

AbbVie Inc.  
Form 10-K  
March 15, 2013

[QuickLinks](#) -- Click here to rapidly navigate through this document

**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, 2012  
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

As of June 30, 2012, the registrant's common stock was not publicly traded.

Number of common shares outstanding as of January 31, 2013: 1,577,334,090

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the 2013 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Proxy Statement will be filed on or about March 15, 2013.

---

**PART I**

**ITEM 1. BUSINESS**

**Separation from Abbott Laboratories**

On January 1, 2013, AbbVie(1) 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. Each Abbott shareholder of record as of the close of business on December 12, 2012 (the Record Date) received one share of AbbVie common stock for each Abbott common share held as of the Record Date.

AbbVie was incorporated in Delaware on April 10, 2012 and is comprised of Abbott's former research-based pharmaceuticals business. AbbVie's Registration Statement on Form 10 was declared effective by the U.S. Securities and Exchange Commission on December 7, 2012. 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 products are used to treat rheumatoid arthritis, psoriasis, Crohn's disease, HIV, cystic fibrosis complications, low testosterone, thyroid disease, Parkinson's disease, ulcerative colitis, and complications associated with chronic kidney disease, among other indications. AbbVie also has a pipeline of promising new medicines, including more than 20 compounds or indications in Phase II or Phase III development across such important medical specialties as immunology, renal care, hepatitis C, women's health, oncology, and neuroscience, including multiple sclerosis and Alzheimer's disease.

The 2010 acquisitions of the U.S. pharmaceuticals business of Solvay Pharmaceuticals and of Facet Biotech Corporation added several new products to AbbVie's portfolio, including the U.S. rights to AndroGel and Creon, and enhanced AbbVie's early- and mid-stage investigational pipeline by adding an investigational biologic for multiple sclerosis and compounds that complement AbbVie's oncology program. These acquisitions are discussed more fully in Note 4, "Acquisitions, Collaborations and Other Arrangements", of the Notes to Combined Financial Statements.

**Segments**

AbbVie operates in one business segment pharmaceutical products. Incorporated herein by reference is Note 14 entitled "Segment and Geographic Area Information" of the Notes to Combined Financial Statements included under Item 8, "Financial Statements and Supplementary Data" and the sales information related to HUMIRA included in "Financial Review."

**Products**

AbbVie's portfolio of proprietary products includes a broad line of adult and pediatric pharmaceuticals.

---

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

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

**HUMIRA.** HUMIRA 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	European Union
Pediatric Crohn's disease (severe)	European Union

HUMIRA is also approved in over 60 other markets, including Japan, Brazil, and Australia. HUMIRA was introduced to the market in January 2003. Its worldwide sales have grown to approximately \$9.3 billion in 2012, compared to \$7.9 billion in 2011 and \$6.5 billion in 2010. HUMIRA accounted for approximately 50 percent of AbbVie's total sales in 2012. 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 EU countries in April 2018.

AbbVie continues to dedicate substantial research and development efforts to expanding indications for HUMIRA, including in the fields of rheumatology (peripheral spondyloarthritis, axial spondyloarthritis and pediatric enthesitis related arthritis), gastroenterology (pediatric Crohn's disease and pediatric ulcerative colitis), dermatology (pediatric psoriasis and hidradenitis suppurativa), and ophthalmology (uveitis). Phase III trials are ongoing in preparation for regulatory applications for: uveitis in the United States and the European Union; peripheral and axial spondyloarthritis in the United States; peripheral spondyloarthritis in the European Union; and hidradenitis suppurativa in the United States and the European Union.

**Metabolics/Hormones products.** Metabolic and hormone products target a number of conditions, including exocrine pancreatic insufficiency, testosterone deficiency, and hypothyroidism, and generated combined sales of \$2.1 billion in 2012. These products include:

*Synthroid.* Synthroid is used in the treatment of hypothyroidism. AbbVie's 2012 sales of Synthroid totaled \$551 million.

*AndroGel.* AndroGel is a daily testosterone replacement therapy that is available in two strengths: 1 percent and 1.62 percent. AbbVie's 2012 sales of AndroGel totaled \$1.2 billion.

*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. AbbVie's 2012 sales of Creon totaled \$353 million.

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

**Virology products.** AbbVie's virology products include two products for the treatment of HIV infection, Kaletra and Norvir. Worldwide sales of these products were \$1.4 billion in 2012.

*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

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

anti-HIV-1 medications to increase the chance of treatment response in people with HIV-1. AbbVie's 2012 sales of Kaletra totaled \$1.0 billion.

*Norvir.* Norvir (ritonavir) is a protease inhibitor that is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. AbbVie's 2012 sales of Norvir totaled \$389 million.

*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. Lupron generated sales of approximately \$800 million in 2012 in select markets worldwide.

*Dyslipidemia products.* AbbVie's dyslipidemia products address the range of metabolic conditions characterized by high cholesterol and/or high triglycerides. These products, which generated sales of \$2.1 billion in 2012, are primarily marketed to primary care physicians, and include:

*TriCor and TRILIPIX.* TriCor and TRILIPIX are fibric acid derivatives that are indicated as adjuncts to diet to reduce total cholesterol, LDL cholesterol, and triglyceride levels, which are key contributors to cardiovascular disease, and to increase HDL cholesterol levels. AbbVie has the rights to sell TriCor and TRILIPIX only in the United States. AbbVie's 2012 combined sales of TriCor and TRILIPIX totaled \$1.1 billion.

*Niaspan.* Niaspan is an extended release form of niacin that is indicated as an adjunct to diet to reduce total cholesterol, LDL cholesterol, and triglyceride levels, and to increase HDL cholesterol levels. AbbVie has the rights to sell Niaspan only in the United States. AbbVie's 2012 sales of Niaspan totaled \$911 million.

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

*Synagis.* Synagis is a product marketed by AbbVie outside of the United States that protects at-risk infants from severe respiratory disease, or respiratory syncytial virus (RSV). AbbVie's 2012 sales of Synagis totaled \$842 million.

*Anesthesia products.* Sevoflurane (sold under the trademarks Ultane and Sevorane) is an anesthesia product that AbbVie sells worldwide for human use. AbbVie's 2012 sales of Sevoflurane totaled \$602 million.

*Duodopa and Duopa.* Duodopa is a levodopa-carbidopa intestinal gel (LCIG) marketed outside of the United States to treat advanced Parkinson's disease. AbbVie's 2012 sales of Duodopa totaled \$149 million. The LCIG therapy has completed Phase III development for the United States under the name Duopa, and AbbVie is pursuing regulatory approval in 2013 in the United States.

*Zemplar.* Zemplar is a product sold worldwide for the prevention and treatment of secondary hyperparathyroidism associated with Stage 3, 4, and 5 chronic kidney disease (CKD). AbbVie's 2012 sales of Zemplar totaled \$383 million.

### Research and Development Activities

AbbVie has numerous compounds in clinical development, including potential treatments for highly prevalent conditions. Over the past five years, AbbVie has more than doubled the number of compounds in its pipeline through a mix of internal development and external collaboration efforts. AbbVie's ability to discover and develop new compounds is enhanced by the company's use of

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

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

Phase II tests the molecule's efficacy against the disease in a relatively small group of patients.

Phase III tests a molecule 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 U.S. Food and Drug Administration (FDA) or similar government agencies outside the U.S. 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 - 12 years and can be even longer. There is a significant amount of uncertainty inherent in the research and development of new pharmaceutical products and 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 IV 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 \$2.8 billion in 2012, \$2.6 billion in 2011, and \$2.5 billion in 2010 on research to discover and develop new products, indications and processes and to improve existing products and processes. These expenses consisted primarily of collaboration fees and expenses, salaries and related expenses for personnel, license fees, consulting payments, contract research, manufacturing, and the costs of laboratory equipment and facilities.

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

Generally, upon approval, products in development may be entitled to 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

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

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 product that does not contain a previously-approved active ingredient, the product is typically entitled to five years of market exclusivity. Other products may be entitled to three years of market exclusivity if approval was based on the FDA's reliance on new clinical studies 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 market exclusivity to which the 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 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 such as HUMIRA are 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. 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 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. Principal trademarks and the products they cover are discussed above in the description of AbbVie's products. 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 2013 to 2031, in the 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 EU 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 fibric acid derivatives (which are sold under the trademarks TriCor and TRILIPIX), those related to niacin (which is sold under the trademarks Niaspan and Simcor), 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. The principal United States non-composition of matter patent covering lopinavir/ritonavir is expected to expire in 2016. The principal United States non-composition of matter patents covering the fibric acid derivative products are expected to expire in 2018, 2020, 2023, and 2025. The principal United States non-composition of matter patents covering the niacin products are expected to expire in 2013, 2017, and 2018. The principal non-composition of matter patent covering AndroGel is expected to expire in 2020 for the 1.62 percent formulation and, due to pediatric exclusivity, in 2021 for the 1 percent formulation. 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.

### **Sales, Marketing, and Distribution Capabilities**

In 2012, AbbVie's products were sold in over 170 countries. AbbVie utilizes a combination of dedicated commercial resources, regional commercial resources and distributorships to market, sell, and distribute its products worldwide.

In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies. In 2012, three wholesale distributors accounted for substantially all of AbbVie's sales in the United States. Sales to McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation accounted for 38 percent, 27 percent, and 26 percent, respectively, of AbbVie's 2012 gross sales in the United States. These wholesalers purchase product from AbbVie under standard terms and conditions of sale.

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 all of the company's products must be sold pursuant to a prescription in the United States. Outside of the United States, AbbVie focuses its marketing efforts on key opinion leaders, payors, physicians, and country regulatory bodies. AbbVie also provides patient support programs closely related to its products.

AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies, and independent retailers from AbbVie-owned distribution centers and public warehouses. Outside the United States, sales are made either directly to customers or through distributors, depending on the market served. Approximately 55-60 percent of



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

sales outside the United States are made through wholesalers or distributors. No wholesaler or distributor outside the United States accounts for more than 3 percent of AbbVie's sales. 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.

### *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 is awaiting regulatory approval for its own syringe-filling and packaging facility in the United States to supply syringes outside of the United States and Puerto Rico. This facility is already approved to provide product to 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, 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 also has collaboration agreements, as discussed in Note 4, "Acquisitions, Collaborations and Other Arrangements," of the Notes to Combined Financial Statements, and has certain agreements with Abbott, as described in Item 13, "Certain Relationships and Related Transactions, and Director Independence."

### *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. There have been no recent significant availability problems or supply shortages.

### *Orders*

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

### *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 2012 were approximately \$1.5 million and \$13.2 million, respectively. Capital and operating expenditures for pollution control in 2013 are estimated to be approximately \$2.2 million and \$19.0 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, AbbVie's virology products compete with protease inhibitors and other anti-HIV treatments, and AbbVie's dyslipidemia products face competition from other fibrates and from statins. 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. While the enactment of federal health care reform legislation in March 2010 was meant to provide a pathway for approval of biosimilars under the Public Health Service Act, recent regulatory guidance suggests that the approval process for biosimilars will be far more extensive than the approval process for generic or other follow-on versions of small molecule products, in order to ensure that the safety and efficacy of biosimilars is highly similar to that of an original biologic, such as HUMIRA. Ultimate approval by the FDA is dependent upon many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity, and potency. The types of data that could ordinarily be required in an application to show similarity would include analytical data and studies to demonstrate chemical similarity, animal studies (including toxicity studies), and clinical studies. Applicable regulations also require that the biosimilar must be for the same indication as the original biologic and involve the same mechanism of action, 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" may be substituted 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. In addition, the first JAK inhibitor, part of a new class of orally administered class of products, was recently approved for use in rheumatoid arthritis in the U.S. and is under regulatory review in Europe. AbbVie will continue to face competitive pressure from these biologics and 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 Biologic Listing Application (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 EU, 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.

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 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 Act 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 (ASP) 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.

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

AbbVie expects debate to continue during 2013 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 U.S. 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 EU has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance, and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the EU 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 EU 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 21,500 persons as of January 31, 2013. 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 or financial condition. The risk factors generally have been separated into three groups: risks related to AbbVie's business, risks related to AbbVie's recent 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, financial condition or results of operations. 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 income.*

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 worsen the effect 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 U.S. composition of matter patent for HUMIRA, which is AbbVie's largest selling product and had worldwide sales of approximately \$9.3 billion in 2012, is expected to expire in December 2016, and the equivalent European Union patent is expected to expire in the majority of EU 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 income.***

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 (ANDAs) with the United States Food and Drug Administration (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. For example, certain companies have filed ANDAs seeking approval to market generic versions of fenofibric acid capsules (TRILIPIX) and niacin extended release tablets (Niaspan). These companies have asserted that the AbbVie patents covering these products are invalid, unenforceable, and/or not infringed by their respective products. AbbVie has entered into settlement agreements resolving substantially all of these challenges. For a description of other material pending challenges, please refer to Item 3, "Legal Proceedings."

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 generates approximately 50 percent of AbbVie's sales. Any significant event that adversely affects HUMIRA's revenues could have a material adverse impact on AbbVie's 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 revenue 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. For example, in 2012 AbbVie discontinued the development of ABT-263, which was in Phase II development for the treatment of hematologic malignancies. 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 standard 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.

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 MS. It is also collaborating with Bristol-Myers Squibb on a treatment for multiple myeloma, and with Biotest AG on a compound for rheumatoid arthritis and psoriasis.

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.

***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, AbbVie's virology products compete with protease inhibitors and other anti-HIV treatments, and AbbVie's dyslipidemia products face competition from other fibrates and from statins. These competitors may introduce new products or develop technological advances that compete with AbbVie's products in therapeutic areas such as immunology, virology, 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.

***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.

***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 relies on single sources of supply for certain products and services, and an interruption in the supply of those products and services could adversely affect AbbVie's business and results of operations.***

AbbVie has a single source of supply for certain products and services. 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 maintains significant inventory of HUMIRA syringes intended to reduce the risk of supply disruption and is awaiting regulatory approval for its own syringe-filling and packaging facility in the United States to supply syringes outside of the United States and Puerto Rico. AbbVie also uses a number of products in the manufacturing process for HUMIRA that are currently sourced from single suppliers. AbbVie believes alternative sources for all products used in the manufacturing process for HUMIRA are currently available.

The failure of a single-source supplier to fulfill its 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 services 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. In addition, due to various product withdrawals and other significant safety issues related to pharmaceutical products, the amount of time to obtain regulatory approval has increased industrywide and some health authorities are re-reviewing select products that are already marketed.

If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase IV trials), or if there are changes in government standards regarding safety, efficacy or labeling, AbbVie may be required to amend the conditions of use for a product. The FDA has authority, based on such new clinical or scientific information, to require post-marketing studies, clinical trials and labeling changes and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on marketing of approved products. Regulatory agencies outside of the United States often have similar authority.

New safety data may emerge from adverse event reports, post-marketing studies, whether conducted by AbbVie or by others and whether mandated by regulatory agencies or voluntary, and other sources and may adversely affect sales of AbbVie's products. 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 serious 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 products, 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 income.***

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 income 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 U.S. 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, there were government-mandated price reductions for many pharmaceutical products in many European countries in 2010, 2011, and 2012, 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 income.

***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. Many of AbbVie's facilities and procedures and those of its suppliers also are subject to ongoing regulation, including periodic inspection by regulatory authorities. AbbVie must incur expense and spend time and effort to ensure compliance with these complex regulations.

Possible regulatory actions in the event of non-compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of AbbVie's products, and criminal prosecution. These 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 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.

***Changes in laws and regulations may adversely affect AbbVie's business.***

As described above, the development, manufacture, marketing, sale, promotion, and distribution of AbbVie's products are subject to comprehensive government regulation. Changes in these regulations could affect AbbVie in various ways. For example, under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, AbbVie pays a fee related to its pharmaceuticals sales to government programs and, beginning in 2013, must record and report any transfers of value to physicians and teaching hospitals. Similar reporting requirements have been enacted on a state level in the United States and within the European Union and an increasing number of countries worldwide have adopted or are considering similar laws. Future legislation and regulation in the markets that AbbVie 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. Such legislation and regulation could adversely affect AbbVie's business, results of operations, cash flow, financial condition and prospects.

***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 U.S. federal and 49 state investigations into its sales and marketing activities for Depakote by pleading guilty to a misdemeanor violation of the Food Drug & Cosmetic Act (FDCA) and agreeing to pay approximately \$700 million in criminal fines and forfeitures and approximately \$900 million to resolve civil claims. A non-cash charge related to these investigations was previously recorded, as discussed in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations." Under the plea agreement, Abbott submitted to a term of probation that was initially set at 5 years, but will be shortened to 3 years. 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 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 Corporate Integrity Agreement (CIA) with the Office of Inspector General for the U.S. 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

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

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. 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.

***AbbVie's compliance with the obligations of the May 7, 2012 resolution of the Department of Justice's investigation into the sales and marketing activities for Depakote will impose additional costs and burdens on AbbVie.***

On May 7, 2012 Abbott settled U.S. federal and 49 state investigations into its sales and marketing activities for Depakote by pleading guilty to a misdemeanor violation of the FDCA, agreeing to pay criminal fines, forfeitures, and civil damages, and submitting to a term of probation. 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 OIG, effective as of October 11, 2012. The obligations of the plea agreement and the CIA have transferred to and become fully binding on AbbVie. 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.

***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. Sales outside of the United States make up approximately 45 percent of AbbVie's net sales. The risks associated with its 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;

Edgar Filing: AbbVie Inc. - Form 10-K

compulsory licensing or diminished protection of intellectual property; and

potential penalties or other adverse consequences for violations of anti-corruption, anti-bribery and other similar laws and regulations, including the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act.

