilutive of the treasury stock or the two-class method. For the years ended December 31, 2014 and 2013, the two-class method was more dilutive. As such, the dilutive effect of outstanding RSUs and RSAs for the years ended December 31, 2014 and 2013 of approximately 4 million and 5 million, respectively, was 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 the years ended December 31, 2014 and 2013 were approximately \$9 million and \$26 million, respectively.

For the years ended December 31, 2014 and 2013, approximately 0.4 million and 1 million common shares issuable under stock-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

For periods prior to the separation, the numerator for both basic and diluted EPS was net earnings attributable to AbbVie. The denominator for basic and diluted EPS was calculated using the 1,577 million AbbVie common shares outstanding immediately following the separation. The same number of shares was used to calculate basic and diluted earnings per share since no AbbVie equity awards were outstanding prior to the separation.

#### **Note 6 Acquisitions, Collaborations and Other Arrangements**

---

In 2014, 2013 and 2012, cash outflows related to collaborations, the acquisition of product rights and other arrangements totaled \$622 million, \$405 million and \$688 million, respectively. AbbVie recorded IPR&D charges of \$352 million, \$338 million and \$288 million in 2014, 2013 and 2012, respectively. In 2014, AbbVie also recorded other expenses of \$750 million related to a collaboration. Significant arrangements impacting 2014, 2013 and 2012, some of which require contingent milestone payments, are summarized below. In addition to the significant arrangements described below, AbbVie entered several other arrangements resulting in charges to IPR&D of \$77 million in 2014 and \$48 million in 2013 and upon the achievement of certain development, regulatory and commercial milestones, could make additional payments of up to \$966 million and \$894 million related to arrangements entered into in 2014 and 2013,

respectively. It is not possible to predict with reasonable certainty whether these milestones will be achieved or the timing for achievement.

Significant arrangements impacting 2014, 2013 and 2012, some of which require contingent milestone payments, include the following:

*Calico Life Sciences LLC*

In September 2014, AbbVie and Calico Life Sciences LLC (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 expense in the consolidated statement of operations related to its commitments under the agreement of which \$250 million was paid in 2014 and \$500 million was paid in early 2015. Calico will be responsible for research and early development during the first five years and 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. Upon the achievement of certain development, regulatory and commercial milestones, AbbVie could make additional payments of up to \$530 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.

In February 2012, AbbVie recorded a charge to IPR&D of \$150 million as a result of entering into a global collaboration with Galapagos to develop and commercialize a next-generation, oral Janus Kinase 1 (JAK1) inhibitor in Phase 2 development with the potential to treat multiple autoimmune diseases. Additional payments of approximately \$1.3 billion could be required for the achievement of certain development, regulatory and commercial milestones under this agreement.



*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. AbbVie could make additional payments totaling up to \$275 million pursuant to this arrangement.

*Action Pharma A/S*

In May 2012, AbbVie recorded a charge to IPR&D of \$110 million as a result of the acquisition of ABT-719 (previously referred to as AP214), a drug under development for the prevention of acute kidney injury associated with major cardiac surgery in patients at increased risk.

**Note 7 Goodwill and Intangible Assets****Goodwill**

The carrying amount of goodwill was \$5.9 billion and \$6.3 billion at December 31, 2014 and 2013, respectively. Changes in the goodwill balance in 2014 were primarily due to foreign currency translation. Changes in the goodwill balance in 2013 were attributable to foreign currency translation and goodwill additions of \$25 million related to product rights acquired during the second quarter. As of December 31, 2014, 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:

(in millions)	December 31, 2014			December 31, 2013		
	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	\$ 4,546	\$ (3,706)	\$ 840	\$ 4,744	\$ (3,503)	\$ 1,241
License agreements	1,097	(869)	228	994	(792)	202
Total definite-lived intangible assets	5,643	(4,575)	1,068	5,738	(4,295)	1,443
<b>Indefinite-lived research and development</b>						
	445		445	447		447
Total intangible assets	\$ 6,088	\$ (4,575)	\$ 1,513	\$ 6,185	\$ (4,295)	\$ 1,890

Intangible assets with finite useful lives are amortized over their estimated useful lives, which range between 3 to 16 years with an average of 13 years and 10 years for developed product rights and license agreements, respectively. 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.

Amortization expense for 2014, 2013 and 2012 was \$403 million, \$509 million and \$625 million, respectively, and is included in cost of products sold in the consolidated statements of earnings. At December 31, 2014, the anticipated annual amortization expense for intangible assets recorded as of December 31, 2014 was \$247 million in 2015, \$164 million in 2016, \$152 million in 2017, \$145 million in 2018 and \$107 million in 2019. 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 is included in cost of products sold.

The indefinite-lived intangible assets as of December 31, 2013 relate to IPR&D acquired in a business combination. In 2012, AbbVie recorded an impairment charge of \$13 million for certain projects under development. The charge was based on a discounted cash flow analysis and was included in R&D expense. In 2014, no material impairment charges were recorded related to indefinite-lived intangible assets.



**Note 8 Restructuring Plans**

In 2014 and prior years, AbbVie management approved plans to realign its worldwide manufacturing operations and selected domestic and international commercial and R&D operations in order to reduce costs in conjunction with the loss and expected loss of exclusivity of certain products. Restructuring charges recorded in 2014 were \$23 million and were primarily recorded in cost of products sold in the consolidated statements of earnings with the remainder recorded in SG&A. Included in the charges were cash costs of \$16 million which primarily related to employee severance and contractual obligations.

In 2013, AbbVie management approved plans to restructure certain commercial operations in conjunction with the loss and expected loss of exclusivity of certain products. Restructuring charges recorded in 2013 were \$83 million and were primarily recorded in SG&A and cost of products sold in the consolidated statements of earnings with the remainder recorded in R&D. Included in the charges were cash costs of \$76 million which mainly related to employee severance and contractual obligations.

In 2012, AbbVie management approved plans to realign its worldwide manufacturing operations and selected domestic and international commercial and R&D operations in order to reduce costs. In 2012, AbbVie incurred restructuring charges of approximately \$191 million for employee severance and contractual obligations, primarily related to the exit from an R&D facility with \$183 million recorded within R&D and \$8 million within SG&A expenses in the consolidated statements of earnings.

The following summarizes the cash activity in the restructuring reserve for the years ended December 31, 2014 and 2013:

(in millions)

Accrued balance at December 31, 2011	\$	149
2012 restructuring charges		191
Payments and other adjustments		(107)
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

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. In 2012, AbbVie recorded additional restructuring charges of \$69 million, primarily for accelerated depreciation.

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

The following is a summary of long-term debt as of December 31, 2014 and 2013:

(in millions)	Effective interest rate in 2014(a)	2014	Effective interest rate in 2013(a)	2013
Floating rate notes due 2015	1.09%	\$ 500	1.14%	\$ 500
1.2% notes due 2015	1.31%	3,500	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
Other		115		98
Fair value hedges		(180)		(432)
Unamortized bond discounts		(49)		(56)
<b>Total long-term debt and lease obligations</b>		<b>14,586</b>		<b>14,310</b>
<b>Current portion</b>		<b>4,021</b>		<b>18</b>
<b>Noncurrent portion</b>		<b>\$ 10,565</b>		<b>\$ 14,292</b>

(a)

Excludes the effect of any related interest rate swaps.

