

AbbVie Inc.  
Form 10-K  
February 27, 2019

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549  
FORM 10-K  
(MARK  
ONE)

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

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

For the fiscal year ended December 31, 2018

Commission file number 001-35565

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware

32-0375147

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. employer  
identification number)

1 North Waukegan Road

(847) 932-7900

North Chicago, Illinois 60064-6400

(Telephone number)

(Address of principal executive offices) (Zip Code)

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

Title of Each Class

Name of Each Exchange on Which  
Registered

Common Stock, par value \$0.01 per share

New York Stock Exchange  
Chicago Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

Smaller Reporting Company  Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Yes  No

The aggregate market value of the 1,498,817,459 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of AbbVie Inc.'s most recently completed second fiscal quarter (June 30, 2018), was \$138,865,437,576. AbbVie has no non-voting common equity.

Number of common shares outstanding as of February 8, 2019: 1,475,083,514

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the 2019 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 22, 2019.

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FORM 10-K  
FOR THE YEAR ENDED DECEMBER 31, 2018  
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PART I  
ITEM 1. BUSINESS

Overview

AbbVie<sup>(1)</sup> is a global, research-based biopharmaceutical company. AbbVie develops and markets advanced therapies that address some of the world's most complex and serious diseases. AbbVie's products are focused on treating conditions such as chronic autoimmune diseases in rheumatology, gastroenterology and dermatology; oncology, including blood cancers; virology, including hepatitis C virus (HCV) and human immunodeficiency virus (HIV); neurological disorders, such as Parkinson's disease; metabolic diseases, including thyroid disease and complications associated with cystic fibrosis; pain associated with endometriosis; as well as other serious health conditions. AbbVie also has a pipeline of promising new medicines in clinical development across such important medical specialties as immunology, oncology and neuroscience, with additional targeted investment in cystic fibrosis and women's health. AbbVie was incorporated in Delaware on April 10, 2012. On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories (Abbott) of 100% of the outstanding common stock of AbbVie to Abbott's shareholders.

Segments

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

Products

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

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

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

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

HUMIRA is sold in numerous other markets worldwide, including Japan, China, Brazil and Australia, and accounted for approximately 61% of AbbVie's total net revenues in 2018.

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



Oncology products. AbbVie's oncology products target some of the most complex and difficult-to-treat cancers. These products are:

**IMBRUVICA.** IMBRUVICA (ibrutinib) is an oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase (BTK). IMBRUVICA was one of the first medicines to receive a United States Food and Drug Administration (FDA) approval after being granted a Breakthrough Therapy Designation and is one of the few therapies to receive four separate designations. IMBRUVICA currently is approved for the treatment of adult patients with:

• Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) and CLL/SLL with 17p deletion;

• Mantle cell lymphoma (MCL) who have received at least one prior therapy\*;

• Waldenström's macroglobulinemia (WM);

• Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy\*; and

• Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

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\* Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

**VENCLEXTA.** VENCLEXTA (venetoclax) is a BCL-2 inhibitor used to treat adults with CLL or SLL, with or without 17p deletion, who have received at least one prior treatment. In addition, VENCLEXTA is used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly-diagnosed acute myeloid leukemia (AML) who are 75 years of age or older or have other medical conditions that prevent the use of standard chemotherapy.

**Virology Products.** AbbVie's virology products address unmet needs for patients living with HCV and HIV.

**HCV products.** AbbVie's HCV products are:

**MAVYRET/MAVIRET.** MAVYRET (glecaprevir/pibrentasvir) is approved in the United States and European Union (MAVIRET) for the treatment of patients with chronic HCV genotype 1-6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). It is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. It is an 8-week, pan-genotypic treatment for patients without cirrhosis and who are new to treatment.

**VIEKIRA PAK AND TECHNIVIE.** VIEKIRA PAK (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) is an all-oral, short-course, interferon-free therapy, with or without ribavirin, for the treatment of adult patients with genotype 1 chronic HCV, including those with compensated cirrhosis. In Europe, VIEKIRA PAK is marketed as VIEKIRAX + EXVIERA and is approved for use in patients with genotype 1 and genotype 4 HCV. AbbVie's TECHNIVIE (ombitasvir, paritaprevir and ritonavir) is FDA-approved for use in combination with ribavirin for the treatment of adults with genotype 4 HCV infection in the United States.

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

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

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

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





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

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

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

AndroGel. AndroGel (testosterone gel) is a testosterone replacement therapy for males diagnosed with symptomatic low testosterone due to certain underlying conditions.