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



***Further deterioration in the economic position and credit quality of certain European countries may negatively affect AbbVie's results of operations.***

Financial instability and fiscal deficits in certain European countries, including Greece, Italy, Portugal, and Spain, may result in additional austerity measures to reduce costs, including health care costs. If economic conditions continue to worsen, this could result in lengthening the time or reducing the collectability of AbbVie's outstanding trade receivables and increasing government efforts to reduce health care spending, leading to reductions in drug prices and utilization of AbbVie's products. Ongoing sovereign debt issues in these countries could increase AbbVie's collection risk given that a significant amount of AbbVie's receivables in these countries are with governmental health care systems.

***AbbVie may not be able to realize the expected benefits of its investments in emerging markets.***

AbbVie seeks to make investments in key emerging markets, including Brazil, China, India, Mexico, Russia, and Turkey, but cannot guarantee that its efforts to expand sales in these markets will succeed. Some emerging markets may be especially vulnerable to periods of financial instability or may have very limited resources to spend on health care. For AbbVie to successfully implement its emerging markets strategy, AbbVie must attract and retain qualified personnel or may be required to increase its reliance on third-party distributors within certain emerging markets. Many of these countries have currencies that fluctuate substantially; if such currencies devalue and AbbVie cannot offset the devaluations, its financial performance within such countries could be adversely affected. In addition, price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization, and other governmental actions could affect AbbVie's business and results of operations in emerging markets.

***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 2012, 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.

***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.***

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 evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.***

AbbVie is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining AbbVie's tax liabilities, and AbbVie's tax returns will be periodically examined by various tax authorities. Although Abbott retains the risk for tax contingencies arising from operations pre-separation, AbbVie bears risks for future tax contingencies arising from operations post-separation. Due to the complexity of tax contingencies, the ultimate resolution of any tax matters related to operations post-separation may result in payments greater or less than amounts accrued.

In addition, AbbVie may be impacted by changes in tax laws, including tax rate changes, changes to the laws related to the treatment and remittance of foreign earnings, new tax laws, and subsequent interpretations of tax law in the United States and other jurisdictions.

***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, including:

requiring a portion of AbbVie's cash flow from operations to make interest payments on this debt;

increasing AbbVie's vulnerability to general adverse economic and industry conditions;

reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow AbbVie's business; and

limiting AbbVie's flexibility in planning for, or reacting to, changes in AbbVie's business and the industry.

To the extent that AbbVie incurs additional indebtedness, the risks described above 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.

The terms of AbbVie's debt contain covenants restricting its financial flexibility in a number of ways, including among other things, restrictions on AbbVie's ability and the ability of certain of AbbVie's subsidiaries to incur mortgages with respect to principal domestic properties and to enter into sale and leaseback transactions with respect to principal domestic properties, and restrictions on AbbVie's ability to merge or consolidate with any other entity or convey, transfer or lease AbbVie's

properties and assets substantially as an entirety. If AbbVie breaches a restrictive covenant under any of its indebtedness, or an event of default occurs in respect of such indebtedness, AbbVie's lenders of such indebtedness may be entitled to declare all amounts owing in respect thereof to be immediately due and payable.

***Challenges in the commercial and credit environment may adversely affect AbbVie's future access to capital.***

AbbVie's ability to issue debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for AbbVie's products or in the solvency of its customers or suppliers or other significantly unfavorable changes in economic conditions. Volatility in the world financial markets could increase borrowing costs or affect AbbVie's ability to access the capital markets. These conditions may adversely affect AbbVie's ability to obtain and maintain investment grade credit ratings.

***The investment of AbbVie's cash balance and investments in marketable securities are subject to risks that may cause losses and affect the liquidity of these investments.***

AbbVie's cash is currently invested in bank deposits and money market mutual funds, which typically hold debt securities issued by the U.S. federal government or high-grade corporate issuers. These investments are, and AbbVie's future investments may be, subject to credit, liquidity, market, and interest rate risks. If such investments suffer market price declines, AbbVie may recognize in its earnings the decline in the fair value of these investments below their cost basis when the decline is judged to be other than temporary. The risks associated with AbbVie's expected cash balance and investment portfolio may have a material adverse effect on AbbVie's results of operations and financial condition.

***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, and may be dilutive to existing stockholders.***

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 through the issuance of equity securities, its stockholders will experience dilution of their ownership interest. 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 pensions, retiree health care, stock 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 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 refers to AbbVie's business as operated by and integrated with Abbott. AbbVie's historical financial information is derived from the consolidated financial statements and accounting records of Abbott. Accordingly, the financial information included in this Annual Report on Form 10-K 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 primarily as a result of the factors described below:

Prior to the separation, AbbVie's business was operated by Abbott as part of its broader corporate organization, rather than as an independent company. Abbott or one of its affiliates performed various corporate functions for AbbVie, such as accounting, information technology, and finance. Abbott currently provides some of these functions to AbbVie, as described in Item 13, "Certain Relationships and Related Transactions, and Director Independence." AbbVie's historical financial results reflect allocations of corporate expenses from Abbott for such functions and are likely to be less than the expenses AbbVie would have incurred had it operated as a separate publicly traded company. AbbVie will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure, and personnel to which AbbVie no longer has access as a result of its separation from Abbott. These initiatives to develop AbbVie's independent ability to operate without access to Abbott's existing operational and administrative infrastructure will be costly to implement. AbbVie may not be able to operate its business efficiently or at comparable costs, and its profitability may decline;

Prior to the separation, AbbVie was able to use Abbott's size and purchasing power in procuring various goods and services and shared economies of scope and scale in costs, employees, vendor relationships and customer relationships. Although AbbVie has entered into transition

agreements with Abbott, these arrangements may not fully capture the benefits AbbVie previously enjoyed as a result of being integrated with Abbott and may result in AbbVie paying higher charges than in the past for these services. As a separate, independent company, AbbVie may be unable to obtain goods and services at the prices and terms obtained prior to the separation, which could decrease AbbVie's overall profitability. As a separate, independent company, AbbVie also may not be as successful in negotiating favorable tax treatments and credits with governmental entities. This could have an adverse effect on AbbVie's results of operations and financial condition;

Generally, AbbVie's working capital requirements and capital for its general corporate purposes, including acquisitions, research and development and capital expenditures, were historically satisfied as part of the corporate-wide cash management policies of Abbott. As a result of the separation, AbbVie may need to obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements; and

The cost of capital for AbbVie's business may be higher than Abbott's cost of capital prior to the separation.

Other significant changes may occur in AbbVie's cost structure, management, financing and business operations as a result of operating as a company separate from Abbott. 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 expects to install and implement 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 or will be 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. These agreements are discussed in greater detail in Item 13, "Certain Relationships and Related Transactions, and Director Independence." 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 will be 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 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. For a description of the separation agreement, see Item 13, "Certain Relationships and Related Transactions, and Director Independence." Among other things, the separation agreement provides for indemnification obligations designed to make AbbVie financially responsible for substantially all 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.

***AbbVie may not be able to engage in certain corporate transactions during the two-year period following the distribution.***

To preserve the tax-free treatment to Abbott of the separation and the distribution, under the tax sharing agreement that AbbVie entered into with Abbott, AbbVie is restricted from taking any action that prevents the distribution and related transactions from being tax-free for U.S. federal income tax purposes. Under the tax sharing agreement, for the two-year period following the distribution, AbbVie is prohibited, except in certain circumstances, from:

entering into any transaction resulting in the acquisition of 25 percent or more of its stock or substantially all of its assets, whether by merger or otherwise;

merging, consolidating, or liquidating;

issuing equity securities beyond certain thresholds;

repurchasing its capital stock; and

ceasing to actively conduct its business.

These restrictions may limit AbbVie's ability to pursue certain strategic transactions or other transactions that it may believe to be in the best interests of its stockholders or that might increase the value of its business. In addition, under the tax sharing agreement, AbbVie is required to indemnify Abbott against any such tax liabilities as a result of the acquisition of AbbVie's stock or assets, even if it did not participate in or otherwise facilitate the acquisition.

***Certain of AbbVie's executive officers and directors may have actual or potential conflicts of interest because of their previous or continuing positions at Abbott.***

Because of their former positions with Abbott, certain of these executive officers and directors own Abbott common shares, options to purchase Abbott common shares or other equity awards. Even though AbbVie's board of directors consists of a majority of directors who are independent, and AbbVie's executive officers who were formerly employees of Abbott ceased to be employees of Abbott, some AbbVie executive officers and directors continue to have a financial interest in Abbott common shares. In addition, four of AbbVie's directors currently serve on the board of directors of Abbott. Continuing ownership of Abbott common shares and equity awards, or service as a director at both companies could create, or appear to create, potential conflicts of interest if AbbVie and Abbott pursue the same corporate opportunities or face decisions that could have different implications for AbbVie and Abbott.

***AbbVie may not achieve some or all of the expected benefits of the separation, and the separation may adversely affect AbbVie's business.***

AbbVie may not be able to achieve the full strategic and financial benefits expected to result from the separation, or such benefits may be delayed or not occur at all. The separation and distribution is expected to provide the following benefits, among others: (i) a distinct investment identity allowing investors to evaluate the merits, performance, and future prospects of AbbVie separately from Abbott; (ii) more efficient allocation of capital for AbbVie; and (iii) direct access by AbbVie to the capital markets.

AbbVie may not achieve these and other anticipated benefits for a variety of reasons, including, among others: (a) AbbVie may be more susceptible to market fluctuations and other adverse events than if it were still a part of Abbott; (b) AbbVie's business is less diversified than Abbott's business prior to the separation; and (c) the other actions required to separate Abbott's and AbbVie's respective businesses could have diverted management's attention from planning to grow and operate AbbVie's business or created disruptions of AbbVie's operations that could, in each case, impact AbbVie's performance in the future. If AbbVie fails to achieve some or all of the benefits expected to result from the separation, or if such benefits are delayed, the business, financial conditions, and results of operations of AbbVie could be adversely affected.

***AbbVie may have received better terms from unaffiliated third parties than the terms it will receive in its agreements with Abbott.***

The agreements AbbVie entered into with Abbott in connection with the separation, 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, were prepared in the context of the separation while AbbVie was still a wholly-owned subsidiary of Abbott. Accordingly, during the period in which the terms of those agreements were prepared, AbbVie did not have an independent board of directors or a management team that was independent of Abbott. As a result, the terms of those agreements may not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. Arm's-length negotiations between Abbott and an unaffiliated third party in another form of transaction, such as a buyer in a sale of a business transaction, may have resulted in more favorable terms to the unaffiliated third party. See Item 13, "Certain Relationships and Related Transactions, and Director Independence."

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

##### ***AbbVie's stock price may fluctuate significantly.***

AbbVie cannot predict the prices at which shares of its common stock may trade. The market price of AbbVie's common stock may fluctuate significantly due to a number of factors, some of which may be beyond AbbVie's control, including:

actual or anticipated fluctuations in AbbVie's operating results;

changes in earnings estimated by securities analysts or AbbVie's ability to meet those estimates;

the operating and stock price performance of comparable companies;

changes to the regulatory and legal environment under which AbbVie operates; and

domestic and worldwide economic conditions.

In addition, when the market price of a company's common stock drops significantly, stockholders often institute securities class action lawsuits against the company. A lawsuit against AbbVie could cause it to incur substantial costs and could divert the time and attention of its management and other resources.

##### ***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 pay a dividend in the future or continue to pay any dividend if AbbVie commences paying dividends.

##### ***Your percentage of ownership in AbbVie may be diluted in the future.***

In the future, your 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 will 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.



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

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;

rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings;

the right of AbbVie's board to issue preferred stock without stockholder approval;

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, because AbbVie has not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that you may favor. Section 203 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

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

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.

Several of the agreements that AbbVie has entered into with Abbott require Abbott's consent to any assignment by AbbVie of its rights and obligations under the agreements. These agreements will generally expire within two years of AbbVie's separation from Abbott, except for certain agreements that will continue for longer terms and in some cases for the life of the products covered by the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that you may consider favorable. See Item 13, "Certain Relationships and Related Transactions, and Director Independence" for a more detailed description of these agreements and provisions.

In addition, an acquisition or further issuance of AbbVie's stock could trigger the application of Section 355(e) of the Internal Revenue Code. Under the tax sharing agreement, AbbVie would be required to indemnify Abbott for the resulting tax, and this indemnity obligation might discourage, delay or prevent a change of control that you may consider favorable.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

**ITEM 2. PROPERTIES**

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

United States	Outside the United States
Abbott Park, Illinois*	Campoverde di Aprilia, Italy
Barceloneta, Puerto Rico	Cork, Ireland
Jayuya, Puerto Rico	Ludwigshafen, Germany
North Chicago, Illinois	Sligo, Ireland
Worcester, Massachusetts	

\*  
Leased property.

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

In the United States, including Puerto Rico, AbbVie owns 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**

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. As of January 31, 2013 (except as noted below), AbbVie is involved in various claims, legal proceedings, and investigations, including those described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on AbbVie's financial position, cash flows, or results of operations.

Several cases are pending against AbbVie that generally allege Abbott and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicare and Medicaid. These cases brought by state Attorneys General generally seek monetary damages and/or injunctive relief and attorneys' fees. The following cases are pending in state courts: *Commonwealth of Kentucky*, filed in September 2003 in the Circuit Court of Franklin County, Kentucky; *State of Wisconsin*, filed in June 2004 in the Circuit Court of Dane County, Wisconsin; *State of Illinois*, filed in February 2005 in the Circuit Court of Cook County, Illinois; and *State of Louisiana*, filed in October 2010 in the Nineteenth Judicial District, Parish of Baton Rouge, Louisiana. All other previously reported cases that were pending against AbbVie in state courts have been settled. As previously reported, certain federal court cases were consolidated for pre-trial purposes in the United States District Court for the District of Massachusetts under the Multi District Litigation Rules as *In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. In the fourth quarter of 2012, the only remaining MDL 1456 case, which was filed in August 2006 on behalf of the State of South Carolina, was settled and dismissed with prejudice.

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

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 an AbbVie patent and seeks declaratory and injunctive relief.

Several pending lawsuits filed against Unimed Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc. (a company Abbott acquired in February 2010) et al. 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 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: *Supervalu, Inc. v. Unimed Pharmaceuticals, Inc. et al.*, filed in April 2010 in the United States District Court for the Northern District of Georgia; and *Rite Aid Corp. et al. v. Unimed Pharmaceuticals, Inc. et al.* and *Walgreen Co. et al. v. Unimed Pharmaceuticals, Inc. et al.*, both of which were filed in June 2009 in the United States District Court for the Middle District of Pennsylvania and subsequently transferred to the United States District Court for the Northern District of Georgia; (b) seven purported class actions: *Meijer, Inc. et al. v. Unimed Pharmaceuticals, Inc. et al.*, *Rochester Drug Co-Operative, Inc. et al. v. Unimed Pharmaceuticals, Inc. et al.*, and *Louisiana Wholesale Drug Co., Inc. et al. v. Unimed Pharmaceuticals, Inc. et al.*, all of which were filed in May 2009 in the United States District Court for the Northern District of Georgia; *Fraternal Order of Police v. Unimed Pharmaceuticals, Inc. et al.*, filed in September 2009 in the United States District Court for the Northern District of Georgia; *Jabo's Pharmacy, Inc. v. Solvay Pharmaceuticals, Inc. et al.*, filed in October 2009 in the United States District Court for the Eastern District of Tennessee; *LeGrand v. Unimed Pharmaceuticals, Inc. et al.*, filed in September 2010 in the United States District Court for the Northern District of Georgia; and *Health Net, Inc. v. Solvay Pharmaceuticals, Inc.*, filed in February 2011 in the Northern District of Georgia; and (c) a lawsuit brought by the FTC, *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. In February 2010, Solvay's motion to dismiss the cases was partially granted and all of the FTC's claims and all of the plaintiffs' claims except those alleging sham litigation were dismissed. In May 2012, that decision was affirmed on appeal by the United States Court of Appeals for the Eleventh Circuit. In December 2012, the United States Supreme Court approved the FTC's October 2012 petition for review of the Eleventh Circuit's decision. In September 2012, the District Court granted summary judgment in favor of Solvay on the remaining claims of the private plaintiffs.

As previously reported, Abbott was seeking to enforce its patent rights relating to fenofibrate tablets (a drug AbbVie sells under the trademark TriCor®). In a case filed in the United States District Court for the District of New Jersey in August 2011, Abbott and the patent owner, Laboratoires Fournier, S.A. (Fournier), alleged infringement of three patents and sought injunctive relief against Mylan Pharmaceuticals Inc. and Mylan, Inc. (Mylan). In a related case where Abbott was involved as a result of its acquisition of Fournier Laboratories Ireland Ltd. (Fournier Ireland), Abbott sought to enforce additional rights relating to fenofibrate tablets. In a case filed in the United States District Court for the District of New Jersey in August 2011, Abbott's subsidiary, Fournier Ireland, and joint patent owner, Alkermes Pharma Ireland Limited (Alkermes), alleged infringement of two jointly-owned patents and sought injunctive relief against Mylan. In the fourth quarter of 2012, these cases were settled and dismissed without prejudice.

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

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

Northern District of Illinois in March 2009, AbbVie alleges that Matrix Laboratories, Inc., Matrix Laboratories, Ltd., and Mylan, Inc.'s proposed generic products infringe AbbVie's patents and seeks declaratory and injunctive relief. 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.

AbbVie is seeking to enforce its patent rights relating to ritonavir tablets (a drug AbbVie sells under the trademark Norvir®). In a case filed in the United States District Court for the District of Delaware in April 2012, AbbVie alleges that Roxane Laboratories, Inc.'s (Roxane) proposed generic product infringes five AbbVie patents and seeks declaratory and injunctive relief. Also in April 2012, Roxane filed a declaratory judgment action in the United States District Court for the Southern District of Ohio alleging that two of the five AbbVie patents are invalid and not infringed by Roxane's proposed generic ritonavir product.