In November 2012, AbbVie issued \$14.7 billion aggregate principal amount of senior notes. Approximately \$3.0 billion of these senior notes were issued to Abbott as partial consideration for the transfer of assets from Abbott to AbbVie. AbbVie used part of the net proceeds from the sale of senior notes (other than the senior notes issued to Abbott) to finance the payment made in November 2012 of a \$10.2 billion distribution to Abbott, as provided by the terms of the separation agreement. The debt was guaranteed by Abbott until AbbVie separated from Abbott on January 1, 2013.

AbbVie may redeem all of the senior notes of each series, other than the floating notes due in 2015, at any time, and some of the senior notes of each series, other than the floating notes due in 2015, from time to time, at a redemption price equal to the principal amount of the senior notes redeemed plus a make-whole premium. AbbVie may not redeem the floating notes due in 2015 prior to maturity. At December 31, 2014, the company was in compliance with its senior note covenants.

**Short-Term Borrowings**

At December 31, 2014 and 2013, short-term borrowings included \$416 million and \$400 million, respectively, of commercial paper borrowings. The weighted-average interest rate on short-term borrowings was 0.2% and 0.2% for 2014 and 2013, respectively.

Prior to October 2014, AbbVie had a \$2.0 billion unsecured five-year revolving credit facility agreement. In October 2014, AbbVie replaced its existing revolving credit facility with the \$3.0 billion five-year revolving credit facility which also supports commercial paper borrowings. At December 31, 2014, AbbVie was in compliance with the financial covenants. No borrowings were outstanding under these facilities at December 31, 2014 and December 31, 2013.

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

The following table summarizes AbbVie's future minimum lease payments under non-cancelable operating leases, debt maturities and future minimum lease payments for capital lease obligations as of December 31, 2014:

as of and for the years ended December 31 (in millions)	Operating leases	Debt maturities and capital leases
2015	\$ 114	\$ 4,021
2016	103	19
2017	92	4,018
2018	81	1,014
2019	74	6
Thereafter	98	5,737
<b>Total obligations and commitments</b>	<b>562</b>	<b>14,815</b>
Fair value hedges and unamortized bond discounts	n/a	(229)
<b>Total debt and lease obligations</b>	<b>\$ 562</b>	<b>\$ 14,586</b>

Lease expense was \$115 million in 2014 and \$107 million in 2013 and was not material for 2012. As part of the separation, AbbVie entered into agreements to lease certain facilities, including office, laboratory, and factory and warehouse space, under principally non-cancelable operating leases with Abbott. 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. Capital lease obligations relate to automobiles and certain facilities. As of December 31, 2014, annual future minimum lease payments for capital lease obligations are not material.

Debt maturities and capital leases in 2015 include the \$500 million floating notes due in 2015 and maturities of \$3.5 billion of 1.2% senior notes.

**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 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

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

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 \$1.4 billion and \$1.5 billion at December 31, 2014 and December 31, 2013, respectively, are designated as cash flow hedges and are recorded at fair value. Accumulated gains and losses as of December 31, 2014 will be included in cost of products sold at the time the products are sold, generally not exceeding twelve months.

The company enters into foreign currency forward exchange contracts to manage its exposure to foreign currency denominated trade payables and receivables and intercompany loans. The contracts are marked-to-market, and resulting gains or losses are reflected in income and are generally offset by losses or gains on the foreign currency exposure being managed. At December 31, 2014 and December 31, 2013, AbbVie held notional amounts of \$6.8 billion and \$5.3 billion, respectively, of such foreign currency forward exchange contracts.

In 2014, the company entered into undesignated forward 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 original maturity is in the 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 loss associated with the Shire-related forward contracts.

AbbVie is a party to interest rate hedge contracts, designated as fair value hedges, totaling \$8.0 billion at both December 31, 2014 and December 31, 2013. 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 as of December 31.

(in millions)	Fair value		Derivatives in asset position	Fair value		Derivatives in liability position
	2014	2013	Balance sheet caption	2014	2013	Balance sheet caption
Interest rate swaps designated as fair value hedges	\$	\$	n/a	\$ 180	\$ 432	Long-term liabilities
Foreign currency forward exchange contracts						
Hedging instruments	141		Prepaid expenses and other		61	Accounts payable and accrued liabilities
Others not designated as hedges	70	17	Prepaid expenses and other	63	12	Accounts payable and accrued liabilities
<b>Total</b>	<b>\$ 211</b>	<b>\$ 17</b>		<b>\$ 243</b>	<b>\$ 505</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 following table summarizes the activity for derivative instruments and the amounts and location of income (expense) and gain (loss) reclassified into net earnings for the years ended December 31, 2014,

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

2013 and 2012, respectively. The amount of hedge ineffectiveness was not significant for the years ended December 31, 2014, 2013 and 2012.

(in millions)	Gain (loss) recognized in other comprehensive (loss) income			(Expense) income and (loss) gain reclassified into income			Income statement caption
	2014	2013	2012	2014	2013	2012	
<b>Foreign currency forward exchange contracts</b>							
Designated as cash flow hedges	\$ 193	\$ (77)	\$ (11)	\$ (79)		\$ 24	Cost of products sold
Not designated as hedges	n/a	n/a	n/a	(523)	81	(23)	Net foreign exchange (loss) gain
Interest rate swaps designated as fair value hedges	n/a	n/a	n/a	252	(351)	(81)	Interest expense (income), net

The gain/(loss) related to fair value hedges is recognized in net interest expense and directly offsets the (loss)/gain on the underlying hedged item, the fixed-rate debt, resulting in no net impact to net interest expense for years ended December 31, 2014 and 2013.

### 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, 2014:

(in millions)	Balance at December 31, 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>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	\$

Edgar Filing: AbbVie Inc. - Form 10-K

<b>Liabilities</b>					
Interest rate hedges	\$	180	\$	\$	180
Foreign currency contracts		63			63
Total liabilities	\$	243	\$	\$	243



## 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, 2013:

(in millions)	Basis of fair value measurement			
	Balance at December 31, 2013	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	\$ 9,595	\$ 684	\$ 8,911	\$
Time deposits	300		300	
Equity securities	10	10		
Foreign currency contracts	17		17	
<b>Total assets</b>	<b>\$ 9,922</b>	<b>\$ 694</b>	<b>\$ 9,228</b>	<b>\$</b>
<b>Liabilities</b>				
Interest rate hedges	\$ 432		\$ 432	\$
Foreign currency contracts	73		73	
Contingent consideration	165			165
<b>Total liabilities</b>	<b>\$ 670</b>	<b>\$</b>	<b>\$ 505</b>	<b>\$ 165</b>

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 value is 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. The contingent consideration is valued using a discounted cash flow technique that reflects management's expectations about probability of payment.