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

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

Other products. AbbVie's other products include:

ORILISSA. ORILISSA (elagolix) is the first and only orally-administered, nonpeptide small molecule gonadotropin-releasing hormone (GnRH) antagonist specifically developed for women with moderate to severe endometriosis pain. The FDA approved ORILISSA under priority review. It represents the first FDA-approved oral treatment for the management of moderate to severe pain associated with endometriosis in over a decade. ORILISSA inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland.

Administration results in dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone, leading to decreased blood concentrations of ovarian sex hormones, estradiol and progesterone.

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

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

#### Marketing, Sales and Distribution Capabilities

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

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

AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. Although AbbVie's business does not have significant seasonality, AbbVie's product revenues may be affected by end customer and retail buying patterns, fluctuations in wholesaler inventory levels and other factors.

In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies and patients. In 2018, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation) accounted for substantially all of AbbVie's sales in the United States. No individual wholesaler accounted for greater than 42% of AbbVie's 2018 gross revenues in the United States. Outside the United States, products are sold primarily to customers or through distributors, depending on the market served. These wholesalers purchase product from AbbVie under standard terms and conditions of sale.

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



business is subject to renegotiation of profits or termination of contracts at the election of the government. Orders are generally filled on a current basis and order backlog is not material to AbbVie's business.

#### Competition

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

**Biosimilars.** Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as "biosimilars." Biologics have added major therapeutic options for the treatment of many diseases, including some for which therapies were unavailable or inadequate. The cost of developing and producing biologic therapies is typically dramatically higher than for conventional (small molecule) medications, and many 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.

HUMIRA is now facing direct biosimilar competition in Europe and other countries, which represent approximately 75% of AbbVie's international HUMIRA business or approximately 25% of total global HUMIRA revenues. AbbVie will continue to face competitive pressure from these biologics and from orally administered products.

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

Furthermore, the law provides that only a biosimilar product that is determined to be "interchangeable" will be considered substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The law continues to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning remains subject to substantial uncertainty.

#### Intellectual Property Protection and Regulatory Exclusivity

Generally, upon approval, products may be entitled to certain kinds of exclusivity under applicable intellectual property and regulatory regimes. AbbVie's intellectual property is materially valuable to the company, and AbbVie seeks patent protection, where available, in all significant markets and/or countries for each product in development. In the United States, the expiration date for patents is 20 years after the filing date. Given that patents relating to pharmaceutical products are often obtained early in the development process and given the amount of time needed to complete clinical trials and other development activities required for regulatory approval, the length of time between product launch and patent expiration is significantly less than 20 years. The Drug Price Competition and Patent Term

Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) permits a patent holder to seek a patent extension, commonly called a “patent term restoration,” for patents on products (or processes for making the product) regulated by the Federal Food, Drug, and Cosmetic Act. The length of the patent extension is roughly based on 50 percent of the period of time from the filing of an Investigational New Drug Application (NDA) for a compound to the submission of the NDA for such compound, plus 100 percent of the time period from NDA submission to regulatory approval. The extension, however, cannot exceed five years and the patent term remaining after

regulatory approval cannot exceed 14 years. Biological products licensed under the Public Health Service Act are similarly eligible for terms of patent restoration.

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

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

Biologics may be entitled to exclusivity under the Biologics Price Competition and Innovation Act, which was passed on March 23, 2010 as Title VII to the Patient Protection and Affordable Care Act. The law provides a pathway for approval of biosimilars following the expiration of 12 years of regulatory exclusivity for the innovator biologic and a potential additional 180 day-extension term for conducting pediatric studies. Biologics are also eligible for orphan drug exclusivity, as discussed above. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability. 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 close regulatory scrutiny over, and more rigorous requirements for approval of, follow-on biosimilar products, which can reduce the effect of biosimilars on sales of the innovator biologic as compared to the sales erosion caused by generic versions of small molecule pharmaceutical products.