AbbVie is seeking to enforce its patent rights relating to niacin extended release tablets (a drug AbbVie sells in the U.S. under the trademark Niaspan®). In a case filed in the United States District Court for the District of Delaware in February 2010, AbbVie alleges that Sun Pharmaceutical Industries Ltd.'s and Sun Pharma Global FZE's generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a second case filed in the United States District Court for the District of Delaware in June 2010, AbbVie alleges Sandoz Inc.'s proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a third case filed in the United States District Court for the District of Delaware in January 2012, AbbVie alleges Zydus Pharmaceuticals (USA), Inc.'s proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a fourth case filed in the United States District Court for the District of Delaware in February 2012, AbbVie alleges that Amneal Pharmaceutical's proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a fifth case filed in the United States District Court for the District of Delaware in March 2012, AbbVie alleges that Mylan Inc. and Mylan Pharmaceutical Inc.'s proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a sixth case filed in the United States District Court for the District of Delaware in March 2012, AbbVie alleges that Watson Laboratories Inc.'s proposed generic product infringes AbbVie's patents and seeks declaratory and injunctive relief. In a seventh case filed in the United States District Court for the District of Delaware in June 2012, AbbVie alleges that Kremers Urban Pharmaceuticals Inc.'s proposed generic 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.

AbbVie is seeking to enforce its patent rights relating to fenofibric acid capsules (a drug AbbVie sells in the U.S. under the trademark TRILIPIX®). In a case filed in the United States District Court for the District of New Jersey in March 2011, AbbVie and its subsidiary Fournier Laboratories Ireland Ltd. allege that Sandoz Inc.'s proposed generic product infringes AbbVie's patent and seek injunctive relief.

#### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**EXECUTIVE OFFICERS OF THE REGISTRANT**

The following table lists AbbVie's executive officers, each of whom was appointed as an AbbVie corporate officer in December 2012.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Richard A. Gonzalez	59	Chairman of the Board and Chief Executive Officer
Laura J. Schumacher	49	Executive Vice President, Business Development, External Affairs and General Counsel
William J. Chase	45	Executive Vice President, Chief Financial Officer
Carlos Alban	50	Executive Vice President, Commercial Operations
John M. Leonard, M.D.	55	Senior Vice President, Chief Scientific Officer
Timothy J. Richmond	46	Senior Vice President, Human Resources
Azita Saleki-Gerhardt, Ph.D.	49	Senior Vice President, Operations
Thomas A. Hurwich	52	Vice President, Controller

Mr. Gonzalez is AbbVie's Chairman 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. Prior to her appointment as General Counsel of Abbott, Ms. Schumacher headed Abbott's litigation department. Ms. Schumacher joined Abbott in 1990.

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, Pharmaceuticals, Western Europe and Canada from 2008 to 2009, as Vice President, Western Europe and Canada from 2007 to 2008, and as Vice President, European Operations from 2006 to 2007. Mr. Alban joined Abbott in 1986.

Dr. Leonard is AbbVie's Senior Vice President, Chief Scientific Officer. He served as Abbott's Senior Vice President, Pharmaceuticals, Research and Development from 2008 to 2012, and as Vice President, Global Pharmaceutical Research and Development from 2006 to 2008. Dr. Leonard joined Abbott in 1992.

## 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 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. 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.

From January 2, 2013 through January 31, 2013, the highest sales price for AbbVie's common stock on the NYSE was \$38.52 per share, and the lowest sales price for AbbVie's common stock on the NYSE was \$33.33 per share.

**Shareholders**

There were 60,713 shareholders of record of AbbVie common stock as of January 31, 2013.

**Dividends**

AbbVie expects that it will pay a regular cash dividend at an annual rate of \$1.60 per share, starting with the quarterly dividend paid in February 2013. However, the timing, declaration, amount of, and payment of any dividends by AbbVie 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.



**ITEM 6. SELECTED FINANCIAL DATA**

The following table sets forth AbbVie's selected financial information derived from its (i) unaudited combined financial statements as of December 31, 2009 and 2008 and for the year ended December 31, 2008; and (ii) audited combined financial statements for the years ended December 31, 2012, 2011, 2010 and 2009 and as of December 31, 2012, 2011 and 2010. The historical financial information presented may not be indicative of the results of operations or financial position that would have been obtained if AbbVie had been an independent company during the periods shown or of AbbVie's future performance as an independent company.

The selected financial information should be read in conjunction with the combined financial statements and accompanying notes and "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)

	2012	2011	2010	2009	2008
<b>Combined statement of earnings data</b>					
Net sales	\$ 18,380	\$ 17,444	\$ 15,638	\$ 14,214	\$ 14,179
Net earnings	5,275	3,433	4,178	4,636	4,058
Basic and diluted earnings per common share	3.35	2.18	2.65	2.94	2.57
Basic and diluted average shares outstanding(a)	1,577	1,577	1,577	1,577	1,577
<b>Combined balance sheet data</b>					
Total assets	\$ 27,008	\$ 19,521	\$ 21,135	\$ 15,858	\$ 16,601
Long-term debt and lease obligations(b)	14,652	48	52	55	64

(a) On January 1, 2013, Abbott Laboratories distributed 1,577 million shares of AbbVie common stock. The computation of basic and diluted shares for all periods through December 31, 2012 is calculated using the shares distributed on January 1, 2013. Refer to Note 2 to the combined financial statements for information regarding earnings per common share.

(b) 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 position and results of operations of AbbVie Inc. for each of the three years in the period ended December 31, 2012. This commentary should be read in conjunction with the combined financial statements and accompanying notes appearing in Item 8, "Financial Statements and Supplementary Data."

**EXECUTIVE OVERVIEW**

**Company Overview**

AbbVie Inc. (AbbVie or the company) 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 rheumatoid arthritis, psoriasis, Crohn's disease, HIV, cystic fibrosis complications, low testosterone, thyroid disease, Parkinson's disease, ulcerative colitis, and complications associated with chronic kidney disease, among other indications. AbbVie also has a pipeline of promising new medicines, including more than 20 compounds or indications in Phase II or Phase III development across such important medical specialties as immunology, renal care, hepatitis C virus (HCV), women's health, oncology, and neuroscience, including multiple sclerosis and Alzheimer's disease. AbbVie has approximately 21,500 employees and its products are sold in over 170 countries. AbbVie operates in one business segment pharmaceutical products.

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. Each Abbott shareholder of record as of the close of business on December 12, 2012, received one share of AbbVie common stock for each Abbott common share held as of the record date. AbbVie was incorporated in Delaware on April 10, 2012 and is comprised of Abbott's former research-based pharmaceuticals business. AbbVie's Registration Statement on Form 10 was declared effective by the U.S. Securities and Exchange Commission on December 7, 2012. AbbVie's common stock began trading "regular-way" under the ticker symbol "ABBV" on the New York Stock Exchange on January 2, 2013. Refer to the "Basis of Presentation" section below for further information.

AbbVie's products include a broad line of adult and pediatric pharmaceuticals manufactured, marketed, and sold worldwide and are generally sold directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies, and independent retailers from distribution centers and public warehouses. 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.

HUMIRA's worldwide sales increased to \$9.3 billion in 2012 compared to \$7.9 billion in 2011 and \$6.5 billion in 2010. In 2003, AbbVie began the worldwide launch of HUMIRA for rheumatoid arthritis, followed by launches for six additional indications in the United States and eight additional indications in the European Union. HUMIRA received approval for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy from the European Commission in April 2012 and from the U.S. Food and Drug Administration (FDA) in October 2012. In July 2012, HUMIRA received approval from the European Commission for the treatment of severe axial spondyloarthritis in adult patients who have no X-ray evidence of structural damage, and in November 2012, it received approval from the European Commission for the treatment of pediatric patients aged 6 to 17 years with severe active Crohn's disease who failed, are intolerant to, or have contraindications to conventional therapy. AbbVie is studying additional indications for HUMIRA. Substantial research and development and selling support has been and continues to be dedicated to maximizing the worldwide potential of HUMIRA. AbbVie forecasts low double-digit growth for worldwide HUMIRA sales in 2013.

The acquisition of Solvay SA's U.S. pharmaceuticals business (Solvay) and certain other product rights for \$1.9 billion in February 2010 added several new products, including the rights to AndroGel and Creon, to AbbVie's portfolio. Generic competition began in November 2012 for TriCor and is expected to begin in the second half of 2013 for Niaspan and in the second half of 2013 or early 2014 for TRILIPIX. As a result, sales for AbbVie's combined lipid franchise including TriCor, TRILIPIX, Niaspan and Simcor, which were \$2.1 billion in 2012 and \$2.5 billion in 2011, are expected to total less than \$1.0 billion in 2013. The decrease in sales of Zemplar from \$596 million in 2010 to \$383 million in 2012 reflects the impact of changes in reimbursement regulations resulting from health care reform legislation. Austerity measures implemented by several European countries reduced health care spending and affected pharmaceuticals pricing in those countries in all years presented.

### **Strategic Objectives**

AbbVie's long-term strategy is to maximize its existing portfolio through new indications, share gains, increased reach and geographic expansion in underserved markets while also advancing its new product pipeline. To successfully execute its long-term strategy, AbbVie will focus on expanding HUMIRA sales, advancing the pipeline, expanding its presence in emerging markets and managing its product portfolio to maximize value.

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 axial and peripheral spondyloarthritis and uveitis. AbbVie will also seek to drive HUMIRA sales growth by expanding its market share and its presence in underserved markets.

Research and development (R&D) efforts will continue to focus a significant portion of expenditures on compounds for immunology, oncology, neuroscience, pain management, virology, renal disease and women's health. AbbVie's goal is to bring to market products that demonstrate strong clinical performance for patients and economic value for payors. Current research and development projects are described in the "Research and Development" section below.

AbbVie plans to continue making investments in key emerging markets, including Brazil, China, Mexico and Russia. Continued penetration of HUMIRA and other leading products is expected to help drive growth in these markets.

AbbVie will continue its investment in products with durable sales, 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.

### **Research and Development**

R&D innovation and scientific productivity continue 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 by other biotechnology or pharmaceutical companies. AbbVie has a pipeline of more than 20 compounds or indications in Phase II or III development individually or under collaboration or license agreements. R&D is focused on therapeutic areas that include virology, renal disease, neuroscience, oncology, immunology, and women's health, among others.

*Virology*

AbbVie has released positive Phase II and Phase IIb results from interferon-free studies for the treatment of HCV. In October 2012, AbbVie initiated a comprehensive Phase III program for genotype 1 HCV that involves combinations of ABT-450; a protease inhibitor for HCV infection; ABT-333, a polymerase inhibitor; and ABT-267, a NS5A inhibitor.

*Renal Disease*

AbbVie's renal care pipeline includes atrasentan, for the treatment of diabetic chronic kidney disease (CKD). A Phase IIb study of atrasentan in patients with diabetic kidney disease, which began in June 2011, has been completed, with results to be presented in 2013. Atrasentan will potentially be the first compound launched to treat diabetic nephropathy by specifically targeting albuminuria and slowing the progression of CKD. AbbVie is also investigating ABT-719, in Phase IIb development, for the treatment of acute kidney injury associated with major surgeries.

In 2010, AbbVie entered into an agreement with Reata Pharmaceuticals Inc. (Reata) for ex-U.S. rights, excluding certain Asian markets, to bardoxolone methyl, an investigational treatment for CKD. A global Phase III clinical trial was initiated in June 2011. On October 17, 2012, Reata informed AbbVie that it is discontinuing the Phase III clinical study. The discontinuation was based on a recommendation from the study's Independent Data Monitoring Committee regarding safety concerns due to excess serious adverse events and mortality in the bardoxolone methyl arm. Reata and AbbVie will closely examine the data from this study to determine whether there is an appropriate path forward for the development of bardoxolone methyl in CKD or other indications.

*Neuroscience and Pain*

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 schizophrenia, pain, Alzheimer's disease, and multiple sclerosis (MS).

AbbVie is collaborating with Biogen Idec to develop 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. Daclizumab, an anti-CD25 monoclonal antibody, is currently in Phase III development.

AbbVie is investigating ABT-126, an  $\alpha$ 7-NNR modulator, in both Alzheimer's disease and cognitive deficits of schizophrenia. Additional Phase IIb studies began in March 2012.

The development of ABT-110 for the treatment of multiple pain indications has been suspended based upon FDA class-wide feedback.

A levodopa-carbidopa intestinal gel completed its Phase III program and AbbVie is pursuing regulatory approval in the United States. This product is sold under the Duodopa name outside the United States.

*Oncology*

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

Elotuzumab, an anti-CD37 antibody for the treatment of multiple myeloma under a collaboration with Bristol-Myers Squibb. Phase III development began in June 2011.

Veliparib, a PARP-inhibitor. A Phase IIb study in BRCA-mutated breast cancer being treated with chemotherapy was initiated in 2011. Veliparib is also in Phase II evaluation for the

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

treatment of a variety of other solid tumors, including brain metastases from non-small-cell lung cancer being treated with radiation therapy and non-small-cell lung cancer in combination with chemotherapy.

ABT-199, a next-generation Bcl-2 inhibitor in development for chronic lymphocytic leukemia is expected to start Phase III evaluation in 2013.

Other molecular targets are being explored with Antibody-Drug Conjugate approaches linking anti-target antibodies with potent cytotoxic agents.

### *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 III study in endometriosis began in mid-2012 and a Phase IIa study for uterine fibroids was initiated in November 2011.

### *Immunology*

AbbVie is developing several additional indications for HUMIRA and has a number of next-generation programs underway to address immune-mediated conditions, including the following.

Dual variable domain immunoglobulin (DVD-Ig) technology, which represents an approach that can target multiple disease-causing antigens with a single biologic agent. 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.

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

GLPG0634, a next-generation, oral Janus Kinase 1 (JAK1) inhibitor, is being developed with Galapagos NV in a collaboration entered into during the first quarter of 2012. GLPG0634 is currently in Phase IIb development to treat rheumatoid arthritis and may be able to address other autoimmune diseases.

In the fourth quarter of 2011, AbbVie entered into a collaboration with Reata for the joint development and commercialization of second-generation, oral antioxidant inflammation modulators.

### *Additional Indications and Formulations*

AbbVie continues to dedicate R&D efforts to expanding indications for HUMIRA, including in the fields of rheumatology (peripheral spondyloarthritis, axial spondyloarthritis and pediatric enthesitis related arthritis), gastroenterology (pediatric Crohn's disease and pediatric ulcerative colitis), dermatology (pediatric psoriasis and hidradenitis suppurativa), and ophthalmology (uveitis). Phase III trials are ongoing in preparation for regulatory applications for: uveitis in the United States and the European Union; peripheral and axial spondyloarthritis in the United States; peripheral spondyloarthritis in the European Union and hidradenitis suppurativa in the United States and the European Union. The following registrations and approvals have occurred since January 1, 2011.

European Union approval for pediatric Crohn's disease was obtained in November 2012.

For ulcerative colitis, European Union approval was obtained in April 2012 and approval in the United States was obtained in September 2012.

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

For axial spondyloarthritis, approval in the European Union was obtained in July 2012. The registration submission was made in the United States in November 2012.

In 2011, new formulations of some of AbbVie's existing pharmaceutical products were approved, including the 6-month and 3-month strengths of Lupron Depot in the United States in June and August, respectively. In the United States, a new strength for Creon was approved in June 2011 and AndroGel 1.62% was approved in April 2011. An additional registration submission for a new strength for Creon was made in September 2012.

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 2012 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. However, AbbVie plans to continue to manage its portfolio of projects to achieve research and development spend equal to approximately 14 to 16 percent of net sales each year. AbbVie does not regularly accumulate or make management decisions based on the total expenses incurred for a particular development phase in a given period.

### **Basis of Presentation**

AbbVie's historical combined financial statements have been prepared on a stand-alone basis and are derived from Abbott's consolidated financial statements and accounting records as if the former research-based pharmaceuticals business of Abbott had been part of AbbVie for all periods presented. The combined financial statements reflect AbbVie's financial position, results of operations, and cash flows as its business was operated as part of Abbott prior to the distribution, in conformity with U.S. generally accepted accounting principles. The combined financial statements principally represent the historical results of operations and assets and liabilities of Abbott's Proprietary Pharmaceutical Products segment.

The historical financial statements included the allocation of certain assets and liabilities that had historically been 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 the cash or investments were held by an entity that was transferred to AbbVie. At December 31, 2012, cash and equivalents and short-term investments reflected AbbVie's direct ownership of these assets. Prior to 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 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 at December 31, 2012.

All intracompany AbbVie transactions have been eliminated. At December 31, 2011 and 2010, all intercompany transactions between AbbVie and Abbott were considered to be effectively settled in the combined financial statements at the time the transactions were recorded. The total net effect of the settlement of these intercompany transactions was reflected in the combined statements of cash flow as a financing activity and in the combined balance sheets as net parent company investment in AbbVie. At December 31, 2012, outstanding intercompany transactions between AbbVie and Abbott are

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

reflected in Due to Abbott Laboratories and Due from Abbott Laboratories on the combined balance sheet.

AbbVie's historical financial statements included an allocation of expenses related to certain Abbott corporate functions, including senior management, legal, human resources, finance, information technology, and quality assurance. These expenses have been 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 a reasonable reflection of the utilization of services provided to, or the benefit received by, the company during the periods presented. The allocations may not, however, reflect the expense the company would have incurred as an independent, publicly-traded company for the periods presented. Subsequent to the separation, AbbVie expects to incur additional costs associated with being an independent, publicly-traded company, primarily from higher charges than in the past from Abbott for various services that will continue to be provided on a transition basis and from newly established or expanded corporate functions. AbbVie expects to incur one-time costs primarily to establish certain stand-alone AbbVie functions and information technology systems, further establish its infrastructure outside the United States and to complete the separation in certain countries. A portion of these expenditures will be capitalized and depreciated over the assets' useful lives while the remainder will be expensed as incurred, depending on the nature of the cost. AbbVie believes that cash flows from operations will be sufficient to fund these additional corporate expenses. The historical financial statements do not necessarily include all of the expenses that would have been incurred had AbbVie been a separate, stand-alone entity and may not necessarily reflect AbbVie's results of operations, financial position and cash flows had AbbVie been a stand-alone company during the periods presented. Refer to Note 13 for further description of transactions between AbbVie and Abbott.