Cumulative net unrealized holding gains on available-for-sale equity securities totaled \$3 million and \$2 million at December 31, 2014 and December 31, 2013, respectively.

There have been no transfers of assets or liabilities between the fair value measurement levels. The following table is a reconciliation of the fair value measurements that use significant unobservable inputs (Level 3), which consist of contingent payments related to acquisitions and investments:

(in millions)	
Fair value as of December 31, 2012	\$ 251
Payments	(131)
Additions	28
Change in fair value recognized in earnings	17
Fair value as of December 31, 2013	165
Payments	(164)
Other	
Change in fair value recognized in earnings	(1)
Fair value as of December 31, 2014	\$

The contingent payments were primarily in connection with the acquisition of Solvay's U.S. pharmaceuticals business in 2010. The achievement of a certain sales milestone resulted in a payment of approximately

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

\$137 million in 2014 and \$131 million in 2013 for which a liability was previously established. Additions of \$28 million related to the acquisition of product rights in 2013. The change in fair value recognized in earnings was recognized in net foreign exchange loss and other income, net in the consolidated statements of earnings.

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 as of December 31, 2014 and 2013 are shown in the table below:

(in millions)	Book values		Approximate fair values	
	2014	2013	2014	2013
<b>Assets</b>				
Investments	\$ 95	\$ 108	\$ 145	\$ 129
<b>Liabilities</b>				
Short-term borrowings	425	413	425	413
Current portion of long-term debt and lease obligations	4,021	18	4,033	18
Long-term debt and lease obligations, excluding fair value hedges	10,745	14,724	10,830	14,493

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

(in millions)	Fair value at December 31, 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>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	4,033	4,012	21	
Long-term debt and lease obligations, excluding fair value hedges	10,830	10,737	93	
Total liabilities	\$ 15,288	\$ 14,749	\$ 539	\$

## 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, 2013.

(in millions)	Basis of fair value measurement			
	Fair value at December 31, 2013	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	\$ 129	\$ 39	\$ 30	\$ 60
<b>Total assets</b>	<b>\$ 129</b>	<b>\$ 39</b>	<b>\$ 30</b>	<b>\$ 60</b>
<b>Liabilities</b>				
Short-term borrowings	\$ 413	\$	\$ 413	\$
Current portion of long-term debt and lease obligations	18		18	
Long-term debt and lease obligations, excluding fair value hedges	14,493	14,413	80	
<b>Total liabilities</b>	<b>\$ 14,924</b>	<b>\$ 14,413</b>	<b>\$ 511</b>	<b>\$</b>

Investments consist of cost method investments and held-to-maturity debt securities. Cost method investments include certain investments for which the fair value is determined by using the published market price per unit multiplied by the number of units held, without consideration of transaction costs. To determine the fair value 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 value of long-term debt, excluding fair value hedges, was 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 counterparties to financial instruments consist of select major international financial institutions.

### Concentrations of Risk

The company invests excess cash in time deposits, money market funds and U.S. Treasury securities 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.

At December 31, 2014, AbbVie had approximately \$240 million of net monetary assets denominated in the Venezuelan bolivar (converted at a rate of 6.3 VEF/USD) in its Venezuelan entity, which had net sales of \$240 million in 2014. If AbbVie's net monetary assets denominated in the Venezuelan bolivar had been converted at a rate of 12 VEF/USD at December 31, 2014, it would have resulted in a devaluation loss of \$114 million in 2014. The company cannot predict whether there will be further devaluations of the Venezuelan currency or whether the use of the official rate of 6.3 will continue to be supported by evolving facts and circumstances. If circumstances change such that the company concludes it would be appropriate to use a different rate, or if a devaluation of the official rate occurs, it could result in a significant change to AbbVie's results of operations.

Three U.S. wholesalers accounted for 49 percent and 38 percent of total net accounts receivable as of December 31, 2014 and December 31, 2013, respectively, and substantially all of AbbVie's sales in the

United States are to these three wholesalers. In addition, net governmental receivables outstanding in Greece, Portugal, Italy and Spain totaled \$446 million at December 31, 2014 and \$781 million at December 31, 2013.

HUMIRA is AbbVie's single largest product and accounted for approximately 63 percent, 57 percent and 50 percent of AbbVie's total net sales in 2014, 2013 and 2012, 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 U.S. retirees, through other post-retirement benefit plans. Net obligations for these plans have been reflected in the consolidated balance sheets as of December 31, 2014 and 2013.

#### **Abbott Sponsored Plans**

Prior to separation, AbbVie employees participated in certain U.S. and international defined benefit pension and other post-employment benefit (OPEB) plans sponsored by Abbott. These plans included participants of Abbott's other businesses and were accounted for as multiemployer benefit plans in AbbVie's combined financial statements as of and for the year ended December 31, 2012. As a result, no asset or liability was recorded by AbbVie in the historical combined balance sheets through December 31, 2012 to recognize the funded status of these plans. Effective January 1, 2013, in connection with the separation of AbbVie from Abbott, these plans were separated and AbbVie assumed net benefit plan obligations that were previously provided by Abbott. For Abbott-sponsored defined benefit and post-employment benefit plans, AbbVie recorded expenses of \$200 million in 2012. Abbott made voluntary contributions to its defined benefit pension plans that AbbVie accounted for as multiemployer benefit plans totaling \$310 million in 2012.

#### **AbbVie Sponsored Plans**

Prior to the separation, AbbVie employees participated in the Abbott Laboratories Annuity Retirement Plan, which was Abbott's principal domestic defined benefit pension plan. In connection with the separation, AbbVie established the AbbVie Pension Plan, which is AbbVie's principal domestic defined benefit pension plan, with substantially the same terms as the Abbott Laboratories Annuity Retirement Plan. AbbVie employees who were eligible to participate in the Abbott Laboratories Annuity Retirement 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 its employees from the Abbott Laboratories Annuity Retirement Plan. AbbVie made voluntary contributions of \$370 million and \$145 million in 2014 and 2013, respectively, to this plan. AbbVie also made a voluntary contribution of \$150 million to this plan subsequent to December 31, 2014.