AbbVie owns or has licensed rights to a substantial number of patents and patent applications. AbbVie licenses or owns a patent portfolio of thousands of patent families, each of which includes United States patent applications and/or issued patents and may also contain the non-United States counterparts to these patents and applications. These patents and applications, including various patents that expire during the period 2019 to the late 2030s, in aggregate are believed to be of material importance in the operation of AbbVie's business. However, AbbVie believes that no single patent, license, trademark (or related group of patents, licenses, or trademarks), except for those related to adalimumab (which is sold under the trademark HUMIRA), are material in relation to the company's business as a whole. The United States composition of matter (that is, compound) patent covering adalimumab expired in December 2016, and the equivalent European Union patent expired in October 2018 in the majority of European Union countries. In the United States, non-composition of matter patents covering adalimumab expire no earlier than 2022. In addition, the following patents, licenses, and trademarks are significant: those related to ibrutinib (which is sold under the trademark IMBRUVICA) and those related to glecaprevir and pibrentasvir (which are sold under the trademarks MAVYRET and MAVIRET). The United States composition of matter patent covering ibrutinib is expected to expire in 2027. The United States composition of matter patents covering glecaprevir and pibrentasvir are expected to expire in 2032.

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

### Licensing and Other Arrangements

In addition to its independent efforts to develop and market products, AbbVie enters into arrangements such as licensing arrangements, option-to-license arrangements, strategic alliances, co-promotion arrangements, co-development and co-marketing agreements, and joint ventures. These licensing and other arrangements typically include, among other terms and conditions, non-refundable upfront license fees, option fees and option exercise payments (if applicable), milestone payments and royalty and/or profit sharing obligations. See Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

### Third Party Agreements

AbbVie has agreements with third parties for process development, product distribution, 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. In addition, AbbVie has agreements with third parties for active pharmaceutical ingredient and product manufacturing, formulation and development services, fill, finish and packaging services, transportation and distribution and logistics services for certain products. AbbVie does not believe that these manufacturing related agreements are material because AbbVie's business is not substantially dependent on any individual agreement. In most cases, AbbVie maintains alternate supply relationships that it can utilize without undue disruption of its manufacturing processes if a third party fails to perform its contractual obligations. AbbVie also maintains sufficient inventory of product to minimize the impact of any supply disruption.

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

### Sources and Availability of Raw Materials

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

### Research and Development Activities

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

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

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

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

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

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

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

launch a new drug or indication.

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In addition to the development of new products and new formulations, research and development projects also may include Phase 4 trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug.

**Regulation—Discovery and Clinical Development**

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

Even if an NDA or a BLA receives approval, the applicant must comply with post-approval requirements. For example, holders of an approval must report adverse reactions, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional materials and activities. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and certain changes to the manufacturing procedures and finished product must be included in the NDA or BLA and approved by the FDA prior to implementation. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and record keeping requirements. In addition, as a condition of approval, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety or efficacy after commercialization, which may require additional clinical trials, patient registries, observational data or additional work on chemistry, manufacturing and controls. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future.

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

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

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

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

**Regulation—Commercialization, Distribution and Manufacturing**

The manufacture, marketing, sale, promotion and distribution of AbbVie's products are subject to comprehensive government regulation. Government regulation by various national, regional, federal, state and local agencies, both in the United States and other countries, addresses (among other matters) inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, labeling, packaging, marketing and promotion, pricing and reimbursement, sampling, distribution, quality control, post-marketing surveillance, record keeping, storage and disposal practices. AbbVie's operations are also affected by trade regulations in many countries that limit the import of raw

materials and finished products and by laws and regulations that seek to prevent corruption and bribery in the marketplace (including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act, which provide guidance on corporate interactions with government officials) and require safeguards for the protection of personal data. In addition, AbbVie is subject to laws and regulations pertaining to health care fraud and abuse, including state and federal anti-kickback and false claims laws in the United States. Prescription drug manufacturers such as AbbVie are also subject to taxes, as well as application, product, user 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 oversight, 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 payers 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. Political and budgetary pressures in the United States and in other countries may also heighten the scope and severity of pricing pressures on AbbVie's products for the foreseeable future.

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

In the United States, most states also have generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed. In addition, the federal government follows a diagnosis-related group (DRG) payment system for certain institutional services provided under Medicare or Medicaid and has implemented a prospective payment system (PPS) for services delivered in hospital outpatient, nursing home and home health settings. DRG and PPS entitle a health care facility to a fixed reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many health care products. Medicare reimburses Part B drugs based on average sales price plus a certain percentage to account for physician administration costs, which have been reduced in the hospital outpatient setting. Medicare enters into contracts with private plans to negotiate prices for most patient-administered medicine delivered under Part D.

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

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs and biologics covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of

countries worldwide either have adopted or are considering similar laws requiring disclosure of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties. AbbVie expects debate to continue during 2019 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.