### RESULTS OF OPERATIONS

#### Net Sales

for the years ended (in millions)	2012	2011	2010	Percent change			
				At actual currency rates		At constant currency rates	
				2012	2011	2012	2011
United States	\$ 10,435	\$ 9,712	\$ 8,971	7%	8%	8%	8%
International	7,945	7,732	6,667	3%	16%	8%	12%
Net sales	\$ 18,380	\$ 17,444	\$ 15,638	5%	12%	8%	9%



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

The increase in sales was primarily due to higher HUMIRA sales, partially offset by the impact of unfavorable foreign currency and the entry of generic TriCor in the fourth quarter of 2012.

The following table details the sales of key products.

years ended December 31 (in millions)	2012	2011	2010	Percent change			
				At actual currency rates		At constant currency rates	
				2012	2011	2012	2011
<b>HUMIRA</b>							
United States	\$ 4,377	\$ 3,427	\$ 2,872	28%	19%	28%	19%
International	4,888	4,505	3,636	8%	24%	15%	17%
Total	\$ 9,265	\$ 7,932	\$ 6,508	17%	22%	21%	18%
<b>AndroGel</b>							
United States	\$ 1,152	\$ 874	\$ 649	32%	35%	32%	35%
<b>TriCor/TRILIPIX</b>							
United States	\$ 1,098	\$ 1,372	\$ 1,355	(20)%	1%	(20)%	1%
<b>Kaletra</b>							
United States	\$ 279	\$ 326	\$ 363	(14)%	(10)%	(14)%	(10)%
International	734	844	860	(13)%	(2)%	(7)%	(5)%
Total	\$ 1,013	\$ 1,170	\$ 1,223	(13)%	(4)%	(9)%	(7)%
<b>Niaspan</b>							
United States	\$ 911	\$ 976	\$ 927	(7)%	5%	(7)%	5%
<b>Synagis</b>							
United States	\$ 17	\$ 17	\$ 16		5%		5%
International	825	775	710	6%	9%	9%	4%
Total	\$ 842	\$ 792	\$ 726	6%	9%	9%	5%
<b>Lupron</b>							
United States	\$ 569	\$ 540	\$ 483	5%	12%	5%	12%
International	231	270	258	(14)%	4%	(11)%	(1)%
Total	\$ 800	\$ 810	\$ 741	(1)%	9%		7%
<b>Sevoflurane</b>							
United States	\$ 82	\$ 88	\$ 126	(7)%	(30)%	(7)%	(30)%
International	520	577	538	(10)%	7%	(5)%	3%
Total	\$ 602	\$ 665	\$ 664	(10)%		(5)%	(3)%
<b>Synthroid</b>							
United States	\$ 551	\$ 522	\$ 451	6%	16%	6%	16%
<b>Norvir</b>							
United States	\$ 276	\$ 289	\$ 241	(4)%	20%	(4)%	20%
International	113	130	103	(13)%	27%	(8)%	22%

Edgar Filing: AbbVie Inc. - Form 10-K

Total	\$	389	\$	419	\$	344	(7)%	21%	(5)%	19%
<b>Zemplar</b>										
United States	\$	230	\$	255	\$	476	(10)%	(46)%	(10)%	(46)%
International		153		154		120	(1)%	28%	6%	25%
Total	\$	383	\$	409	\$	596	(6)%	(31)%	(4)%	(32)%
<b>Creon</b>										
United States	\$	353	\$	332	\$	246	6%	35%	6%	35%
Other	\$	1,021	\$	1,171	\$	1,208	(13)%	(3)%	(11)%	(4)%
Total	\$	18,380	\$	17,444	\$	15,638	5%	12%	8%	9%

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

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 have 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.

The increase in HUMIRA sales reflects market growth and higher market share across various countries as well as higher pricing in certain geographies. HUMIRA received approval from the European Commission in April 2012 and from the FDA in October 2012 for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy. With its approval from the European Commission, HUMIRA became the first and only self-injectable biologic therapy for the treatment of moderately to severely active ulcerative colitis in adults. In July 2012, HUMIRA received approval from the European Commission for the treatment of severe axial spondyloarthritis in adult patients who have no X-ray evidence of structural damage. In November 2012, HUMIRA received approval from the European Commission for the treatment of pediatric patients aged 6 to 17 years with severe active Crohn's disease who failed, are intolerant to, or have contraindications to conventional therapy. The approval marked the ninth indication for HUMIRA in the European Union.

The decline in TriCor, TRILIPIX, and Niaspan sales reflects softness in the overall branded cholesterol market and the introduction of a generic version of TriCor in the United States market in November 2012. As a result, sales for AbbVie's combined lipid franchise including TriCor, TRILIPIX and Niaspan declined 14 percent in 2012 compared to 2011. Under a license agreement for TRILIPIX 45 mg and 135 mg, generic competition may begin in January 2014, except that under certain circumstances the license may commence as early as July 2013. Under an agreement relating to AbbVie's niacin products acquired with the Kos Pharmaceuticals acquisition, Niaspan may become subject to generic competition in September 2013.

The decline in Kaletra revenues was primarily due to lower market share in various countries due to the impact of competition.

The increase in AndroGel sales reflected higher prices, market share gains, the launch of AndroGel 1.62% in the second quarter of 2011, and volume growth in the U.S. testosterone replacement market where AndroGel holds the number one market share position. AndroGel 1% sales are expected to be impacted by generic competition in 2015.

Sales of Sevoflurane were impacted by generic competition in 2012 and 2011. Sales of Zemplar in 2011 and 2010 were impacted by changes in reimbursement regulations resulting from health care reform legislation.

**Gross Margin**

years ended December 31 (in millions)	2012	2011	2010	Percent change	
				2012	2011
Gross margin	\$ 13,872	\$ 12,805	\$ 11,345	8%	13%
as a % of net sales	75%	73%	73%		

The increase in the gross profit margin in 2012 was primarily due to product mix, improved efficiencies, higher prices in certain geographies, and the favorable impact of foreign currency, partially offset by pricing pressures in various other markets. The improvement also reflects lower amortization expense for intangible assets and the impact of restructuring programs implemented in 2011 to realign various manufacturing operations. Changes in various governmental rebate programs continue to have a negative effect on the gross profit margins. The 2010 health care reform legislation in the United States resulted in increased and additional Medicaid rebates beginning in 2010 and in additional rebates related to the Medicare Part D "donut hole" beginning in 2011, which negatively affected AbbVie's business. The negative impact of the rebates resulting from the 2010 health care reform legislation grew from more than \$200 million in 2010 to approximately \$300 million in 2011 and 2012.

**Selling, General and Administrative**

years ended December 31 (in millions)	2012	2011	2010	Percent change	
				2012	2011
Selling, general and administrative	\$ 4,989	\$ 5,894	\$ 3,820	(15)%	54%
as a % of net sales	27%	34%	24%		

Selling, general and administrative (SG&A) expenses in 2012 included \$213 million of costs associated with the separation of AbbVie from Abbott. SG&A expenses in 2012 and 2011 included litigation charges of \$100 million and \$1.5 billion, respectively, related to the Depakote investigation. SG&A expenses in 2011 and 2010 included \$11 million and \$56 million, respectively, related to restructuring and integration projects associated with the 2010 acquisition of Solvay. Refer to Note 12 for information on the Depakote charge and Note 4 for information on the Solvay acquisition.

Excluding separation costs, litigation charges and Solvay-related restructuring and integration costs from all years, SG&A expenses increased 7 percent, 16 percent and 12 percent in 2012, 2011 and 2010, respectively. The increases in SG&A expenses over the three-year period were due primarily to increased selling and marketing support for new and existing products, including continued spending for HUMIRA, and in 2012 and 2011, the impact of the pharmaceutical fee imposed by U.S. health care reform legislation.

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

years ended December 31 (in millions)	2012	2011	2010	Percent change	
				2012	2011
Research and development	\$ 2,778	\$ 2,618	\$ 2,495	6%	5%
as a % of net sales	15%	15%	16%		
Acquired in-process research and development	\$ 288	\$ 673	\$ 313	(57)%	115%

R&D increased in 2012 and 2011, reflecting continued pipeline spending on programs in biologics, neuroscience and virology as well as a \$50 million R&D milestone payment related to a product in development for the treatment of chronic kidney disease in 2012. R&D expenses also included restructuring charges of \$169 million in 2012 and \$69 million in 2011.

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

Acquired in-process research and development (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. IPR&D expenses in 2011 included a charge of \$188 million for the achievement of a developmental milestone under a licensing agreement for the treatment of CKD, and charges of \$400 million and \$85 million for entering into collaboration agreements for second-generation oral antioxidant inflammation modulators and an anti-CD4 biologic for the treatment of rheumatoid arthritis and psoriasis, respectively. IPR&D expenses in 2010 included charges of \$238 million and \$75 million as a result of entering into a licensing agreement for the treatment of CKD and entering into a collaboration agreement for the treatment of endometriosis, respectively.

### **Interest Expense**

Interest expense, net in 2012 of \$84 million was comprised primarily of interest expense on outstanding debt and bridge facility fees related to the separation from Abbott, partially offset by interest income. In November 2012, AbbVie issued \$14.7 billion of long-term debt with maturities ranging from three to 30 years. AbbVie 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. In addition, AbbVie issued \$1.0 billion of commercial paper in the fourth quarter of 2012. AbbVie expects to incur approximately \$300 million of net interest expense in 2013.

### **Other (Income) Expense**

Other (income) expense, net, for 2012 included income of \$21 million from the resolution of a contractual agreement and a loss of \$52 million for the impairment of an equity security. Other (income) expense, net, included losses of \$29 million in 2012 and \$56 million in 2011 of fair value adjustments and accretion in the contingent consideration related to the acquisition of Solvay. Other (income) expense, net, for 2012, 2011 and 2010 also included ongoing contractual payments from Takeda associated with the conclusion of the TAP Pharmaceutical Products Inc. joint venture in 2008.

### **Income Tax Expense**

The income tax rates were 7.9 percent in 2012, 6.4 percent in 2011 and 13.6 percent in 2010. Income taxes in 2012 and 2011 included the recognition of tax benefits totaling approximately \$195 million and \$410 million, respectively, as a result of favorable resolutions of various tax positions pertaining to prior years. Income taxes in 2011 also reflected the non-deductibility of a litigation reserve. Excluding these discrete items, the effective tax rates are less than the statutory federal income tax rate of 35 percent principally due to the benefit of lower statutory tax rates and tax exemptions in Puerto Rico and other foreign taxing jurisdictions that reduced the tax rates by 23.5, 25.4 and 22.5 percentage points in 2012, 2011 and 2010, respectively.

AbbVie expects that its effective income tax rate in 2013 will be approximately 22 percent, excluding any discrete items.

In October 2010, 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 was included in cost of products sold. The majority of the tax is creditable for U.S. income tax purposes. In 2012 and 2011, the excise tax totaled approximately \$180 million and \$105 million, respectively.

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

The combined financial statements reflect the operating results and financial position of AbbVie as it was operated by Abbott, rather than as an independent company. AbbVie will incur additional ongoing operating expenses to operate as an independent company. These costs will include 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. In order to establish these stand-alone functions, AbbVie will also incur non-recurring expenses and capital expenditures.

The transition services agreement in the United States covers 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 term of the service under the agreement varies by activity. This agreement facilitates the separation by allowing AbbVie to operate independently prior to establishing stand-alone back office systems across its organization.

The operating costs of various information technology systems maintained by Abbott have been allocated to AbbVie on bases which management believes are reasonable. Included in these allocations was AbbVie's proportionate share of fixed operating costs. As an independent company, AbbVie's information technology operating costs may be higher than the costs allocated in the historical combined financial statements. In addition, AbbVie will incur non-recurring expenses and capital expenditures to establish its independent information technology systems.

In markets outside the United States, AbbVie does not currently have sufficient back office infrastructure to operate without transition service agreements with Abbott. Abbott has entered into a transition services agreement with AbbVie to provide services outside the United States, including back office services in certain countries, for up to two years after separation. The back office services provided include information technology, accounts payable, payroll, receivables collection, treasury and other financial functions, as well as order entry, warehousing, and other administrative services. This transition services agreement allows 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 will incur non-recurring expenses to expand its international infrastructure. In addition, in certain international markets, the marketing authorizations to sell AbbVie's products will continue to be held by Abbott post-separation until the authorizations can 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.

**FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES**

years ended December 31 (in millions)	2012	2011	2010
<b>Cash flows provided by/(used in):</b>			
Operating activities	\$ 6,345	\$ 6,247	\$ 4,976
Investing activities	(2,418)	553	(5,031)
Financing activities	1,931	(6,783)	65

Strong cash flows from operating activities in all three years were driven by higher net earnings and focused working capital management. In 2011, AbbVie recorded non-cash charges of \$1.5 billion in

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

accrued liabilities to accrue a litigation reserve related to claims on AbbVie's previous sales and marketing activities for Depakote. AbbVie made payments of \$1.6 billion in 2012 to settle these claims.

AbbVie issued senior notes of \$14.7 billion in November 2012 and \$1.0 billion of commercial paper in December 2012. Abbott's guarantee of the senior notes terminated upon the distribution of AbbVie common stock to the shareholders of Abbott upon the separation on January 1, 2013. The senior notes, which have maturities ranging from three to 30 years, may be redeemed, at any time, except the floating rate notes and some of the senior notes of each series, at a redemption price equal to the principal amount plus a make-whole premium. The balance of commercial paper outstanding at December 31, 2012, was \$1.0 billion at a weighted-average interest rate of 0.4%. AbbVie may retire or issue additional commercial paper to meet liquidity requirements as needed. Historically, cash flows from financing activities represented cash transactions with Abbott.

The company's cash and equivalents and short-term investments increased from \$653 million at December 31, 2011 to \$7,976 million at December 31, 2012. During 2012, Abbott contributed approximately \$4.4 billion of cash to newly formed AbbVie entities, and AbbVie distributed \$13.2 billion in cash and debt securities to Abbott. Subsequent to the separation, effective January 1, 2013, AbbVie no longer participates in cash management and funding arrangements with Abbott.

While a significant portion of cash and equivalents at December 31, 2012 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, 2012 can be considered to be reinvested indefinitely.

On February 15, 2013, the company announced a \$1.5 billion stock repurchase program, which was effective immediately. Purchases of AbbVie shares may be made from time to time at management's discretion. The plan has no time limit and can be discontinued at any time.

A dividend of \$0.40 per share was paid on February 15, 2013 to stockholders of record on January 15, 2013. The board of directors declared a quarterly cash dividend of \$0.40 per share for stockholders of record on April 15, 2013, which will be payable May 15, 2013. AbbVie expects to pay a regular cash dividend at an annual rate of \$1.60 per share; however, the timing, declaration, amount of, and payment of any dividends is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets, and other factors deemed relevant by its board of directors.

Substantially all of AbbVie's trade receivables in Greece, Portugal, Italy and Spain are with governmental health systems. Global economic conditions and liquidity issues in these countries have resulted, and may continue to result, in delays in the collection of receivables and credit losses. The time to collect outstanding receivables increased in 2011; however, with the exception of Greece, collection times improved in 2012 relative to 2011 and amounts over one year past due decreased in 2012 relative to 2011.

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

Outstanding net governmental receivables in these countries at December 31 were as follows.

(in millions)	Net receivables		Net receivables over one year past due	
	2012	2011	2012	2011
Greece	\$ 52	\$ 44	\$ 13	\$ 2
Portugal	80	121	23	31
Italy	308	372	40	42
Spain	285	589	2	240
<b>Total</b>	<b>\$ 725</b>	<b>\$ 1,126</b>	<b>\$ 78</b>	<b>\$ 315</b>

With the exception of Greece, AbbVie historically has collected almost all of the outstanding receivables in these countries. AbbVie continues to monitor the creditworthiness of customers located in these and other geographic areas and establishes an allowance against an accounts receivable when it is probable they will not be collected. In addition to closely monitoring economic conditions and budgetary and other fiscal developments in these countries, 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 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. 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.

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

#### *Credit Facility*

AbbVie currently has a \$2.0 billion unsecured five-year revolving credit facility from a syndicate of lenders, entered into in July 2012, which also supports commercial paper borrowings. As of the date of separation, January 1, 2013, Abbott's obligations under this facility were relieved and AbbVie became the sole obligor. The credit facility enables the company to borrow funds at floating interest rates. At December 31, 2012, the company was in compliance with all its credit facility covenants. Commitment fees under the new credit facility are not material. There were no amounts outstanding on the credit facility on December 31, 2012.

#### *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*

In late October 2012, Moody's Investor Service and Standard & Poor's Corporate assigned ratings of Baa1 and A, respectively, to AbbVie. 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



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

credit facility and would not result in an acceleration of the 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, 2012.

(in millions)	Total	Less than one year	One to three years	Three to five years	More than five years
Short-term borrowings	\$ 1,020	\$ 1,020	\$	\$	\$
Long-term debt and capital lease obligations, including current maturities	14,804	22	4,027	4,009	6,746
Interest on long-term debt(a)	5,009	283	596	627	3,503
Purchase obligations and other(b)	2,060	1,737	82	67	174
Other long-term liabilities(c)	533		403	69	61
<b>Total</b>	<b>\$ 23,426</b>	<b>\$ 3,062</b>	<b>\$ 5,108</b>	<b>\$ 4,772</b>	<b>\$ 10,484</b>

- (a) Includes estimated future interest payments on long-term debt securities. Interest payments on debt are calculated for future periods using interest rates in effect at the end of 2012. 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, 2012. Refer to Notes 7 and 8 for further discussion regarding the company's debt instruments and related interest rate agreements outstanding at December 31, 2012.
- (b) Includes the company's significant unconditional purchase obligations. These commitments do not exceed the company's projected requirements and are made in the normal course of business.
- (c) Excludes 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. Included in this amount are components of other long-term liabilities including restructuring and the expected payment related to the contingent sales-based payment recognized as part of the acquisition of Solvay. Refer to Notes 4, 6 and 8 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 4 for further discussion of these collaboration arrangements.