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

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

as of and for the years ended December 31 (in millions)	Defined benefit plans		Other post-employment plans	
	2014	2013	2014	2013
<b>Projected benefit obligations</b>				
Beginning of period	\$ 4,484	\$ 1,669	\$ 403	\$ 231
Service cost	173	184	22	23
Interest cost	217	196	22	19
Employee contributions	1	1		
Plan amendments	1	(1)	(13)	
Assumption of plan liabilities		3,009		209
Removal of plans				(12)
Actuarial (gain) loss	1,108	(455)	111	(55)
Benefits paid	(163)	(146)	(8)	(12)
Other, primarily foreign currency translation loss	(140)	27	1	
End of period	\$ 5,681	\$ 4,484	\$ 538	\$ 403
<b>Fair value of plan assets</b>				
Beginning of period	\$ 3,666	\$ 898	\$	\$
Actual return on plan assets	282	491		
Company contributions	430	198	8	12
Employee contributions	1	1		
Assumption of plan assets		2,221		
Benefits paid	(163)	(146)	(8)	(12)
Other, primarily foreign currency translation gain	(43)	3		
End of period	\$ 4,173	\$ 3,666	\$	\$
Funded status at December 31	\$ (1,508)	\$ (818)	\$ (538)	\$ (403)
<b>Amounts recognized in consolidated balance sheets</b>				
Other assets	\$ 210	\$ 442	\$	\$
Current liabilities	(26)	(27)	(10)	(8)
Long-term liabilities	(1,692)	(1,233)	(528)	(395)
Net liability at December 31	\$ (1,508)	\$ (818)	\$ (538)	\$ (403)
Actuarial losses, net	\$ 2,216	\$ 1,194	\$ 181	\$ 74
Prior service cost	19	22	(53)	(47)
AOCI at December 31	\$ 2,235	\$ 1,216	\$ 128	\$ 27

The projected benefit obligations (PBO) in the table above included \$1.4 billion and \$1.2 billion at December 31, 2014 and 2013, respectively, related to international defined benefit pension plans, a number of which generally are not funded in accordance with local regulations. Benefit payments under those plans are funded from company assets. The funded status at December 31, 2014 reflects that AbbVie considered the release of the new mortality tables and projection scales by the Society of Actuaries as an improvement of the estimate of future mortality and opted to change to the new tables in 2014.

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

For plans reflected in the table above, the accumulated benefit obligations (ABO) were \$5.0 billion and \$3.9 billion at December 31, 2014 and 2013, respectively. For those plans reflected in the table above in which the ABO exceeded plan assets at December 31, 2014, the ABO, PBO and aggregate plan assets were \$2.9 billion, \$3.5 billion and \$1.8 billion, respectively.

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

### *Amounts Recognized in AOCI and OCI*

The defined benefit pension and other post-employment plans' actuarial gains or losses and prior service costs or credits not yet recognized in net periodic benefit cost are recognized on a net-of-tax basis in AOCI and will be amortized to net periodic benefit cost in the future. The following is a summary of the pretax gains and losses included in OCI.

years ended December 31 (in millions)	2014	2013	2012
<b>Defined benefit plans</b>			
Actuarial (gain) loss	\$ 1,127	\$ (715)	\$ 98
Prior service cost	1	15	9
Amortization of actuarial losses and prior service costs	(68)	(114)	(7)
Foreign exchange loss	(41)	2	5
<b>Total pretax (gain) loss recognized in OCI</b>	<b>\$ 1,019</b>	<b>\$ (812)</b>	<b>\$ 105</b>

<b>Other post-employment plans</b>			
Actuarial (gain) loss	\$ 111	\$ (42)	\$ 69
Prior service cost	(13)	(53)	
Amortization of actuarial losses and prior service costs	3		
<b>Total pretax (gain) loss recognized in OCI</b>	<b>\$ 101</b>	<b>\$ (95)</b>	<b>\$ 69</b>

The pretax amount of actuarial (gain) loss and prior service cost included in AOCI at December 31, 2014 that is expected to be recognized in the net periodic benefit cost in 2015 is \$114 million for defined benefit plans and \$2 million for other post-employment plans.

### *Net Periodic Benefit Cost*

years ended December 31 (in millions)	2014	2013	2012
<b>Defined benefit plans</b>			
Service cost	\$ 173	\$ 184	\$ 21
Interest cost	217	196	38
Expected return on plan assets	(302)	(259)	(29)
Amortization of actuarial losses and prior service costs	68	114	7
<b>Net periodic pension benefit cost</b>	<b>\$ 156</b>	<b>\$ 235</b>	<b>\$ 37</b>

<b>Other post-employment plans</b>			
Service cost	\$ 22	\$ 23	\$
Interest cost	22	19	
Amortization of actuarial gain and prior service costs	(2)	(1)	
<b>Net periodic OPEB cost</b>	<b>\$ 42</b>	<b>\$ 41</b>	<b>\$</b>

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

**2014      2013**



<b>Defined benefit plans</b>		
Discount rate	3.9%	4.9%
Rate of compensation increases	4.4%	5.0%
<b>Other post-employment plans</b>		
Discount rate	4.5%	5.3%
Rate of compensation increases		6.0%

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

The assumptions above, which were used in calculating the December 31, 2014 measurement date benefit obligations, will be used in the calculation of net periodic benefit cost in 2015.

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

	2014	2013	2012
<b>Defined benefit plans</b>			
Discount rate	4.9%	4.3%	5.1%
Expected long-term rate of return on plan assets	7.9%	8.2%	8.5%
Expected rate of change in compensation	5.0%	5.0%	4.2%
<b>Other post-employment plans</b>			
Discount rate	5.3%	4.5%	N/A

For 2014, for purposes of measuring post-retirement health care obligations as of the measurement date, the company assumed a 7.5% pre-65 (7.3% 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% in 2064 and remain at that level thereafter. For purposes of measuring post-retirement health care costs, the company assumed a 7.9% pre-65 (7.6% post-65) annual rate of increase in the per capita cost of covered health care benefits. The rate was assumed to decrease gradually to 5% for 2051 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, 2014, a 1 percentage point change in assumed health care cost trend rates would have the following effects:

year ended December 31, 2014 (in millions)	One percentage point	
	Increase	Decrease
Service cost and interest cost	\$ 9	\$ (7)
Projected benefit obligation	121	(92)

### *Defined Benefit Pension Plan Assets*

(in millions)	Basis of fair value measurement			
	Balance at December 31, 2014	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(a)	\$ 1,314	\$ 588	\$ 726	\$
U.S. mid cap(b)	267	67	200	
International(c)	608	137	471	
<b>Fixed income securities</b>				
U.S. government securities(d)	216		216	
Corporate debt instruments(e)	326	101	225	
Government Securities International	425	201	224	
Other	37	29	8	
Absolute return funds(f)	848	3	371	474
Real assets	53	7	46	
Other(g)	79	79		
<b>Fair value of plan assets</b>	<b>\$ 4,173</b>	<b>\$ 1,212</b>	<b>\$ 2,487</b>	<b>\$ 474</b>

(in millions)	Balance at December 31, 2013	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(a)	\$ 1,197	\$ 576	\$ 621	\$
U.S. mid cap(b)	244	62	182	
International(c)	614	225	389	
<b>Fixed income securities</b>				
U.S. government securities(d)	292	35	257	
Corporate debt instruments(e)	212	57	155	
Government Securities International	216	159	57	
Other	52	45	7	
Absolute return funds(f)	704	3	290	411
Real assets	70	8	62	
Other(g)	65	62	3	
<b>Fair value of plan assets</b>	<b>\$ 3,666</b>	<b>\$ 1,232</b>	<b>\$ 2,023</b>	<b>\$ 411</b>

- (a) 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) Securities held by actively managed accounts, pooled index funds, and mutual funds.
- (f) 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.
- (g) Investments in cash and cash equivalents.