**European Union.** The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the European Union and permits member states to supplement these standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent to launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical products. Differences between national pricing regimes create price differentials within the European Union that can lead to significant parallel trade in pharmaceutical products. Most governments also promote generic substitution by mandating or permitting a pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed and by permitting or mandating that health care professionals prescribe generic versions in certain circumstances. Many governments are also following a similar path for biosimilar therapies. 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/biosimilar alternatives to branded pharmaceuticals.

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

#### Environmental Matters

AbbVie believes that its operations comply in all material respects with applicable laws and regulations concerning environmental protection. Regulations under federal and state environmental laws impose stringent limitations on emissions and discharges to the environment from various manufacturing operations. AbbVie's capital expenditures for pollution control in 2018 were approximately \$20 million and operating expenditures were approximately \$31 million. In 2019, capital expenditures for pollution control are estimated to be approximately \$26 million and operating expenditures are estimated to be approximately \$33 million.

Abbott was identified as one of many potentially responsible parties in investigations and/or remediations at several locations in the United States, including Puerto Rico, under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. Some of these locations were transferred to AbbVie in connection with the separation and distribution, and AbbVie has become a party to these investigations and remediations. Abbott was also engaged in remediation at several other sites, some of which have been transferred to

AbbVie in connection with the separation and distribution, in cooperation with the Environmental Protection Agency or similar agencies. While it is not feasible to predict with certainty the final costs related to those investigations and remediation activities, AbbVie believes that such costs, together with other expenditures to maintain compliance with applicable laws and regulations concerning environmental protection, should not have a material adverse effect on the company's financial position, cash flows, or results of operations.

## Employees

AbbVie employed approximately 30,000 persons as of January 31, 2019. Outside the United States, some of AbbVie's employees are represented by unions or works councils. AbbVie believes that it has good relations with its employees.

## Internet Information

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

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

## ITEM 1A. RISK FACTORS

You should carefully consider the following risks and other information in this Form 10-K in evaluating AbbVie and AbbVie's common stock. Any of the following risks could materially and adversely affect AbbVie's results of operations, financial condition or cash flows. The risk factors generally have been separated into two groups: risks related to AbbVie's business and risks related to AbbVie's common stock. Based on the information currently known to it, AbbVie believes that the following information identifies the most significant risk factors affecting it in each of these categories of risks. However, the risks and uncertainties AbbVie faces are not limited to those set forth in the risk factors described below and may not be in order of importance or probability of occurrence. Additional risks and uncertainties not presently known to AbbVie or that AbbVie currently believes to be immaterial may also adversely affect its business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods.

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

### Risks Related to AbbVie's Business

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

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

As patents for certain of its products expire, AbbVie will or could face competition from lower priced generic or biosimilar 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, biosimilars 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 or biosimilars. Any such proposals that are enacted into law could increase the impact of generic competition.

AbbVie's principal patents and trademarks are described in greater detail in Item 1, "Business—Intellectual Property Protection and Regulatory Exclusivity" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations," and litigation regarding these patents is described in Item 3, "Legal Proceedings." The United States composition of matter patent for HUMIRA, which is AbbVie's largest product and had worldwide net revenues of approximately \$19.9 billion in 2018, expired in December 2016, and the equivalent European Union patent expired in the majority of European Union countries in October 2018.





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

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

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

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

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

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

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

HUMIRA accounted for approximately 61% of AbbVie's total net revenues in 2018. Any significant event that adversely affects HUMIRA's revenues could have a material adverse impact on AbbVie's results of operations and cash flows. These events could include loss of patent protection for HUMIRA, the commercialization of biosimilars of HUMIRA, the discovery of previously unknown side effects or impaired efficacy, increased competition from the introduction of new, more effective or less expensive treatments and discontinuation or removal from the market of HUMIRA for any reason.

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

To remain competitive, AbbVie must continue to launch new products and new indications and/or brand extensions for existing products, and such launches must generate revenue sufficient both to cover its substantial research and development costs and to replace revenues of profitable products that are lost to or displaced by competing products

or therapies. Failure to do so would have a material adverse effect on AbbVie's revenue and profitability. Accordingly, AbbVie commits substantial effort, funds, and other resources to research and development and must make ongoing substantial expenditures without any assurance that its efforts will be commercially successful. A high rate of failure in the biopharmaceutical industry is inherent in the research and development of new products, and failure can occur at any point in the research and development process, including after significant funds have been invested. Products that appear promising in development may fail to reach the market for numerous reasons, including failure to demonstrate effectiveness, safety concerns, superior safety or efficacy of

competing therapies, failure to achieve positive clinical or pre-clinical outcomes beyond the current standards of care, inability to obtain necessary regulatory approvals or delays in the approval of new products and new indications, limited scope of approved uses, excessive costs to manufacture, the failure to obtain or maintain intellectual property rights, or infringement of the intellectual property rights of others.