### CRITICAL ACCOUNTING POLICIES

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. 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 2012, 2011 and 2010 totaled \$4.3 billion, \$3.7 billion and \$3.4 billion, respectively, or 28 percent, 25 percent and 28 percent, respectively, of the gross sales subject to rebate. A one-percentage point increase in the percentage of rebates to related gross sales would decrease net sales by \$152 million in 2012. 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 \$667 million, \$617 million and \$453 million in 2012, 2011 and 2010, 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, pharmacy benefit manager 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, 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 price rebate percentage, systems and calculations are used to track sales by product and

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

by customer and to estimate the contractual or statutory price. AbbVie's systems and calculations have developed over time as rebates have become more significant, and AbbVie believes they are reliable.

The following table is an analysis of the three largest rebate accruals and chargeback allowances, which comprise approximately 85 percent of the combined rebate provisions charged against revenues in 2012. 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>Pharmacy Benefit Manager Rebates</b>	<b>Wholesaler Chargebacks</b>
Balance at January 1, 2010	\$ 352	\$ 239	\$ 160
Provisions	899	841	1,162
Payments	(617)	(670)	(1,163)
Balance at December 31, 2010	634	410	159
Provisions	985	831	1,361
Payments	(899)	(735)	(1,349)
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

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 employees participate in various pension and post-employment health care plans sponsored by Abbott. In AbbVie's financial statements, these plans are accounted for as multiemployer benefit plans and no liabilities have been reflected in AbbVie's combined balance sheets as there were no unfunded contributions due at the end of any reporting period. Effective January 1, 2013, in connection with the separation of AbbVie from Abbott, AbbVie will record the net benefit plan obligations transferred from Abbott. AbbVie's combined statements of earnings included expense allocations for these benefits. These expenses were funded through intercompany transactions with Abbott which are reflected within net parent company investment in AbbVie.

Certain pension plans in Germany, Puerto Rico, Canada, Ireland, United Kingdom and the United States are direct obligations of AbbVie and are recorded in the combined financial statements as of December 31, 2012. AbbVie engages outside actuaries to assist in the determination of the obligations and costs under these plans. The valuation of the funded status and the net periodic benefit cost for the 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 discount rate is selected based on current market rates on high-quality, fixed-income investments at December 31 each year. The expected long-term rate of return is based on the asset allocation, historical performance and the current view of expected future returns. The health care cost trend rate is selected by reviewing historical trends and current views on projected future health care cost increases. The significant assumptions used in determining these calculations are disclosed in Note 9 to the combined financial statements.

### **Income Taxes**

In AbbVie's combined financial statements, income tax expense and deferred tax balances have been calculated on a separate tax return basis although AbbVie's operations have historically been included in the tax returns filed by the respective Abbott entities of which the AbbVie business was a part. In the future, as a stand-alone company, AbbVie will file tax returns on its own behalf and its deferred taxes and the effective tax rate may differ from those in the historical periods.

AbbVie and Abbott have entered into a tax sharing agreement effective on the date of separation, January 1, 2013. For tax contingencies prior to the separation, Abbott will indemnify and hold AbbVie harmless if the tax positions are settled for amounts in excess of recorded liabilities, and AbbVie will not benefit if prior tax positions are resolved more favorably than recorded amounts.

### **Litigation**

The company is subject to contingencies, such as legal proceedings and claims that arise in the normal course of business. Refer to Note 12 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 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, 2012.

### **Valuation of Intangible Assets and Goodwill**

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 combined financial statements for further information.

For its impairment reviews, 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, 2012 and 2011, goodwill and other intangible assets totaled \$8,453 million and \$9,010 million, respectively, and amortization expense for intangible assets was \$625 million, \$764 million and \$708 million in 2012, 2011 and 2010, respectively. There were no impairments of goodwill in 2012, 2011 or 2010 and the results of the last impairment test indicated that the fair value of each reporting unit was substantially in excess of its carrying value. In 2012 and 2011, AbbVie recorded impairment charges of \$13 million and \$46 million, respectively, for certain projects under development.

## **CERTAIN REGULATORY MATTERS**

### **Legislative Issues**

In the first quarter of 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively referred to herein as "health care reform legislation") were signed into law in the United States. Health care reform legislation included an increase in the basic Medicaid rebate rate from 15.1 percent to 23.1 percent and extended the rebate to drugs provided through Medicaid managed care organizations. Starting in 2011, additional rebates were incurred related to the Medicare Part D coverage gap "donut hole." These Medicare and Medicaid rebate changes will continue to have a negative effect on AbbVie's gross profit margin in future years.

In 2011, AbbVie began recording the annual fee imposed by health care reform legislation on companies that sell branded prescription drugs to specified government programs. The amount of the annual fee, which totaled approximately \$100 million in both 2012 and 2011, is based on the ratio of certain of AbbVie's sales as compared to the total such sales of all covered entities multiplied by a fixed dollar amount specified in the legislation by year. The fee is not tax deductible and is included in SG&A expenses.

AbbVie's markets are highly competitive and subject to substantial government regulations. AbbVie expects debate to continue over the availability, method of delivery, and payment for health care products and services. It is not possible to predict the extent to which AbbVie or the health care industry in general might be adversely affected by these factors in the future. A more complete discussion of these factors is contained in Item 1, "Business" and Item 1A, "Risk Factors."

**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 8 for further information regarding the company's financial instruments and hedging strategies.

**Foreign Currency Risk**

AbbVie's primary net foreign currency translation exposures are the euro, British pound, Japanese yen and Canadian dollar. 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 are designated as cash flow hedges of the variability of the cash flows due to changes in foreign currency exchange rates and are marked-to-market with the resulting gains or losses reflected in accumulated other comprehensive income (loss). 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 within twelve months. At December 31, 2012 and 2011, AbbVie held \$1.0 billion and \$249 million, respectively, of such contracts, which all mature in the following calendar year.

AbbVie enters into foreign currency forward exchange contracts to manage its exposure to foreign currency denominated trade payables and receivables. The contracts, which are not designated as hedges, 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, 2012 and 2011, AbbVie held \$4.3 billion and \$3.0 billion, respectively, of such foreign currency forward exchange contracts.

The following table reflects the total foreign currency forward contracts outstanding at December 31.

(in millions)	2012			2011		
	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	\$ 3,649	1.315	\$ (10)	\$ 1,656	1.329	\$ (2)
British pound	91	1.612		143	1.571	
Japanese yen	323	84.4	5	578	80.3	(15)
Canadian dollar	154	0.992		50	1.026	
All other currencies	1,045	N/A	(5)	794	N/A	13
<b>Total</b>	<b>\$ 5,262</b>		<b>\$ (10)</b>	<b>\$ 3,221</b>		<b>\$ (4)</b>

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 \$526 million at December 31, 2012. If realized, this appreciation would negatively affect earnings over the remaining life of the contacts. A 10 percent appreciation is believed to be a reasonably possible near-term change in foreign currencies.

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 is not expected to have a material impact on the financial results of the company.

#### **Interest Rate Risk**

Interest rate swaps are used to manage the company's exposure of changes in interest rates on 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 December 31, 2012, 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 \$510 million. 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 \$976 million. A 100-basis point change is believed to be a reasonably possible near-term change in rates.

#### **Market Price Sensitive Investments**

AbbVie holds available-for-sale equity securities from strategic technology acquisitions. The market value of these investments was approximately \$12 million and \$58 million as of December 31, 2012 and 2011, 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 an immaterial decrease to their fair value at December 31, 2012. 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 \$72 million and \$171 million as of December 31, 2012 and 2011, 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>Combined Financial Statements</b>	
Combined Statements of Earnings	60
Combined Statements of Comprehensive Income	61
Combined Statements of Cash Flows	62
Combined Balance Sheets	63
Combined Statements of Parent Company Equity	64
Notes to Combined Financial Statements	65
Report of Independent Registered Public Accounting Firm	95



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

years ended December 31 (in millions, except per share data)	2012	2011	2010
<b>Net sales</b>	\$ 18,380	\$ 17,444	\$ 15,638
Cost of products sold	4,508	4,639	4,293
Selling, general and administrative	4,989	5,894	3,820
Research and development	2,778	2,618	2,495
Acquired in-process research and development	288	673	313
Total operating costs and expenses	12,563	13,824	10,921
<b>Operating earnings</b>	<b>5,817</b>	<b>3,620</b>	<b>4,717</b>
Interest expense, net	84	(20)	(28)
Net foreign exchange (gain) loss	17	(30)	(30)
Other (income) expense, net	(9)	2	(61)
<b>Earnings before income tax</b>	<b>5,725</b>	<b>3,668</b>	<b>4,836</b>
Income tax expense	450	235	658
<b>Net earnings</b>	<b>\$ 5,275</b>	<b>\$ 3,433</b>	<b>\$ 4,178</b>
<b>Per share data</b>			
Basic and diluted earnings per share(a)	\$ 3.35	\$ 2.18	\$ 2.65

(a) On January 1, 2013, Abbott Laboratories distributed 1,577 million shares of AbbVie common stock. The computation of basic and diluted earnings per common share for all periods through December 31, 2012 was calculated using the shares distributed on January 1, 2013.

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

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

years ended December 31 (in millions)	2012	2011	2010
<b>Net earnings</b>	\$ 5,275	\$ 3,433	\$ 4,178
Foreign currency translation gain (loss) adjustments	173	(295)	(383)
Pension and post-employment benefits, net of tax benefit of \$(24) in 2012, \$(12) in 2011 and \$(2) in 2010	(150)	(7)	(22)
Unrealized (loss) gains on marketable equity securities, net of tax (benefit) expense of \$(15) in 2012, \$10 in 2011 and \$4 in 2010	(25)	17	7
Hedging activities, net of tax (benefit) expense of \$(8) in 2012, \$(8) in 2011 and \$10 in 2010	(27)	(28)	5
Other comprehensive loss	(29)	(313)	(393)
<b>Comprehensive income</b>	\$ 5,246	\$ 3,120	\$ 3,785

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

## AbbVie Inc. and Subsidiaries

## Combined Statements of Cash Flows

years ended December 31 (in millions) (brackets denote cash outflows)	2012	2011	2010
<b>Cash flows from operating activities</b>			
Net earnings	\$ 5,275	\$ 3,433	\$ 4,178
Adjustments to reconcile earnings to net cash from operating activities:			
Depreciation	525	508	476
Amortization of intangible assets	625	764	708
Stock-based compensation	187	163	167
Acquired in-process research and development	288	673	313
Other	66		
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable	223	(498)	(60)
Inventories	(203)	(87)	(73)
Prepaid expenses and other assets	90	(206)	(38)
Accounts payable and other liabilities	(731)	1,497	(695)
<b>Cash flows from operating activities</b>	<b>6,345</b>	<b>6,247</b>	<b>4,976</b>
<b>Cash flows from investing activities</b>			
Acquisitions and investments, net of cash acquired	(688)	(273)	(2,621)
Acquisitions of property and equipment	(333)	(356)	(448)
Release of (deposit of) restricted funds		1,870	(1,870)
Purchases of investment securities	(2,550)	(1,943)	(93)
Sales of investment securities	1,153	1,255	1
<b>Cash flows from investing activities</b>	<b>(2,418)</b>	<b>553</b>	<b>(5,031)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of long-term debt	14,586		
Net change in short-term borrowings	1,000		
Other	(151)	(21)	(32)
Net transactions with Abbott Laboratories, excluding noncash items	(13,504)	(6,762)	97
<b>Cash flows from financing activities</b>	<b>1,931</b>	<b>(6,783)</b>	<b>65</b>
Effect of exchange rate changes on cash and equivalents	16		
<b>Net increase in cash and equivalents</b>	<b>5,874</b>	<b>17</b>	<b>10</b>
Cash and equivalents, beginning of year	27	10	
<b>Cash and equivalents, end of year</b>	<b>\$ 5,901</b>	<b>\$ 27</b>	<b>\$ 10</b>

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

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

as of December 31 (in millions)	2012	2011
<b>Assets</b>		
<b>Current assets</b>		
Cash and equivalents	\$ 5,901	\$ 27
Short-term investments	2,075	626
Accounts receivable	3,602	3,817
Due from Abbott Laboratories	696	
Inventories	1,091	872
Deferred income taxes	1,446	1,469
Prepaid expenses and other	543	543
<b>Total current assets</b>	<b>15,354</b>	<b>7,354</b>
Investments	119	229
Net property and equipment	2,247	2,144
Intangible assets, net of amortization	2,323	2,910
Goodwill	6,130	6,100
Other assets	835	784
<b>Total assets</b>	<b>\$ 27,008</b>	<b>\$ 19,521</b>
<b>Liabilities and net parent company investment in AbbVie Inc.</b>		
<b>Current liabilities</b>		
Short-term borrowings	\$ 1,020	\$
Current maturities of long-term debt and lease obligations	22	16
Accounts payable and accrued liabilities	4,811	5,881
Due to Abbott Laboratories	923	
<b>Total current liabilities</b>	<b>6,776</b>	<b>5,897</b>
Long-term liabilities	2,239	1,660
Long-term debt and lease obligations	14,630	32
Commitments and contingencies		
<b>Parent company equity</b>		
Net parent company investment in AbbVie Inc.	3,713	11,957
Accumulated other comprehensive (loss)	(350)	(25)
<b>Total parent company equity</b>	<b>3,363</b>	<b>11,932</b>
<b>Total liabilities and net parent company investment in AbbVie Inc.</b>	<b>\$ 27,008</b>	<b>\$ 19,521</b>

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

## AbbVie Inc. and Subsidiaries

## Combined Statements of Parent Company Equity

years ended December 31 (in millions)	Net parent company investment	Accumulated other comprehensive income	Total
<b>Balance at January 1, 2010</b>	\$ 10,973	\$ 681	\$ 11,654
Net earnings	4,178		4,178
Net transactions with Abbott Laboratories	264		264
Other comprehensive loss		(393)	(393)
<b>Balance at December 31, 2010</b>	15,415	288	15,703
Net earnings	3,433		3,433
Net transactions with Abbott Laboratories	(6,891)		(6,891)
Other comprehensive loss		(313)	(313)
<b>Balance at December 31, 2011</b>	11,957	(25)	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		(29)	(29)
<b>Balance at December 31, 2012</b>	\$ 3,713	\$ (350)	\$ 3,363

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

**AbbVie Inc. and Subsidiaries**  
**Notes to Combined Financial Statements**

**Note 1 Basis of Presentation**

---

The principal business of AbbVie Inc. (AbbVie or the company) is the discovery, development, manufacture and sale of a broad line of proprietary 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.

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 was incorporated in Delaware on April 10, 2012. Abbott's Board of Directors approved the distribution of its shares of AbbVie on November 28, 2012. AbbVie's Registration Statement on Form 10 was declared effective by the U.S. Securities and Exchange Commission on December 7, 2012. 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's 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.

The accompanying combined financial statements have been prepared on a stand-alone basis and are 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. The combined financial statements reflected AbbVie's financial position, results of operations and cash flows as its business was operated as part of Abbott prior to the distribution, in conformity with U.S. generally accepted accounting principles.

The combined financial statements included the allocation of certain assets and liabilities that have historically been held at the Abbott corporate level but which are 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 for AbbVie legal entities. All intracompany transactions and accounts have been eliminated. Prior to 2012, all intercompany transactions between AbbVie and Abbott were considered to be effectively settled in the combined financial statements at the time the transaction was recorded. As a result, the total net effect of settlement of these intercompany transactions was reflected in the combined statements of cash flows as a financing activity and in the combined balance sheet as net parent company investment in AbbVie. As of December 31, 2012, outstanding intercompany transactions between AbbVie and Abbott are reflected as Due from Abbott Laboratories and Due to Abbott Laboratories in the combined balance sheet.

AbbVie's combined financial statements included an allocation of expenses related to certain Abbott corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses have been 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 for all periods presented. 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 presented.

AbbVie employees participated in various benefit and stock-based compensation programs maintained by Abbott. A portion of the cost of those programs was included in AbbVie's financial statements. However, AbbVie's combined balance sheet does not include any equity related to stock-based

compensation plans. See Note 9 and Note 10 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 generally accepted accounting principles in the United States 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, income taxes, pension and post-employment benefits, valuation of intangible assets and goodwill, litigation, financial instruments, and inventory and accounts receivable exposures.

### **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.

### **Advertising**

Costs associated with advertising are expensed in the year incurred and are included in selling, general and administrative expenses (SG&A). Advertising expenses were \$506 million, \$375 million and \$290 million in 2012, 2011 and 2010, respectively.

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

AbbVie records annual expenses relating to its pension benefit 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 over a five-year period.

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

AbbVie employees participate in defined benefit pension and other post-employment plans sponsored by Abbott, which include participants of Abbott's other businesses. Such plans are accounted for as multiemployer plans in the historical financial statements for AbbVie and, 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 will be separated from the Abbott defined benefit pension plans at which time the funded status for each plan will be reflected in the AbbVie combined balance sheets using a December 31, 2012 measurement date. In addition to participation in defined benefit pension and other post-employment plans sponsored by Abbott, AbbVie is the sole sponsor for certain defined benefit pension and other post-employment plans. The funded status of these plans have been recorded in the combined balance sheets for AbbVie at December 31, 2012.

Refer to Note 9 for information regarding AbbVie's pension and post-employment plans.

### **Income Taxes**

Income taxes on earnings reflect the annual effective rates, including charges for interest and penalties. Deferred income taxes are provided for the tax effect of temporary differences between the tax bases of assets and liabilities and their reported amounts in the financial statements based on enacted tax laws and rates. The combined balance sheet as of December 31, 2011 has been appropriately revised to increase deferred tax liabilities in long-term liabilities by \$156 million, decrease deferred tax assets in other assets by \$136 million, and decrease net parent company investment in AbbVie by \$292 million to properly reflect temporary differences attributable to AbbVie assets.