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.

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

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

(in millions)	2014	2013
Balance as of January 1	\$ 411	\$ 33
Actual return on plan assets on hand at year end	21	4
Assumption of level 3 assets		372
Purchases, sales and settlements, net	42	2
<b>Balance as of December 31</b>	<b>\$ 474</b>	<b>\$ 411</b>

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 50% in equity securities, 20% in fixed income securities and 30% 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 assets, 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 Pension and Other Post-Employment Payments*

(in millions)	Defined benefit plans	Other post-employment plans
2015	\$ 161	\$ 10
2016	170	12
2017	180	14
2018	192	15
2019	204	17
2020 to 2024	1,239	115

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**

Prior to the separation, AbbVie employees also participated in the Abbott Laboratories Stock Retirement Plan, which was Abbott's principal defined contribution plan. AbbVie recorded expense of \$67 million in 2012 related to this plan. In connection with the separation, AbbVie established the AbbVie Savings Plan, which is AbbVie's principal defined contribution plan, with substantially the same terms as the Abbott Laboratories Stock Retirement Plan. AbbVie employees who were eligible to participate in the Abbott Laboratories Stock Retirement Plan on December 31, 2012 automatically became eligible for the AbbVie Savings Plan. AbbVie recorded expense of \$67 million in 2014 and \$62 million in 2013 related to this plan.

AbbVie provides certain other post-employment benefits, primarily salary continuation plans, 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 \$241 million, \$212 million and \$187 million in 2014, 2013 and 2012, respectively, and is principally classified in SG&A for all periods presented with the remainder classified in R&D and cost of products sold. The related tax benefit recognized was \$73 million, \$68 million and \$56 million in 2014, 2013 and 2012, respectively. Stock-based compensation expense for 2012 was allocated to AbbVie based on the portion of Abbott's incentive stock program in which AbbVie employees participated.

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.

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 2014 and 2013, realized excess tax benefits associated with stock-based compensation totaled \$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.

*Stock Options*

The exercise price for options granted is at least equal to 100 percent of the market 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.

The fair value of stock options is determined using the Black-Scholes model. The weighted-average grant-date fair values of the stock options granted were \$9.83, \$6.87, and \$6.80 for 2014, 2013 and 2012, respectively. Stock-based compensation expense attributable to options during each of the years presented was not material.

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

The following table summarizes AbbVie stock option activity for both AbbVie and Abbott employees for the year ended December 31, 2014:

(options in thousands, aggregate intrinsic value in millions)	Options	Weighted-average exercise price	Weighted-Average remaining life (in years)	Aggregate intrinsic value
Outstanding at December 31, 2013	35,994	\$ 27.48	3.6	\$ 912
Granted	1,134	51.53		
Exercised	(8,765)	27.18		
Lapsed	(83)	25.97		
Outstanding at December 31, 2014	28,280	\$ 28.53	3.3	\$ 1,044
Exercisable at December 31, 2014	25,497	\$ 27.20	2.8	\$ 975

The aggregate intrinsic value in the table above represents the difference between the exercise price and the company's closing stock price on the last day of trading for the year ended December 31, 2014. The total intrinsic value of options exercised in 2014 and 2013 was \$253 million and \$229 million, respectively. For options issued under Abbott's incentive stock programs to AbbVie employees prior to the separation, the total intrinsic value of options exercised in 2012 was \$170 million. The total fair value of options vested during 2014 was \$8 million.

The excess tax benefit realized from option exercises totaled \$46 million for 2014. As of December 31, 2014, \$4 million of unrecognized compensation cost related to stock options is expected to be recognized as expense over approximately the next two years.

### RSAs & RSUs

RSAs generally vest over three or five years. For RSAs that vest over five years, no more than one-third of the award vests in any one year. RSUs vest over three years and, upon vesting, the recipient receives one share of common stock for each vested RSU. In addition, AbbVie grants selected executives and other key employees performance-based RSAs and RSUs with vesting contingent upon meeting various company-wide performance goals, including 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 the common stock on the date of grant. AbbVie assumes that the performance goals will be achieved. If such goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

The following table summarizes AbbVie RSA and RSU activity (including performance-based awards) for both AbbVie and Abbott employees for the year ended December 31, 2014:

(share units in thousands)	Share units	Weighted-average grant date fair value
Outstanding at December 31, 2013	14,910	\$ 32.07
Granted	5,112	51.55
Vested	(6,638)	29.43
Lapsed	(569)	38.48
Outstanding at December 31, 2014	12,815	\$ 40.98

The fair market value of RSAs and RSUs vested in 2014 and 2013 was \$338 million and \$285 million, respectively. For RSAs and RSUs issued under Abbott's incentive stock programs prior to the separation, the fair market value of RSAs and RSUs vested in 2012 was \$123 million. The weighted-average grant-date fair



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

value per share of RSAs and RSUs granted in 2012 was \$56.07. Such amounts have not been adjusted to reflect the separation from Abbott.

As of December 31, 2014, \$192 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 December 12, 2013, the board of directors declared a quarterly cash dividend of \$0.40 per share of common stock for stockholders of record on January 15, 2014, which was paid on February 14, 2014. Additionally, the quarterly cash dividend declared by the board of directors on February 20, 2014 of \$0.42 per share, which represented an increase of 5 percent over the previous quarterly rate of \$0.40 per share was paid on May 15. On June 18 and September 19, 2014, the board of directors declared quarterly cash dividends of \$0.42 per share which were paid on August 15 and November 17, 2014, respectively. Additionally, on October 20, 2014, the board of directors declared an increase in the company's quarterly cash dividend from \$0.42 per share to \$0.49 per share of common stock, for stockholders of record on January 15, 2015, which was paid on February 13, 2015.

### **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 supersedes the previous authorization, and is expected to be executed over the next several years. The 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 plan has no time limit and can be discontinued at any time.

During 2014 and 2013, AbbVie repurchased approximately 9 million shares and 4 million shares for \$550 million and \$223 million, respectively, in the open market. Shares repurchased under this program are recorded at acquisition cost, including related expenses, and are available for general corporate purposes. AbbVie's remaining share repurchase authorization was \$4.7 billion as of December 31, 2014.



Edgar Filing: AbbVie Inc. - Form 10-K

**Accumulated Other Comprehensive Loss**

The following table summarizes the changes in balances of each component of AOCI, net of tax for the years ended December 31, 2013 and 2014:

(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, 2011	\$ 8	\$ (65)	\$ 26	\$ 6	\$ (25)
Other comprehensive income before reclassifications	173	(157)	(25)	(9)	\$ (18)
Amounts reclassified from accumulated other comprehensive income		7		(18)	\$ (11)
Net current-period other comprehensive income	173	(150)	(25)	(27)	\$ (29)
Separation-related adjustments		(296)			\$ (296)
Balance as of December 31, 2012	\$ 181	\$ (511)	\$ 1	\$ (21)	\$ (350)
Other comprehensive income before reclassifications	48	519	1	(77)	\$ 491
Amounts reclassified from accumulated other comprehensive income		79			\$ 79
Net current-period other comprehensive income	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 income before reclassifications	(1,073)	(827)	1	187	\$ (1,712)
Amounts reclassified from accumulated other comprehensive income		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 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 the foreign currencies accumulated in anticipation of the terminated proposed combination with Shire plc.