In AbbVie's combined financial statements, income tax expense and deferred tax balances have been calculated on a separate tax return basis although AbbVie's operations have historically been included in the tax returns filed by the respective Abbott entities of which the AbbVie business is a part. In the future, as a stand-alone entity, AbbVie will file tax returns on its own behalf and its deferred taxes and effective tax rate may differ from those in the historical periods.

AbbVie does not maintain an income taxes payable to/from account with Abbott. With the exception of certain entities outside the United States that transferred to AbbVie at separation, AbbVie is deemed to have settled current tax balances with the Abbott tax paying entities in the respective jurisdictions. These settlements were reflected as changes in net parent company investment.

### **Cash and Equivalents**

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

### **Investments**

Short-term investments consist primarily of time deposits and U.S. Treasury securities and are carried at fair value. 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 income (loss). 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 market 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 market 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 income and the available-for-sale securities'



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

unrealized loss is recognized as a charge to income and removed from accumulated other comprehensive income (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 \$178 million at December 31, 2012 and \$161 million at December 31, 2011.

### 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)	2012	2011
Finished goods	\$ 547	\$ 429
Work-in-process	286	207
Materials	258	236
Inventories, net	\$ 1,091	\$ 872

### Property and Equipment

as of December 31 (in millions)	2012	2011
Land	\$ 94	\$ 106
Buildings	1,278	1,305
Equipment	4,865	4,331
Construction in progress	305	206
Property and equipment, gross	6,542	5,948
Less accumulated depreciation	(4,295)	(3,804)
Property and equipment, net	\$ 2,247	\$ 2,144

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 15 to 66 years, with an average depreciation period of 25 years, and five to 35 years for equipment, with an average depreciation period of 10 years. 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, 2012, 2011 and 2010 was \$525 million, \$508 million and \$476 million, respectively. Equipment includes certain computer software and software development costs incurred in connection with developing or obtaining software for internal use. Assets under capital leases included in property and equipment in the combined balance sheets are not material.

### Litigation

Loss contingency provisions are recorded for probable losses at management's best estimate of a loss. When a best estimate cannot be made, a minimum loss contingency amount 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. Receivables for insurance recoveries 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 as of 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 purchase price 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 earnings. The allocation of purchase price in certain cases may be subject to revision based on the final determination of fair value. Legal costs, audit fees, business valuation costs and all other business acquisition costs are expensed when incurred.

### **Goodwill and Intangible Assets**

Purchased intangible assets 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, terminal values and 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. Impairment is reviewed by comparing 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 identifiable.

Goodwill and indefinite-lived assets are not amortized but are subject to an impairment review annually and whenever 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, calculated using a weighting of the income approach and the market approach. The fair value under the income approach is calculated as the present value of estimated cash flows discounted using a risk-free market rate adjusted for a market participant's view of similar companies and perceived risks in cash flows. The fair value under the market approach is calculated using market multiples for peer groups applied to the operating results of the reporting units to determine fair value. The implied fair value of goodwill is then determined by subtracting the fair value of all identifiable net assets other than goodwill from the fair value of the reporting units, with an impairment charge recorded for the excess, if any, of the carrying amount of goodwill over the implied fair value. Based on the company's most recent annual impairment test performed in the third quarter, the fair value of the reporting units was substantially in excess of their carrying value.

Indefinite-lived assets are tested for impairment by comparing the fair value of each intangible asset with its carrying value. The value of indefinite-lived is based on the present value of projected cash flows using an income approach. If the carrying value exceeds fair value, the intangible asset is considered impaired and is reduced to fair value.

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

The initial costs of rights to acquired in-process research and development (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 current 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 income (OCI). 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 the combined balance sheets and are classified as current or long-term based on the scheduled maturity of the instrument. The accounting for changes in the fair value of a derivative instrument depends on whether it has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship.

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

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

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

Refer to Note 8 for information regarding AbbVie's derivative and hedging activities.

**Earnings per Share**

The numerator for both basic and diluted earnings per common share (EPS) is net earnings attributable to AbbVie. The denominator for basic and diluted EPS is based on the number of shares of AbbVie common stock outstanding on the distribution date. On January 1, 2013, the distribution date, Abbott 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's common stock held as of the record date.

Basic and diluted earnings per common share and the average number of common shares outstanding were calculated using the number of AbbVie common shares outstanding immediately following the distribution. 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 distribution.

years ended December 31 (in millions, except per share amounts)	2012	2011	2010
Net earnings	\$ 5,275	\$ 3,433	\$ 4,178
Basic and diluted earnings per common share	3.35	2.18	2.65
Basic and diluted average shares outstanding	1,577	1,577	1,577

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

years ended December 31 (in millions)	2012	2011	2010
Interest and dividend income	\$ (20)	\$ (20)	\$ (28)
Interest expense	104		
Interest expense, net	\$ 84	\$ (20)	\$ (28)

**Other (Income) Expense**

Other (income) expense, net, for 2012 included income of \$21 million from the resolution of a contractual agreement and a loss of \$52 million for the impairment of an equity security. Other (income) expense, net, included losses of \$29 million in 2012 and \$56 million in 2011 of fair value adjustments and accretion in the contingent consideration related to the acquisition of Solvay SA's U.S. pharmaceuticals business (Solvay). Other (income) expense, net, for 2012, 2011 and 2010 also included ongoing contractual payments from Takeda associated with the conclusion of the TAP Pharmaceutical Products Inc. joint venture in 2008.

**Accounts Payable and Accrued Liabilities**

as of December 31 (in millions)	2012	2011
Sales rebates	\$ 1,616	\$ 1,537
Accounts payable	556	417
Salaries, wages and commissions	523	435
Royalty license arrangements	398	417
Government investigation		1,509
Acquired IPR&D		400
Other	1,718	1,166
Accounts payable and accrued liabilities	\$ 4,811	\$ 5,881

**Long-Term Liabilities**

as of December 31 (in millions)	2012	2011
Deferred income taxes	\$ 360	\$ 646
Pension and other post-employment benefits	979	397
Other	900	617
Long-term liabilities	\$ 2,239	\$ 1,660

**Accumulated Other Comprehensive Income (Loss)**

The net-of-tax components of AOCI, a component of parent company equity, were as follows.

as of December 31 (in millions) (brackets denote loss)	2012	2011
Cumulative foreign currency translation gain adjustments	\$ 181	\$ 8
Pension and other post-employment benefits	(511)	(65)
Cumulative unrealized gains on marketable equity securities	1	26
Cumulative losses/gains on derivative instruments designated as cash flow hedges	(21)	6
Accumulated other comprehensive loss	\$ (350)	\$ (25)

**Note 4 Acquisitions, Collaborations and Other Arrangements**

In 2012, 2011 and 2010, cash outflows related to acquisitions, collaborations and other arrangements totaled \$688 million, \$273 million and \$2.6 billion, respectively. AbbVie recorded IPR&D charges of \$288 million, \$673 million and \$313 million in 2012, 2011 and 2010, respectively. The following are the more significant acquisitions and investments, including licensing and collaboration agreements, some of which require contingent milestone payments.

**Acquisitions***Solvay SA Pharmaceuticals*

In February 2010, AbbVie acquired Solvay and certain other product rights for approximately \$1.9 billion, in cash, plus contingent payments of up to EUR 100 million per year if certain sales milestones are met in 2011, 2012 and 2013. The total consideration was valued at \$2.2 billion, which includes the \$1.9 billion cash payment plus the estimated fair value of the milestone-based contingent payments of approximately \$290 million. The estimated fair value of the contingent consideration was based on the estimated probability of achieving the specified sales milestones discounted based on the expected timing of payment. Subsequent changes to the fair value of contingent payments are recognized in earnings.

This transaction provides AbbVie with a complementary pharmaceutical product portfolio including the U.S. rights to AndroGel and Creon, worldwide rights to Duodopa, and various research and development projects. AbbVie acquired control of this business on February 15, 2010, and the financial results of the acquired operations are included in these financial statements beginning on that date. Net sales of the acquired operations were approximately \$1.1 billion in 2010. Had the Solvay acquisition taken place on January 1, 2010, combined net sales and net earnings would not have been significantly different from reported amounts. The acquisition was funded with cash and short-term investments.

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

The allocation of the fair value of the arrangement as of the acquisition date is shown in the table below.

(in billions)

Acquired intangible assets, non-deductible	\$ 1.8
IPR&D, non-deductible	0.5
Goodwill, non-deductible	0.4
Deferred income taxes	(0.5)
<b>Total consideration</b>	<b>\$ 2.2</b>

The excess of the purchase price over the fair value of the assets acquired and liabilities assumed of approximately \$400 million was recorded as goodwill. Goodwill is attributable to expected synergies and other benefits AbbVie believed would result from the acquisition. Acquired intangible assets consist primarily of product rights for currently marketed products and are amortized over 2 to 13 years (average of 8 years). Acquired IPR&D projects are accounted for as indefinite-lived intangible assets until regulatory approval or discontinuation.

### *Facet Biotech Corporation*

In April 2010, AbbVie acquired the outstanding shares of Facet Biotech Corporation (Facet) for approximately \$430 million, in cash, net of cash held by Facet. The acquisition enhances AbbVie's early-and mid-stage pharmaceutical pipeline, including daclizumab, a biologic for multiple sclerosis, and an oncology compound. A substantial portion of the fair value of the acquisition, including \$381 million for daclizumab, has been allocated to acquired IPR&D projects that are accounted for as indefinite-lived intangible assets until regulatory approval or discontinuation. Had the Facet acquisition taken place on January 1, 2010, combined net sales and net earnings would not have been significantly different from reported amounts.

### **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 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. Royalty and sales-based milestones are expensed as cost of products sold when incurred.

### *Reata Pharmaceuticals, Inc.*

During 2010 and 2011, AbbVie entered into a series of transactions with Reata Pharmaceuticals, Inc. (Reata). AbbVie acquired equity interests in Reata of \$62 million each in 2011 and 2010. In 2010, AbbVie entered into an agreement to acquire licensing rights outside the United States, excluding certain Asian markets, to bardoxolone methyl, a product in development for the treatment of chronic kidney disease, resulting in a charge to IPR&D of \$238 million. The achievement of certain development milestones under the license agreement resulted in charges of \$50 million in 2012 to R&D and \$188 million in 2011 to IPR&D. Additional payments of up to \$150 million could be

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

required for the achievement of certain development and regulatory milestones associated with the chronic kidney disease compound in development.

In the fourth quarter of 2011, AbbVie entered into a collaboration with Reata for the joint development and commercialization of second-generation oral antioxidant inflammation modulators resulting in a charge to IPR&D of \$400 million, which was paid in the first quarter of 2012.

On October 17, 2012, Reata informed AbbVie that it is discontinuing the Phase III clinical study for bardoxolone methyl for chronic kidney disease. Reata and AbbVie will closely examine the data from this study to determine whether there is an appropriate path forward for the development of bardoxolone methyl in chronic kidney disease or other indications. In the fourth quarter of 2012, AbbVie recorded a charge of \$52 million in other (income) expense, net for the impairment of the equity investment in Reata.

### *Seattle Genetics, Inc.*

In October 2012, AbbVie recorded a charge to IPR&D of \$28 million as a result of entering into a two-year collaboration agreement with Seattle Genetics, Inc. to research, develop and commercialize up to three compounds with Antibody-Drug Conjugate approaches. Additional payments of up to \$220 million for each licensed compound may be required based on the achievement of specified development, regulatory and commercial milestones under this agreement.

### *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.

### *Galapagos NV*

In February 2012, AbbVie recorded a charge to IPR&D of \$150 million as a result of entering into a global collaboration with Galapagos NV to develop and commercialize a next-generation, oral Janus Kinase 1 (JAK1) inhibitor in Phase II development with the potential to treat multiple autoimmune diseases. Additional payments of approximately \$1.2 billion could be required for the achievement of certain development, regulatory and commercial milestones under this agreement.

### *Biotest AG*

In June 2011, AbbVie entered into a global agreement with Biotest AG to develop and commercialize an anti-CD4, a treatment for rheumatoid arthritis and psoriasis, resulting in an \$85 million charge to IPR&D. AbbVie could, in the future, be required to make additional payments totaling up to \$395 million based on the achievement of certain development, regulatory and commercial milestones under this agreement.

### *Neurocrine Biosciences, Inc.*

In June 2010, AbbVie entered into an exclusive worldwide agreement with Neurocrine Biosciences, Inc. to develop and commercialize a product for the treatment of endometriosis, resulting in a \$75 million charge to IPR&D. AbbVie could, in the future, be required to make additional payments of up to \$500 million based on the achievement of certain development, regulatory and commercial milestones under this agreement.

**Note 5 Goodwill and Intangible Assets**

The carrying amount of goodwill at December 31, 2012 and 2011 was \$6,130 million and \$6,100 million, respectively. Changes in the goodwill balance were due to foreign currency translation. As of December 31, 2012, there were no accumulated goodwill impairment losses.

The following table summarizes AbbVie's intangible assets.

(in millions)	December 31, 2012			December 31, 2011		
	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	\$ 4,699	\$ (3,031)	\$ 1,668	\$ 4,675	\$ (2,492)	\$ 2,183
License agreements	969	(734)	235	949	(647)	302
Total definite-lived intangible assets	5,668	(3,765)	1,903	5,624	(3,139)	2,485
Indefinite-lived research and development	420		420	425		425
Total intangible assets	\$ 6,088	\$ (3,765)	\$ 2,323	\$ 6,049	\$ (3,139)	\$ 2,910

The indefinite-lived intangible assets relate to IPR&D acquired in a business combination. Amortization expense for 2012, 2011 and 2010 was \$625 million, \$764 million and \$708 million, respectively. In 2012 and 2011, AbbVie recorded impairment charges of \$13 million and \$46 million, respectively, for certain projects under development. These charges are included in R&D expenses. At December 31, 2012, the anticipated annual amortization expense for intangible assets recorded as of December 31, 2012 was \$511 million in 2013, \$348 million in 2014, \$267 million in 2015, \$140 million in 2016 and \$116 million in 2017. Intangible asset amortization is included in cost of products sold in the combined statements of earnings. Amortizable intangible assets are amortized over 2 to 16 years with an average of 11 years for both developed product rights and license agreements.

**Note 6 Restructuring Plans**

In 2012 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 2012, AbbVie recorded a charge of approximately \$177 million for employee severance and contractual obligations, primarily related to the exit from an R&D facility with \$169 million classified in R&D and \$8 million as SG&A expenses. In 2011, AbbVie recorded a charge of \$160 million reflecting employee severance and other related charges, with \$42 million classified as cost of products sold, \$69 million as R&D and \$49 million as SG&A expenses. The following summarizes the activity for these restructurings.

(in millions)

Accrued balance at December 31, 2009	\$ 54
Payments and other adjustments	(54)
Accrued balance at December 31, 2010	
2011 restructuring charges	160
Payments and other adjustments	(70)
Accrued balance at December 31, 2011	90
2012 restructuring charges	177
Payments and other adjustments	(74)
Accrued balance at December 31, 2012	\$ 193



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

An additional \$69 million, \$26 million and \$7 million were subsequently recorded in 2012, 2011 and 2010, respectively, relating to these restructurings, primarily for accelerated depreciation.

### Solvay Plans

In 2010, AbbVie management approved restructuring plans primarily related to the acquisition of Solvay. This plan streamlined operations, improved efficiencies and reduced costs in certain Solvay sites and functions as well as in certain AbbVie and Solvay commercial organizations in various countries. In 2010, AbbVie recorded a charge of \$147 million, with \$6 million classified in cost of products sold, \$126 million classified in R&D and \$15 million classified in SG&A expenses. The following summarizes the employee severance activity for this restructuring.

(in millions)

2010 employee severance charge	\$ 147
Payments and other adjustments	(35)
Accrued balance at December 31, 2010	112
Payments and other adjustments	(92)
Accrued balance at December 31, 2011	20
Payments and other adjustments	(20)
Accrued balance at December 31, 2012	\$

An additional \$27 million and \$17 million were recorded in 2011 and 2010, respectively, relating to this restructuring, primarily for accelerated depreciation and asset impairments.

### Note 7 Debt, Credit Facilities, and Commitments and Contingencies

#### Long-Term Debt

The following is a summary of long-term debt as of December 31, 2012.

(in millions)	Effective interest rate in 2012(a)	2012
Floating rate notes due 2015	1.13%	500
1.2% notes due 2015	1.24%	3,500
1.75% notes due 2017	1.82%	4,000
2.0% notes due 2018	2.12%	1,000
2.9% notes due 2022	3.01%	3,100
4.4% notes due 2042	4.50%	2,600
Other		104
Fair value hedges and unamortized bond discounts		(152)
Total long-term debt and lease obligations		14,652
Current portion		22
Noncurrent portion		\$ 14,630

(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.



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

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.

Debt issuance costs incurred in connection with the senior note debt offering, which totaled \$63 million, are being amortized over the respective terms of the notes to interest expense in the combined statements of earnings.

At December 31, 2012, the company was in compliance with its senior note covenants.

### Short-Term Borrowings

At December 31, 2012, short-term borrowings included \$1.0 billion of commercial paper borrowings. The weighted-average interest rate on short-term borrowings was 0.4% at December 31, 2012. AbbVie has a \$2.0 billion unsecured bank credit facility agreement, which backs the commercial paper program, and matures in July 2017. Abbott was relieved of its obligations under the credit facility upon separation of AbbVie from Abbott on January 1, 2013, and AbbVie became the sole obligor of this facility. The credit facility enables the company to borrow funds on an unsecured basis at floating interest rates. At December 31, 2012, the company was in compliance with its credit facility covenants. Compensating balances and commitment fees are not material.

### Leases

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. The leases generally provide for the company to pay taxes, maintenance, insurance and other operating costs of the leased property. AbbVie also leases office space on a short-term basis typically under cancelable operating leases. The company has capital lease obligations principally for automobiles. As of December 31, 2012, annual future minimum lease payments are not material.