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

The table below presents the significant amounts reclassified out of each component of accumulated other comprehensive loss for the years ended December 31, 2014 and 2013:

years ended December 31 (in millions)	2014	2013
<b>Pension and post-employee benefits</b>		
Amortization of actuarial losses and other	\$ 66	\$ 114
Less tax expense	(20)	(35)
Total reclassification, net of tax	\$ 46	\$ 79

<b>Hedging activities</b>		
Gains (losses) on designated cash flow hedges	\$ (79)	\$
Less tax expense	2	
Total reclassification, net of tax	\$ (77)	\$

### 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, 2014, no shares of preferred stock were issued or outstanding.

### Note 13 Income Taxes

#### Earnings Before Income Taxes

years ended December 31 (in millions)	2014	2013	2012
Domestic	\$ (3,245)	\$ (581)	\$ 625
Foreign	5,614	5,913	5,100
Total earnings before income taxes	\$ 2,369	\$ 5,332	\$ 5,725

The increase in the domestic loss before income taxes for the year ended December 31, 2014 was driven by transaction and financing-related costs associated with the terminated proposed combination with Shire. Refer to Note 4 for further information.

#### Income Taxes

years ended December 31 (in millions)	2014	2013	2012
<b>Current</b>			
Domestic	\$ 634	\$ 226	\$ 94
Foreign	341	354	252
Total current taxes	\$ 975	\$ 580	\$ 346

Edgar Filing: AbbVie Inc. - Form 10-K

<b>Deferred</b>						
Domestic	\$	(301)	\$	678	\$	89
Foreign		(79)		(54)		15
Total deferred taxes		(380)		624		104
Total income taxes	\$	595	\$	1,204	\$	450

**Effective Tax Rate Reconciliation**

years ended December 31	2014	2013	2012
Statutory tax rate	35.0%	35.0%	35.0%
State taxes, net of federal benefit		0.3	0.1
Effect of foreign operations	(11.3)	(11.5)	(23.5)
U.S. tax credits	(8.9)	(2.7)	(1.5)
Branded prescription drug fee	3.7	0.4	0.3
Valuation allowances	3.6	0.1	
Resolution of uncertain tax positions			(3.4)
Non-deductible litigation loss			0.6
All other, net	3.0	1.0	0.3
Effective tax rate	25.1%	22.6%	7.9%

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 rate in 2014, 2013 and 2012 differs 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 rate for these periods also reflects 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 credit for 2014 was due to legislation enacted in the fourth quarter that extended the credit to December 31, 2014.

The increase in the effective tax rate in 2014 was principally driven by additional expenses of \$129 million related to the Branded Prescription Drug Fee, which is non-deductible, and state tax valuation allowances of \$129 million as further discussed in the "Deferred Tax Assets and Liabilities" section following. 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 2014 and 2013 reflects income tax expenses relating to current earnings outside the United States that are not deemed indefinitely reinvested. In 2012, the effective income tax rate includes the recognition of tax benefits totaling approximately \$195 million as a result of favorable resolutions of various tax positions pertaining to prior years.

Puerto Rico enacted legislation 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.

**Deferred Tax Assets and Liabilities**

as of December 31 (in millions)	2014	2013
<b>Deferred tax assets</b>		
Compensation and employee benefits	\$ 627	\$ 279
Accruals and reserves	376	252
Chargebacks and rebates	297	333
Deferred revenue	382	348
Depreciation	53	64
State income taxes	62	67
Other	230	122
Net operating losses and other credit carryforwards	125	115
Total deferred tax assets	2,152	1,580
Valuation allowances	(172)	(43)
Total net deferred tax assets	\$ 1,980	\$ 1,537
<b>Deferred tax liabilities</b>		
Excess of book basis over tax basis of intangible assets	\$ (331)	\$ (508)
Repatriation of foreign earnings	(326)	(606)
Total deferred tax liabilities	\$ (657)	\$ (1,114)
Net deferred tax asset	\$ 1,323	\$ 423

Gross federal net operating loss carryforwards as of December 31, 2014 were \$19 million and are available for use through 2030. Gross state net operating loss and tax credit carryforwards as of December 31, 2014 were \$1.1 billion and \$91 million, respectively. The state tax carryforwards expire in periods between 2017 and 2034. As of December 31, 2014, foreign net operating loss carryforwards were \$113 million. The majority of the foreign loss carryforwards do not have an expiration period.

As of December 31, 2014 and 2013, the company had valuation allowances of \$172 million and \$43 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 \$23 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**

years ended December 31 (in millions)	2014	2013	2012
Balance as of January 1	\$ 247	\$ 1,140	\$ 1,039
Increase due to current year tax positions	115	195	370
Increase due to prior year tax positions	67		1
Decrease due to prior year tax positions	(6)		(220)
Settlements			(50)
Lapse of statutes of limitations	(2)		
Separation-related adjustments		(1,088)	
Balance as of December 31	\$ 421	\$ 247	\$ 1,140



## 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.

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.

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. As a result, AbbVie has continued to account for these tax uncertainties. To the extent that these obligations relate to periods prior to the separation, a reimbursement receivable of approximately \$41 million has been recorded within other assets at December 31, 2014.

If recognized, the net amount of potential tax benefits that would impact the company's effective tax rate is \$389 million and \$218 million in 2014 and 2013, respectively. 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 \$31 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.

AbbVie recognizes accrued interest and penalties related to uncertain tax positions in income tax expense. The amounts expensed and the liabilities accrued are immaterial as of and for the years ended December 31, 2014, 2013, and 2012. Uncertain tax positions are generally included as a long-term liability on the consolidated balance sheets.

### Note 14 Legal Proceedings and Contingencies

---

Subject to certain exceptions specified in the separation agreement, 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. AbbVie is involved in various claims, legal proceedings and investigations, including those described below. The recorded accrual balance for litigation at December 31, 2014 was not significant. Within the next year, other legal proceedings may occur that may result in a change in the estimated loss accrued by AbbVie. While it is not feasible to predict the outcome of all other proceedings and exposures with certainty, management believes that their ultimate disposition should not have a material adverse effect on AbbVie's consolidated financial position, cash flows, or results of operations.

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 were consolidated for pre-trial purposes in the United States District Court for the Northern District of Georgia under the Multi-District Litigation 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

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

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 2084 includes: (a) three individual plaintiff lawsuits; (b) seven purported class actions; and (c) *Federal Trade Commission v. Watson Pharmaceuticals, Inc. et al.*, filed in May 2009 in the United States District Court for the Northern District of Georgia. 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.

In September 2014, the Federal Trade Commission (FTC) filed suit in the United States District Court for the Eastern District of Pennsylvania against AbbVie and others, alleging that 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 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 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. On August 14, 2014, the district court dismissed all of the plaintiffs' claims with prejudice. Plaintiffs have appealed the district court's decision to the United States Court of Appeals for the Seventh Circuit, where the matter is currently pending.

Lawsuits have been filed 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 Laboratories 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. In September 2013, all of these pending putative class action lawsuits were centralized for consolidated or coordinated pre-trial proceedings in the United States District Court for the Eastern District of Pennsylvania under the Multi-District Litigation Rules as *In re Niaspan Antitrust Litigation*, MDL No. 2460.

In November 2007, GlaxoSmithKline filed a lawsuit against Abbott Laboratories in the United States District Court for the Northern District of California alleging that Abbott violated antitrust 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 the plaintiff. In January 2014, a 3-judge panel of 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 has been returned to the trial court for further proceedings. AbbVie assumed the liability for and control of this proceeding in connection with its separation from Abbott.

AbbVie is seeking to enforce its patent rights relating to testosterone gel (a drug AbbVie sells under the trademark AndroGel® 1.62%). In a case filed in the United States District Court for the District of Delaware in February 2013, AbbVie alleges that Perrigo Company's and Perrigo Israel Pharmaceutical Ltd.'s proposed generic product infringes AbbVie patents and seeks declaratory and injunctive relief. In a second case filed in the United States District Court for the District of Delaware in March 2013, AbbVie alleges that Watson Laboratories Inc.'s and Actavis Inc.'s proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In November 2014, AbbVie, Watson and Actavis entered into a confidential settlement and license agreement. The litigation was dismissed by stipulation of the parties.

AbbVie is seeking to enforce its patent rights relating to ritonavir/lopinavir tablets (a drug AbbVie sells under the trademark Kaletra®). In a case filed in the United States District Court for the Northern District of Illinois in March 2009, AbbVie alleges that Matrix Laboratories, Inc.'s, Matrix Laboratories, Ltd.'s, and Mylan, Inc.'s proposed generic products infringe AbbVie's patents and seeks declaratory and injunctive relief.



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

Upon Matrix's motion in November 2009, the court granted a five-year stay of the litigation unless good cause to lift the stay is shown. On July 1, 2014, the stay was lifted pursuant to the original terms of the court order entered in 2009.

AbbVie is seeking to enforce its patent rights relating to ritonavir tablets (a drug AbbVie sells under the trademark Norvir®). In a case pending in the United States District Court for the Southern District of Ohio since April 2012, AbbVie alleges that Roxane Laboratories, Inc.'s (Roxane) proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In another case filed in the United States District Court for the Southern District of Ohio in July 2013, AbbVie alleges that Roxane's proposed generic ritonavir product infringes additional AbbVie patents and seeks declaratory and injunctive relief on these additional patents. In September 2014, AbbVie and Roxane entered into a settlement and license agreement, the date of which license is confidential. The parties entered into a stipulation to dismiss the Ohio litigation. In a separate case filed in the United States District Court for the District of Delaware in May 2013, AbbVie alleges that Hetero USA Inc.'s and Hetero Labs Limited's proposed generic ritonavir tablets product infringes AbbVie's patents and seeks declaratory and injunctive relief. In November 2014, AbbVie and Hetero entered into a confidential settlement and license agreement and the litigation was dismissed by stipulation of the parties. In a separate case filed in the United States District Court for the District of Delaware in July 2014, AbbVie alleges that Aurobindo Pharma Limited and Aurobindo Pharma USA Inc.'s proposed generic ritonavir tablets product infringes AbbVie's patents and seeks declaratory and injunctive relief. In December 2014, AbbVie and Aurobindo entered into a confidential settlement and license agreement and the litigation was dismissed by stipulation of the parties. In a separate case filed in the United States District Court for the District of Delaware in October 2014, AbbVie alleges that Mylan Pharmaceutical Inc.'s proposed generic ritonavir tablets product infringes AbbVie's patents and seeks declaratory and injunctive relief.

AbbVie is seeking to enforce certain patent rights that cover the use of fully human anti-TNF alpha antibodies with methotrexate to treat rheumatoid arthritis. In a case filed in the United States District Court for the District of Massachusetts in May 2009, AbbVie alleges Centocor Ortho Biotech, Inc.'s (now Janssen Biotech, Inc.'s) product Simponi® infringes AbbVie's patents and seeks damages and injunctive relief. In December 2014, the parties entered into a settlement and license agreement, the terms of which are confidential. The litigation was dismissed with prejudice.

In November 2014, five individuals filed a putative class action lawsuit on behalf of purchasers and sellers of certain Shire plc 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 unspecified monetary damages and injunctive relief.

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 Racketeer Influenced and Corrupt Organizations Act and state consumer fraud and deceptive trade practices laws. The complaint seeks unspecified monetary 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 Shire transaction approval and termination. The lawsuit seeks unspecified compensatory 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 U.S. sales are to three wholesalers. Outside the United States, products are sold primarily to health care providers or through distributors, depending on the market served. Worldwide net sales of key products were as follows:

years ended December 31 (in millions)	2014	2013	2012
HUMIRA	\$ 12,543	\$ 10,659	\$ 9,265
AndroGel	934	1,035	1,152
Kaletra	870	962	1,013
Synagis	835	827	825
Lupron	778	785	800
Synthroid	709	622	551
Sevoflurane	550	568	602
Creon	516	412	353
Dyslipidemia products	328	1,076	2,145
Duodopa	220	178	149
VIEKIRA	48		
All other	1,629	1,666	1,525
Net sales	\$ 19,960	\$ 18,790	\$ 18,380

Net sales to external customers, based on the country that sold the product, were as follows:

years ended December 31 (in millions)	2014	2013	2012
United States	\$ 10,845	\$ 10,181	\$ 10,435
Germany	1,035	911	756
The Netherlands	969	858	776
United Kingdom	722	606	552
France	584	540	500
Japan	581	625	718
Canada	551	538	500
Spain	534	543	525
Brazil	435	439	434
Italy	432	404	408
All other countries	3,272	3,145	2,776
Net sales	\$ 19,960	\$ 18,790	\$ 18,380

Long-lived assets include net property and equipment of \$2.5 billion and \$2.3 billion as of December 31, 2014 and 2013, of which \$1.8 billion and \$1.6 billion, respectively, was located in the United States and Puerto Rico and \$551 million and \$591 million, respectively, was located in Europe.