### Future Minimum Lease Payments and Long-Term Debt Maturities

as of and for the years ended December 31 (in millions)

2013	\$	22
2014		15
2015		4,012
2016		9
2017		4,000
Later years		6,746
Total obligations and commitments		14,804
Fair value hedges and unamortized bond discounts		(152)
Current and long-term debt and lease obligations	\$	14,652

### Contingencies and Guarantees

In connection with the distribution, 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. Since AbbVie no longer maintains a business relationship with the other parties, AbbVie is unable to develop an estimate of the maximum potential amount of future payments, if any, under these obligations. 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 8 Financial Instruments and Fair Value Measures**

---

**Risk Management Policy**

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

**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, totaling \$1.0 billion and \$249 million at December 31, 2012 and 2011, respectively, are designated as cash flow hedges and are recorded at fair value. Accumulated gains and losses as of December 31, 2012 will be included in cost of products sold at the time the products are sold, generally through the next 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, 2012 and 2011, AbbVie held \$4.3 billion and \$3.0 billion, respectively, of such foreign currency forward exchange contracts.

AbbVie was a party to interest rate hedge contracts, designated as fair value hedges, totaling \$8.0 billion at December 31, 2012. 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.

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

The following table summarizes the amounts and location of AbbVie's derivative instruments as of December 31.

(in millions)	Fair value assets			Fair value liabilities		
	2012	2011	Balance sheet caption	2012	2011	Balance sheet caption
Interest rate swaps designated as fair value hedges	\$	\$		\$ 81	\$	Long-term liabilities
Foreign currency forward exchange contracts						
Hedging instruments	1	18	Prepaid expenses and other	10		Accounts payable and accrued liabilities
Others not designated as hedges	14	21	Prepaid expenses and other	15	43	Accounts payable and accrued liabilities
<b>Total</b>	<b>\$ 15</b>	<b>\$ 39</b>		<b>\$ 106</b>	<b>\$ 43</b>	

The following table summarizes the activity for derivative instruments and the amounts and location of income (expense) and gain (loss) reclassified into income and for certain other derivative instruments for the years ended December 31. The amount of hedge ineffectiveness was not significant in 2012, 2011 and 2010.

(in millions)	(Loss) gain recognized in other comprehensive (loss) income			Income (expense) and gain (loss) reclassified into income			Income statement caption
	2012	2011	2010	2012	2011	2010	
Foreign currency forward exchange contracts							
Designated as cash flow hedges	\$ (11)	\$ (2)	\$ 75	\$ 24	\$ 18	\$ 45	Cost of products sold
Not designated as hedges	n/a	n/a	n/a	(23)	30	30	Net foreign exchange (gain) loss
Interest rate swaps designated as fair value hedges	n/a	n/a	n/a	(81)			Interest expense, net

The loss of \$81 million related to fair value hedges recognized in net interest expense in 2012 was offset equally by \$81 million in gains on the underlying hedged item, the fixed-rate debt.

### 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.



## 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 combined balance sheets as of December 31.

(in millions)	Basis of fair value measurement			
	Balance at December 31, 2012	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	\$ 5,901	\$ 675	\$ 5,226	\$
Certificates of deposit	1,775		1,775	
U.S. Treasury securities	300	300		
Equity securities	12	12		
Foreign currency forward contracts	15		15	
<b>Total assets</b>	<b>\$ 8,003</b>	<b>\$ 987</b>	<b>\$ 7,016</b>	<b>\$</b>
<b>Liabilities</b>				
Interest rate hedges	\$ 81		\$ 81	\$
Foreign currency forward contracts	25		25	
Contingent consideration	251			251
<b>Total liabilities</b>	<b>\$ 357</b>	<b>\$</b>	<b>\$ 106</b>	<b>\$ 251</b>

(in millions)	Basis of fair value measurement			
	Balance at December 31, 2011	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	\$ 27	\$ 27		\$
U.S. Treasury securities	626	626		
Equity securities	58	58		
Foreign currency forward contracts	39		39	
<b>Total assets</b>	<b>\$ 750</b>	<b>\$ 711</b>	<b>\$ 39</b>	<b>\$</b>
<b>Liabilities</b>				
Foreign currency forward contracts	\$ 43		\$ 43	\$
Contingent consideration	349			349
<b>Total liabilities</b>	<b>\$ 392</b>	<b>\$</b>	<b>\$ 43</b>	<b>\$ 349</b>

Available-for-sale equity securities consist 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 and forward prices for foreign currency hedges and publicized swap curves for interest rate hedges. The contingent payments are valued using a discounted cash flow technique that reflects management's expectations about probability of payment.

Gross unrealized holding gains on available-for-sale equity securities totaled \$1 million and \$44 million at December 31, 2012 and 2011, respectively.





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

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.

(in millions)

Fair value as of December 31, 2010	\$ 295
Other	(2)
Loss recognized in earnings	56
Fair value as of December 31, 2011	349
Payments	(134)
Other	7
Loss recognized in earnings	29
Fair value as of December 31, 2012	\$ 251

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 \$134 million in 2012 for which a liability was previously established.

In addition to the financial instruments that the company is required to recognize at fair value on the combined 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 are shown in the table below.

(in millions)	Book values		Approximate fair values	
	2012	2011	2012	2011
<b>Assets</b>				
Investments	\$ 107	\$ 171	\$ 104	\$ 171
<b>Liabilities</b>				
Short-term borrowings	1,020		1,020	
Current maturities of long-term debt and lease obligations	22	16	22	16
Long-term debt and lease obligations	14,630	32	15,066	32

The following table summarizes the bases used to measure the approximate fair values of the financial instruments as of December 31, 2012.

(in millions)	Fair value at December 31, 2012	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	\$ 104	\$	\$ 32	\$ 72
Total assets	\$ 104	\$	\$ 32	\$ 72
<b>Liabilities</b>				
Short-term borrowings	\$ 1,020	\$	\$ 1,020	\$
Current maturities of long-term debt and lease obligations	22	\$	22	\$
Long-term debt and lease obligations	15,066	\$	15,066	\$
Total liabilities	\$ 16,108	\$	\$ 16,108	\$

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

Investments consist of cost method investments and held-to-maturity debt securities. In determining the fair value of 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 and long-term debt 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. There were no material adjustments to fair value during the years ended December 31, 2012 and 2011, of assets and liabilities that are not measured at fair value on a recurring basis, except as discussed in Note 4 regarding the impairment of the company's investment in Reata. 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.

Three U.S. wholesalers accounted for 48 percent and 43 percent of total net accounts receivables as of December 31, 2012 and 2011, respectively, and substantially all of AbbVie's U.S. sales are to these three wholesalers. In addition, governmental accounts in Greece, Portugal, Italy and Spain accounted for 20 percent and 30 percent of total net accounts receivable as of December 31, 2012 and 2011, respectively.

### Note 9 Post-Employment Benefits

---

#### Abbott Sponsored Plans

AbbVie employees participated in certain U.S. and international defined benefit pension and other post-employment plans sponsored by Abbott. These plans included participants of Abbott's other businesses and were accounted for as multiemployer plans in AbbVie's combined financial statements. As a result, no asset or liability was recorded by AbbVie in the historical balance sheets through December 31, 2012 to recognize the funded status of these plans. Abbott made voluntary contributions to its defined benefit pension funds that AbbVie accounts for as multiemployer plans totaling \$310 million, \$289 million and \$439 million in 2012, 2011 and 2010, respectively. The multiemployer pension plans were approximately 94 percent and 99 percent funded as of December 31, 2012 and 2011, respectively. In connection with the separation of AbbVie from Abbott on January 1, 2013, these plans will be separated and Abbott will transfer certain liabilities and assets of these plans to AbbVie. The estimated amounts that will be assumed by AbbVie in 2013 are shown in the table below.

(in millions)	Defined benefit plans	Other post-employment plans
Accumulated benefit obligations	\$ 2,456	\$ 318
Deferred losses	(1,422)	(59)
Projected benefit obligations	2,929	318
Fair value of assets	2,295	
Net liability	\$ 634	\$ 318

For Abbott sponsored defined benefit and post-employment benefit plans, AbbVie recorded expenses of \$200 million in 2012 and \$150 million in both 2011 and 2010.

**AbbVie Sponsored Plans**

AbbVie is the sole sponsor for certain other defined benefit pension and other post-employment plans, which have been reflected in the combined balance sheets as of December 31, 2012 and 2011. During 2012, in preparation for the separation from Abbott, certain pension and other post-employment benefit plans were assumed by AbbVie and have been reflected in the December 31, 2012 combined balance sheet. AbbVie made voluntary contributions to the AbbVie sponsored pension plans of \$46 million, \$64 million and \$50 million in 2012, 2011 and 2010, respectively. In the first quarter of 2013, AbbVie made a voluntary contribution of \$145 million to its main domestic defined benefit pension plan, which was assumed in 2013.

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

as of and for the years ended December 31 (in millions)	Defined benefit plans		Other post-employment plans
	2012	2011	2012
<b>Projected benefit obligations</b>			
Beginning of period	\$ 649	\$ 636	\$
Service cost	21	18	
Interest cost	38	32	
Assumption of plan liabilities	797		231
Actuarial loss (gain)	182	(1)	
Benefits paid	(40)	(35)	
Other, primarily foreign currency translation loss (gain)	22	(1)	
End of period	\$ 1,669	\$ 649	\$ 231
<b>Fair value of plan assets</b>			
Beginning of period	\$ 230	\$ 201	\$
Actual return on plans assets	42		
Company contributions	46	64	
Assumption of plan assets	620		
Benefits paid	(40)	(35)	
End of period	898	230	
Funded status at December 31	\$ (771)	\$ (419)	\$ (231)
<b>Amounts recognized in combined balance sheets</b>			
Other assets	\$ 11	\$	\$
Current liabilities	(27)	(22)	(7)
Long-term liabilities	(755)	(397)	(224)
Net liability at December 31	\$ (771)	\$ (419)	\$ (231)
Actuarial losses, net	\$ 526	\$ 97	\$ 69
Prior service cost	10	1	(1)
AOI at December 31	\$ 536	\$ 98	\$ 68

The projected benefit obligations (PBO) in the table above included \$1.1 billion and \$405 million at December 31, 2012 and 2011, respectively, related to international defined benefit pension plans which are generally not funded, in accordance with local regulations. Benefit payments for those plans are funded from company assets.

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

For plans reflected in the table above, the accumulated benefit obligations (ABO) were \$1.5 billion and \$620 million at December 31, 2012 and 2011, respectively. For those plans reflected in the table above in which the ABO exceeded plan assets at December 31, 2012, the ABO, PBO and aggregate plan assets were \$951 million, \$1.0 billion and \$278 million, respectively.

### *Amounts Recognized in AOCI and OCI*

The pension and other post-employment plans' 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 losses included in OCI for 2012 and 2011.

(in millions)

Actuarial loss	\$ 167
Prior service cost	9
Amortization of prior service cost and actuarial losses	(7)
Foreign exchange loss	5
<b>Total pretax loss recognized in OCI at December 31, 2012</b>	<b>\$ 174</b>
Actuarial loss	\$ 19
Amortization of prior service cost and actuarial losses	(2)
Foreign exchange loss	2
<b>Total pretax loss recognized in OCI at December 31, 2011</b>	<b>\$ 19</b>

The pretax amount of actuarial losses and prior service cost included in AOCI at December 31, 2012 that is expected to be recognized in the net periodic benefit cost in 2013 is \$32 million for defined benefit plans and \$3 million for other post-employment plans.

### *Net Periodic Benefit Cost*

years ended December 31 (in millions)	2012	2011	2010
Service cost	\$ 21	\$ 18	\$ 15
Interest cost	38	32	32
Expected return on plans assets	(29)	(21)	(16)
Amortization of actuarial losses and prior service costs	7	2	1
<b>Net periodic pension benefit cost</b>	<b>\$ 37</b>	<b>\$ 31</b>	<b>\$ 32</b>

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

	2012	2011
Discount rate	4.0%	5.1%
Rate of compensation increases	3.9%	4.2%

The assumptions above, which were used in calculating the December 31, 2012 measurement date benefit obligations, will be used in the calculation of net periodic benefit cost in 2013.

Edgar Filing: AbbVie Inc. - Form 10-K

Weighted-Average Assumptions Used in Determining Net Periodic Benefit Cost

	2012	2011	2010
Discount rate	5.1%	5.0%	5.4%
Expected long-term rate of return on plan assets	8.5%	8.5%	8.5%
Expected rate of change in compensation	4.2%	4.1%	3.7%

Pension Plan Assets

(in millions)	Balance at December 31, 2012	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)	\$ 232	\$ 232	\$	\$
U.S. mid cap(b)	45	31	14	
International(c)	276	234	42	
<b>Fixed income securities</b>				
U.S. government securities(d)	73	24	49	
Corporate debt instruments(e)	109	93	16	
Government Securities International	26	26		
Other	2	1	1	
Absolute return funds(f)	90	22	37	31
Real assets	18	9	7	2
Other(g)	27	27		
<b>Fair value of plan assets</b>	<b>\$ 898</b>	<b>\$ 699</b>	<b>\$ 166</b>	<b>\$ 33</b>

(in millions)	Balance at December 31, 2011	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)	\$ 54	\$ 53	\$ 1	\$
U.S. mid cap(b)	17	5	12	
International(c)	27	2	25	
<b>Fixed income securities</b>				
U.S. government securities(d)	35	16	19	
Corporate debt instruments(e)	14	3	11	
Other	2	2		
Absolute return funds(f)	71	12	32	27
Other(g)	10	2	8	
<b>Fair value of plan assets</b>	<b>\$ 230</b>	<b>\$ 95</b>	<b>\$ 108</b>	<b>\$ 27</b>

(a) A mix of index funds that track the S&P 500 (50 percent in 2012 and 45 percent in 2011) and separate actively managed equity accounts that are benchmarked to the Russell 1000 (50 percent in 2012 and 55 percent in 2011).

(b)

Edgar Filing: AbbVie Inc. - Form 10-K

A mix of index funds (75 percent) and separate actively managed equity accounts (25 percent) that track or are benchmarked to the S&P 400 midcap index.

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

- (c) Primarily separate actively managed pooled investment accounts that are benchmarked to the MSCI emerging market and various local indices.
- (d) Index funds (50 percent in 2012 and 45 percent in 2011) and separate actively managed accounts (50 percent in 2012 and 55 percent in 2011).
- (e) Index funds (20 percent in 2012 and 40 percent in 2011) and separate actively managed accounts (80 percent in 2012 and 60 percent in 2011).
- (f) Primarily funds invested by managers that have a global mandate 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, interest rate futures, currencies and other securities to outperform an agreed upon benchmark with specific return and volatility targets.
- (g) Primarily investments in liquid commodity future contracts, private energy funds, 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.

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

(in millions)	2012	2011
January 1	\$ 27	\$ 22
Transfers in from other categories		3
Actual return on plan assets on hand at year end	3	(1)
Purchases, sales and settlements, net	3	3
December 31	\$ 33	\$ 27

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 made across a range of markets, industry sectors, capitalization sizes, and in the case of fixed income securities, maturities and credit quality. There are no known significant concentrations of risk in the 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
2013	\$ 58	\$ 7
2014	59	7
2015	60	8
2016	64	8
2017	65	9
2018 to 2022	363	53

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

**Other**

AbbVie employees also participate in the Abbott Laboratories Stock Retirement Plan, which is Abbott's principal defined contribution plan. AbbVie recorded expense of \$67 million, \$68 million and \$65 million for the years ended December 31, 2012, 2011 and 2010, respectively, 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 10 Stock-Based Compensation**

Prior to separation, AbbVie employees participated in Abbott's incentive stock program. In conjunction with the separation, the company adopted the AbbVie Incentive Stock Program, which provides for the assumption of certain awards granted under the Abbott incentive stock program and authorizes the grant of several different forms of benefits including nonqualified stock options, restricted stock awards (RSAs), and restricted stock units (RSUs). The AbbVie Incentive Stock Program initially reserved 100 million shares of common stock for issuance with respect to awards for participants. Subsequent to year-end, this reserve was reduced by approximately 7 million shares for stock option, RSA and RSU awards granted by AbbVie's Board of Directors.

The following disclosures represent the portion of Abbott's incentive stock program in which AbbVie employees participated. All awards granted under the program consisted of Abbott common shares. As such, all related equity account balances are reflected in Abbott's consolidated statements of stockholders' equity and have not been reflected in AbbVie's combined financial statements. AbbVie's combined statements of earnings reflects compensation expense for these stock-based awards associated with the portion of Abbott's incentive stock program in which AbbVie employees participated; accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that AbbVie would have experienced as an independent, publicly-traded company for the periods presented.

All equity award amounts presented below have not been converted to reflect the separation from Abbott. 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. The value of the combined Abbott and AbbVie stock-based awards after separation was designed to generally preserve the intrinsic value and the fair value of the award immediately prior to separation. The per share data presented in this Note has not been adjusted to reflect the impact of the separation.



**Stock Compensation Expense**

Stock compensation expense recognized in the combined statements of earnings was \$187 million, \$163 million and \$167 million in 2012, 2011 and 2010, respectively. The related tax benefit recognized was \$56 million, \$48 million and \$51 million in 2012, 2011 and 2010, respectively. More than half of stock-compensation expense was classified in SG&A, with the remainder classified in R&D and cost of products sold. Compensation costs capitalized in the combined balance sheets at December 31, 2012 and 2011 was not significant.

Compensation expense for stock-based awards is measured based on the fair value of the awards, as of the date the share-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 are 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.

**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 except for options with a replacement feature. Pre-2005 options were granted with a replacement option feature. The terms and conditions of the replacement option are the same in all material respects as those applicable to the original grant. When the exercise price of an option with a replacement option feature is paid with the common shares held by the employee, a replacement option is granted for the number of shares used to make that payment. The closing price of the common share on the business day before the exercise is used to determine the number of shares required to exercise the related option and the exercise price of the replacement option. The replacement option is exercisable in full six months after the date of grant, and has a term expiring on the expiration date of the original option.