**Note 16 Quarterly Financial Data (unaudited)**

(in millions except per share data)	2014	2013
<b>First Quarter</b>		
Net sales	\$ 4,563	\$ 4,329
Gross margin	3,463	3,176
Net earnings	980	968
Basic earnings per share	0.61	0.61
Diluted earnings per share	0.61	0.60
Cash dividends declared per common share	0.42	0.80(a)
<b>Second Quarter</b>		
Net sales	\$ 4,926	\$ 4,692
Gross margin	3,813	3,638
Net earnings	1,098	1,068
Basic earnings per share	0.69	0.67
Diluted earnings per share	0.68	0.66
Cash dividends declared per common share	0.42	0.40
<b>Third Quarter</b>		
Net sales	\$ 5,019	\$ 4,658
Gross margin	3,925	3,566
Net earnings	506	964
Basic earnings per share	0.32	0.60
Diluted earnings per share	0.31	0.60
Cash dividends declared per common share	0.42	0.40
<b>Fourth Quarter</b>		
Net sales	\$ 5,452	\$ 5,111
Gross margin	4,333	3,829
Net (loss) earnings	(b) (810)	1,128
Basic (loss) earnings per share	(c) (0.51)	0.70
Diluted (loss) earnings per share	(c) (0.51)	0.70
Cash dividends declared per common share	0.49	0.40

- (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. Refer to Note 12 for additional information regarding cash dividends declared in 2013.
- (b) Results for the fourth quarter of 2014 include transaction and financing-related and other costs incurred in connection with the terminated proposed combination with Shire, a \$750 million after-tax charge related to a research and development collaboration agreement with Calico, and a \$173 million after-tax charge as a result of entering into a global collaboration with Infinity. Refer to Notes 4 and 6 for further information relating to the termination of the proposed combination with Shire and the collaborations with Calico and Infinity, respectively.
- (c) 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 sheet of AbbVie Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of earnings, comprehensive income, equity and cash flows for the years then ended. 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 audit.

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, 2014 and 2013, and the consolidated results of their operations and their cash flows for the years then ended, 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, 2014, 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 20, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Chicago, Illinois  
February 20, 2015

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of AbbVie Inc.:

We have audited the accompanying combined statements of earnings, comprehensive income, equity and cash flows of AbbVie Inc. and subsidiaries (the "Company") for the year ended December 31, 2012. These combined financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 the combined financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, such combined financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

As described in Note 1, the accompanying combined financial statements have been derived from the consolidated financial statements and accounting records of Abbott Laboratories. The combined financial statements also include expense allocations for certain corporate functions historically provided by Abbott Laboratories. These allocations may not be reflective of the actual expense which would have been incurred had the Company operated as a separate entity apart from Abbott Laboratories.

/s/ Deloitte & Touche LLP

Chicago, Illinois  
March 15, 2013

**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 Exchange Act 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 103 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 104 hereof.

**Changes in internal control over financial reporting.** As part of its separation from Abbott, 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 are expected to be completed in 2015, will include modifications to the design and operation of controls over financial reporting. AbbVie reviews 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 Exchange Act) that have materially affected, or are reasonably likely to materially affect, AbbVie's internal control over financial reporting during the quarter ended December 31, 2014.

**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, 2014. 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, 2014, based on the COSO criteria.

The effectiveness of AbbVie's internal control over financial reporting as of December 31, 2014 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing on page 104 hereof, which expresses an unqualified opinion on the effectiveness of AbbVie's internal control over financial reporting as of December 31, 2014.

**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, 2014, 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.

In our opinion, AbbVie Inc. and subsidiaries' maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, 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 sheet as of December 31, 2014 and 2013, and the related consolidated statements of earnings, comprehensive income, equity and cash flows for the years then ended, and our report dated February 20, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Chicago, Illinois  
February 20, 2015



## 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 2015 AbbVie Inc. Proxy Statement. The 2015 Proxy Statement will be filed on or about March 20, 2015. Also incorporated herein by reference is the text found under the caption, "Executive Officers of the Registrant" on pages 27 and 28 hereof.

AbbVie's code of business conduct requires all its business activities to be conducted in compliance with 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 2015 Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Compensation Committee Report" is incorporated herein by reference. The 2015 Proxy Statement will be filed on or about March 20, 2015.

**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, 2014 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	39,352,086	\$ 28.53	91,010,677
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>39,352,086</b>	<b>\$ 28.53</b>	<b>91,010,677</b>



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

- (1) Includes 28,203,371 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 2015 Proxy Statement. The 2015 Proxy Statement will be filed on or about March 20, 2015.

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

The material to be included in the 2015 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 2015 Proxy Statement will be filed on or about March 20, 2015.

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

The material to be included in the 2015 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 2015 Proxy Statement will be filed on or about March 20, 2015.

**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 56 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 109 through 111 of this Form 10-K.
- (b) *Exhibits filed (see Exhibit Index on pages 109 through 111).*
- (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 20, 2015

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 20, 2015 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**  
**2014**

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	*Separation and Distribution Agreement dated as of November 28, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 2.1 of Amendment No. 6 to the Company's Registration Statement on Form 10 filed on November 30, 2012).
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 (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).
10.1	*U.S. Transition Services Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.2	*Ex-U.S. Transition Services Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.3	*Tax Sharing Agreement entered into as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.4	*Special Products Master Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.5	*Employee Matters Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.6	*Information Technology Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.8 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.11	*Transitional Trademark License Agreement dated as of December 31, 2012 by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.9 of the Company's Current Report on Form 8-K filed on January 2, 2013).

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

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.12	*Form of Finished Goods Supply Agreements by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.11 of Amendment No. 2 to the Company's Registration Statement on Form 10 filed on September 4, 2012).
10.13	*Form of Contract Manufacturing Agreements by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.12 of Amendment No. 2 to the Company's Registration Statement on Form 10 filed on September 4, 2012).
10.14	*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).**
10.15	*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).**
10.16	*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).**
10.17	*AbbVie 2013 Performance Incentive Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.18	*AbbVie Deferred Compensation Plan (incorporated by reference to Exhibit 10.16 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.19	*AbbVie Non-Employee Directors' Fee Plan (incorporated by reference to Exhibit 10.17 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.20	*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).**
10.21	*AbbVie Supplemental Savings Plan (incorporated by reference to Exhibit 10.19 of the Company's Annual Report on Form 10-K filed on March 15, 2013).**
10.22	*Purchase Agreement dated November 5, 2012 between AbbVie Inc., Abbott Laboratories, as guarantor, and Morgan Stanley & Co. LLC, Barclays Capital Inc., J.P. Morgan Securities LLC, and Merrill Lynch, Pierce, Fenner & Smith Incorporated (incorporated by reference to Exhibit 10.21 of Amendment No. 6 to the Company's Registration Statement on Form 10 filed on November 30, 2012).
10.23	*Form of AbbVie Inc. Non-Employee Director Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.24	*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).**
10.25	*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).**
10.26	*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).**

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

Exhibit Number	Exhibit Description
10.27	*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).**
10.28	*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).**
10.29	*Form of AbbVie Inc. Non-Qualified Replacement Stock Option Agreement (incorporated by reference to Exhibit 10.8 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013).**
10.30	*Revolving Credit Agreement, dated as of August 18, 2014, among AbbVie, New AbbVie, Foreign HoldCo, 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).
12	Ratio of Earnings to Fixed Charges
21	Subsidiaries of AbbVie Inc.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	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, 2014 filed on February 20, 2015, 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. 2015 Proxy Statement will be filed with the Securities and Exchange Commission under separate cover on or about March 20, 2015.

---

\*  
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.