The fair value of stock options is determined using the Black-Scholes model. The weighted-average assumptions used in estimating the fair value of stock options granted during each year, along with weighted-average grant-date fair values, were as follows.

years ended December 31	2012	2011	2010
Risk-free interest rate	1.2%	2.7%	2.9%
Average life of options (years)	6.0	6.0	6.0
Volatility	21.0%	21.0%	22.0%
Dividend yield	3.6%	4.1%	3.2%
Fair value per stock option	\$ 6.80	\$ 6.23	\$ 9.24

The risk-free interest rate is based on the rates available at the time of the grant for zero-coupon U.S. government issues with a remaining term equal to the option's expected life. The average life of an option is based on both historical and projected exercise and lapsing data. Expected volatility is based on implied volatilities from traded options on Abbott's stock and historical volatility of Abbott's stock over the expected life of the option. Dividend yield is based on the option's exercise price and annual dividend rate at the time of grant.

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

The following table summarizes stock option activity for the year ended December 31, 2012 and stock option outstanding balances at December 31, 2012 under Abbott's Incentive Stock Programs for AbbVie employees.

(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, 2011	25,783	\$ 49.77	4.1	
Granted	944	62.54		
Exercised	(13,347)	49.62		
Lapsed	(95)	53.88		
<b>Outstanding at December 31, 2012</b>	<b>13,285</b>	<b>\$ 50.80</b>	<b>3.7</b>	<b>\$ 196</b>
Exercisable at December 31, 2012	12,329	\$ 50.09	3.6	\$ 190

The aggregate intrinsic value in the table above represents the difference between the exercise price and the closing stock price on the last day of trading of the year. The total intrinsic value of options exercised in 2012, 2011 and 2010 was \$170 million, \$31 million and \$20 million, respectively.

As of December 31, 2012, \$1 million of unrecognized compensation cost related to stock options is expected to be recognized as expense over the next three years.

### **RSAs & RSUs**

Restricted stock awards generally vest between three and five years. For restricted stock awards 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 restricted stock unit. The fair value of RSAs and RSUs is determined based on the number of shares granted and the quoted price of the common stock on the date of grant.

The following table summarizes RSAs and RSUs balances and activity under Abbott's Incentive Stock Programs for AbbVie employees.

(share units in thousands)	Share units	Weighted average grant date fair value
Nonvested shares December 31, 2011	4,710	\$ 50.29
Granted	2,749	56.07
Vested	(2,164)	51.23
Lapsed	(251)	48.62
<b>Nonvested shares December 31, 2012</b>	<b>5,044</b>	<b>\$ 53.12</b>

The fair market value of restricted stock awards and units vested in 2012, 2011 and 2010 was \$123 million, \$74 million and \$53 million, respectively. As of December 31, 2012, \$90 million of unrecognized compensation cost related to RSAs and RSUs is expected to be recognized as expense over the next three years.

**Note 11 Income Taxes****Earnings Before Income Taxes**

years ended December 31 (in millions)	2012	2011	2010
Domestic	\$ 625	\$ 626	\$ (191)
Foreign	5,100	3,042	5,027
Total earnings before income taxes	\$ 5,725	\$ 3,668	\$ 4,836

**Income Taxes**

years ended December 31 (in millions)	2012	2011	2010
<b>Current</b>			
Domestic	\$ 94	\$ 177	\$ 987
Foreign	252	390	408
Total current taxes	\$ 346	\$ 567	\$ 1,395
<b>Deferred</b>			
Domestic	\$ 89	\$ (198)	\$ (624)
Foreign	15	(134)	(113)
Total deferred taxes	104	(332)	(737)
Total income taxes	\$ 450	\$ 235	\$ 658

**Effective Tax Rate Reconciliation**

years ended December 31 (in millions)	2012	2011	2010
Statutory tax rate	35.0%	35.0%	35.0%
Benefit of lower tax rates and tax exemptions, primarily in Puerto Rico	(23.5)	(25.4)	(22.5)
Resolution of certain tax positions pertaining to prior years	(3.4)	(11.2)	
Effect of non-deductible litigation loss accrual	0.6	12.9	
Puerto Rico excise tax credit	(1.2)	(3.2)	
State taxes, net of federal benefit	0.1	0.3	0.2
All other, net	0.3	(2.0)	0.9
Effective tax rate	7.9%	6.4%	13.6%

Income taxes in 2012 and 2011 included the recognition of tax benefits totaling approximately \$195 million and \$410 million, respectively, as a result of favorable resolutions of various tax positions pertaining to prior years. Income taxes in 2011 also reflected the non-deductibility of a litigation reserve. Excluding these discrete items, the effective tax rates were less than the statutory U.S. federal income tax rate of 35 percent principally due to the benefit of lower statutory tax rates and tax exemptions in Puerto Rico and other foreign taxing jurisdictions, which reduced the tax rates by 23.5, 25.4 and 22.5 percentage points in 2012, 2011 and 2010, respectively.

In 2010, 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 combined statements of earnings. The majority of the tax is creditable for U.S. income tax purposes. In 2012 and 2011, the excise tax totaled approximately \$180 million and \$105 million, respectively.

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

At December 31, 2012, U.S. income taxes have not been provided on approximately \$19.4 billion of undistributed foreign earnings as these earnings have been indefinitely reinvested for continued use in foreign operations. It is not practicable to determine the amount of deferred income taxes not provided on these earnings.

### Deferred Tax Assets and Liabilities

as of December 31 (in millions)	2012	2011
<b>Deferred tax assets</b>		
Compensation and employee benefits	\$ 295	\$ 290
Trade receivable reserves	412	371
Inventory reserves	42	49
Deferred intercompany profit	777	592
State income taxes	106	125
Other	1,039	1,196
Total deferred tax assets	\$ 2,671	\$ 2,623
<b>Deferred tax liabilities</b>		
Depreciation		(20)
Other, primarily the excess of book basis over tax basis of intangible assets	(857)	(983)
Total deferred tax liabilities	(857)	(1,003)
Net deferred tax asset	\$ 1,814	\$ 1,620

### Unrecognized Tax Benefits

years ended December 31 (in millions)	2012	2011	2010
January 1	\$ 1,039	\$ 1,645	\$ 1,319
Increase due to current year tax positions	370	294	346
Increase due to prior year tax positions	1	149	110
Decrease due to current year tax positions		(15)	
Decrease due to prior year tax positions	(220)	(604)	(48)
Settlements	(50)	(430)	(82)
December 31	\$ 1,140	\$ 1,039	\$ 1,645

AbbVie and Abbott entered into a tax sharing agreement effective on the date of separation. For tax contingencies prior to the separation, Abbott will indemnify and hold AbbVie harmless if the tax positions are settled for amounts in excess of recorded liabilities, and AbbVie will not benefit if prior tax positions are resolved more favorably than recorded amounts. As a result, no liability for uncertain tax positions was recorded in the combined financial statements as of December 31, 2012, 2011 and 2010.

### Note 12 Litigation

There are a number of patent disputes with third parties who claim AbbVie's products infringe their patents. On February 21, 2012, the U.S. Supreme Court denied Centocor Inc.'s and New York University's petition to review a February 2011 Federal Circuit Court of Appeals decision reversing a \$1.67 billion judgment in favor of Centocor and New York University on a patent they claimed AbbVie's HUMIRA infringed. This decision concludes the case.

The U.S. Department of Justice, through the U.S. Attorney for the Western District of Virginia, and various state Attorneys General investigated AbbVie's sales and marketing activities for Depakote. The

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

government sought to determine whether any of these activities violated civil and/or criminal laws, including the Federal False Claims Act, the Food, Drug and Cosmetic Act, and the Anti-Kickback Statute in connection with Medicare and/or Medicaid reimbursement to third parties. The state Attorneys General offices sought to determine whether any of these activities violated various state laws, including state consumer fraud/protection statutes. AbbVie recorded charges of \$1.5 billion in the third quarter of 2011 and \$100 million in the first quarter of 2012 related to civil and criminal claims arising from this matter. In May 2012, AbbVie reached resolution of all Depakote-related federal claims, Medicaid-related claims with 49 states and the District of Columbia, and consumer protection claims with 45 states and the District of Columbia. In 2012, AbbVie paid approximately \$1.6 billion for the settlement. The payments were material to AbbVie's cash flows in 2012.

The recorded accrual balance for litigation at December 31, 2012 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 financial position, cash flows, or results of operations.

### **Note 13 Related Party Transactions with Abbott**

---

In the historical financial statements, 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 will be provided to AbbVie on a temporary basis after the separation. The financial information in these combined financial statements does not necessarily include all the expenses that would have been incurred had AbbVie been a separate, stand-alone entity. As such, the financial information herein may not necessarily reflect the combined financial position, results of operations and cash flows of AbbVie in the future or what they would have been had AbbVie been a separate, stand-alone entity during the periods presented. Management believes that the methods used to allocate expenses to AbbVie are reasonable. The allocation methods included relative sales, headcount, square footage, number of transactions or other measures. These allocations totaled \$838 million, \$801 million and \$677 million for the years ended December 31, 2012, 2011 and 2010, respectively. In 2012, AbbVie incurred \$288 million of separation-related expenses, including legal, information technology and regulatory fees, which were principally classified in SG&A. As of December 31, 2012, outstanding intercompany transactions between AbbVie and Abbott are reflected as Due from Abbott Laboratories and Due to Abbott Laboratories in the combined balance sheet.

**Note 14 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. Net sales of key products were as follows.

years ended December 31 (in millions)	2012	2011	2010
HUMIRA	\$ 9,265	\$ 7,932	\$ 6,508
AndroGel	1,152	874	649
TriCor/TRILIPIX	1,098	1,372	1,355
Kaletra	1,013	1,170	1,223
Niaspan	911	976	927
Synagis	842	792	726
Lupron	800	810	741
Sevoflurane	602	665	664
Synthroid	551	522	451
Norvir	389	419	344
Zemplar	383	409	596
Creon	353	332	246
All other	1,021	1,171	1,208
Net sales	\$ 18,380	\$ 17,444	\$ 15,638

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

years ended December 31 (in millions)	2012	2011	2010
United States	\$ 10,435	\$ 9,712	\$ 8,971
The Netherlands	776	904	845
Germany	756	701	635
Japan	718	616	484
United Kingdom	552	496	418
Spain	525	569	515
France	500	516	479
Canada	500	446	374
Brazil	434	382	287
Italy	408	428	385
All other countries	2,776	2,674	2,245
Net sales	\$ 18,380	\$ 17,444	\$ 15,638

Long-lived assets, consisting of net property and equipment in the United States and Puerto Rico, totaled approximately \$1.6 billion and \$1.5 billion as of December 31, 2012 and 2011, respectively.

**Note 15 Quarterly Financial Data (unaudited)**

---

(in millions except per share data)	2012	2011
<b>First Quarter</b>		
Net sales	\$ 4,173	\$ 3,897
Gross margin	3,017	2,689
Net earnings	883	723
Basic and diluted earnings per share	0.56	0.46
<b>Second Quarter</b>		
Net sales	\$ 4,493	\$ 4,274
Gross margin	3,420	3,168
Net earnings	1,267	1,540
Basic and diluted earnings per share	0.80	0.98
<b>Third Quarter</b>		
Net sales	\$ 4,508	\$ 4,409
Gross margin	3,494	3,260
Net earnings	1,585	13
Basic and diluted earnings per share	1.01	0.01
<b>Fourth Quarter</b>		
Net sales	\$ 5,206	\$ 4,864
Gross margin	3,941	3,688
Net earnings	1,540	1,157
Basic and diluted earnings per share	0.98	0.73

The computation of basic and diluted earnings per share for all periods was calculated using the shares distributed on January 1, 2013.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying combined balance sheets of AbbVie Inc. and subsidiaries (the "Company") as of December 31, 2012 and 2011 and the related combined statements of earnings, comprehensive income, statement of parent company equity and cash flows for each of the three years in the period 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 audits.

We conducted our audits in accordance with auditing 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 audits 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 audits provide a reasonable basis for our opinion.

In our opinion, such combined financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2012 and 2011 and the results of its operations and its cash flows for each of the three years in the period 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 legal 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**

As previously reported on AbbVie's Current Report on Form 8-K, dated December 20, 2012, the Audit Committee of AbbVie's Board of Directors approved the dismissal of Deloitte & Touche LLP (Deloitte) as AbbVie's independent registered public accountant, effective as of the date of Deloitte's completion of the audit services for the fiscal year ending December 31, 2012 and the filing of AbbVie's 2012 Annual Report on Securities and Exchange Commission Form 10-K, and approved the appointment of Ernst & Young LLP as AbbVie's independent registered public accounting firm to perform independent audit services beginning with the fiscal year ending December 31, 2013.

During the fiscal years ended December 31, 2012, 2011 and 2010, and through March 15, 2013, (i) there were no disagreements (as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between AbbVie and Deloitte on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to the satisfaction of Deloitte, would have caused Deloitte to make reference to the subject matter of the disagreement in connection with its reports on AbbVie's combined financial statements for such years, and (ii) there were no "reportable events" (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

**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.** This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

**Changes in internal control over financial reporting.** During the quarter ended December 31, 2012, there were no 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.

**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 error 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

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

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.

**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 2013 AbbVie Inc. Proxy Statement. The 2013 Proxy Statement will be filed on or about March 15, 2013. Also incorporated herein by reference is the text found under the caption, "Executive Officers of the Registrant" on pages 35 through 36 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.

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 both 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 2013 Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Compensation Committee Report" is incorporated herein by reference. The 2013 Proxy Statement will be filed on or about March 15, 2013.

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

- (a) *Equity Compensation Plan Information.* AbbVie did not have any outstanding shares issued under a company equity compensation plan as of December 31, 2012.
- (b) *Information Concerning Security Ownership.* Incorporated herein by reference is the material under the heading "Ownership of Securities Security Ownership of Executive Officers and Directors" in the 2013 Proxy Statement. The 2013 Proxy Statement will be filed on or about March 15, 2013.

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

The material to be included in the 2013 Proxy Statement under the headings "The Board of Directors and its Committees," "Corporate Governance Materials," "Procedures for Approval of Related Person Transactions," and "Transactions with Abbott" is incorporated herein by reference. The 2013 Proxy Statement will be filed on or about March 15, 2013.

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

The material to be included in the 2013 Proxy Statement under the headings "Audit Information Audit Fees and Non-Audit Fees" and "Audit Information Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of the Independent Auditor" is incorporated herein by reference. The 2013 Proxy Statement will be filed on or about March 15, 2013.

**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 59 hereof, for a list of financial statements.
- (2) *Financial Statement Schedules:* All schedules omitted are inapplicable or the information required is shown in the combined 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 101 through 103 of this Form 10-K.
- (b) *Exhibits filed (see Exhibit Index on pages 101 through 103).*
- (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: March 15, 2013

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 March 15, 2013 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**  
**2012**

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 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).
4.3	*Registration Rights Agreement dated November 8, 2012 by and among AbbVie Inc., Abbott Laboratories, Morgan Stanley & Co. LLC, Barclays Capital Inc., J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated (incorporated by reference to Exhibit 4.3 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 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 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 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 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 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).

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

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.6	*International Commercial Operations Agreement by and between Abbott Laboratories and AbbVie Inc. (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.7	*Luxembourg International Commercial Operations Agreement by and between Abbott Investments Luxembourg S.à.r.l. and AbbVie Investments S.à.r.l. (incorporated by reference to Exhibit 10.7 of the Company's Current Report on Form 8-K filed on January 2, 2013).
10.8	*Information Technology Agreement 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).
10.9	*Transitional Trademark License Agreement 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).
10.10	*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).
10.11	*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).
10.12	*Form of Agreement Regarding Change in Control (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).**
10.13	*AbbVie 2013 Incentive Stock Program (incorporated by reference to Exhibit 10.14 of Amendment No. 6 to the Company's Registration Statement on Form 10 filed on November 30, 2012).**
10.14	AbbVie 2013 Management Incentive Plan.**
10.15	AbbVie 2013 Performance Incentive Plan.**
10.16	AbbVie Deferred Compensation Plan.**
10.17	AbbVie Non-Employee Directors' Fee Plan.**
10.18	AbbVie Supplemental Pension Plan.**
10.19	AbbVie Supplemental Savings Plan.**
10.20	*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).
21.1	Subsidiaries of AbbVie Inc.
23.1	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)).

Edgar Filing: AbbVie Inc. - Form 10-K

<b>Exhibit Number</b>	<b>Exhibit Description</b>
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.

The AbbVie Inc. 2013 Proxy Statement will be filed with the Securities and Exchange Commission under separate cover on or about March 15, 2013.

---

\*  
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 shareholder upon written request to the Secretary, AbbVie Inc., 1 North Waukegan Road, North Chicago, Illinois 60064.



QuickLinks

PART I

ITEM 1. BUSINESS

ITEM 1A. RISK FACTORS

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

ITEM 1B. UNRESOLVED STAFF COMMENTS

ITEM 2. PROPERTIES

ITEM 3. LEGAL PROCEEDINGS

ITEM 4. MINE SAFETY DISCLOSURES

EXECUTIVE OFFICERS OF THE REGISTRANT

PART II

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

ITEM 6. SELECTED FINANCIAL DATA

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AbbVie Inc. and Subsidiaries Combined Statements of Earnings

AbbVie Inc. and Subsidiaries Combined Statements of Comprehensive Income

AbbVie Inc. and Subsidiaries Combined Statements of Cash Flows

AbbVie Inc. and Subsidiaries Combined Balance Sheets

AbbVie Inc. and Subsidiaries Combined Statements of Parent Company Equity

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

ITEM 9A. CONTROLS AND PROCEDURES

ITEM 9B. OTHER INFORMATION

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

ITEM 11. EXECUTIVE COMPENSATION

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

SIGNATURES