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act creates a framework for the approval of biosimilars in the United States and could allow competitors to reference data from biologic products already approved. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies are

developing biosimilars in other countries that could and do compete with AbbVie's biologic products, including HUMIRA. As competitors obtain marketing approval for biosimilars referencing AbbVie's biologic products, AbbVie's products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of AbbVie's applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, AbbVie could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to its biologic products.

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

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

The manufacture of many of AbbVie's products is a highly exacting and complex process, and if AbbVie or one of its suppliers encounters problems manufacturing AbbVie's products, AbbVie's business could suffer.

The manufacture of many of AbbVie's products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for AbbVie's products, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and AbbVie may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

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

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

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Investigators may also conduct additional, and perhaps more extensive, studies. If new safety or efficacy issues are reported or if new scientific information becomes available (including results of post-marketing Phase 4 trials), or if governments change standards regarding safety, efficacy or labeling, AbbVie may be required to amend the conditions of use for a product. For example, AbbVie may voluntarily provide or be required to provide updated information on a

product's label or narrow its approved indication, either of which could reduce the product's market acceptance. If safety or efficacy issues with an AbbVie product arise, sales of the product could be halted by AbbVie or by regulatory authorities. Safety or efficacy issues affecting suppliers' or competitors' products also may reduce the market acceptance of AbbVie's products.

New data about AbbVie's products, or products similar to its products, could negatively impact demand for AbbVie's products due to real or perceived safety issues or uncertainty regarding efficacy and, in some cases, could result in product

withdrawal. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of AbbVie's products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of AbbVie's products.

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

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

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

Cost-containment efforts by governments and private organizations are described in greater detail in Item 1, "Business—Regulation—Commercialization, Distribution and Manufacturing." To the extent these cost containment efforts are not offset by greater demand, increased patient access to health care, or other factors, AbbVie's future revenues and operating earnings will be reduced. In the United States, the European Union and other countries, AbbVie's business has experienced downward pressure on product pricing, and this pressure could increase in the future.

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

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

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

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

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

In addition, AbbVie cannot guarantee that it will remain compliant with applicable regulatory requirements once approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling and advertising and post-marketing reporting, including adverse event reports and



field alerts due to manufacturing quality concerns. AbbVie must incur expense and spend time and effort to ensure compliance with these complex regulations.

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

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

The health care industry is subject to various federal, state and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.

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

AbbVie's business is subject to risks associated with doing business internationally, including in emerging markets. Net revenues outside of the United States make up approximately 34% of AbbVie's total net revenues in 2018. The risks associated with AbbVie's operations outside the United States include:

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

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



If AbbVie does not effectively and profitably commercialize its products, AbbVie's revenues and financial condition could be adversely affected.

AbbVie must effectively and profitably commercialize its principal products by creating and meeting continued market demand; achieving market acceptance and generating product sales; ensuring that the active pharmaceutical ingredient(s) for a product and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with acceptable quality and pricing to meet commercial demand; and ensuring that the entire supply chain efficiently and consistently delivers AbbVie's products to its customers. The commercialization of AbbVie products may not be successful due to, among other things, unexpected challenges from competitors, new safety issues or concerns being reported that may impact or narrow approved indications, the relative price of AbbVie's product as compared to alternative treatment options and changes to a product's label that further restrict its marketing. If the commercialization of AbbVie's principal products is unsuccessful, AbbVie's ability to generate revenue from product sales will be adversely affected.

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

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

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

In 2018, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation) accounted for substantially all of AbbVie's sales in the United States. If one of its significant wholesale distributors encounters financial or other difficulties, such distributor may decrease the amount of business that it does with AbbVie, and AbbVie may be unable to collect all the amounts that the distributor owes it on a timely basis or at all, which could negatively impact AbbVie's business and results of operations.

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

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

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

AbbVie may need to seek additional financing for its general corporate purposes. For example, it may need to increase its investment in research and development activities or need funds to make acquisitions. AbbVie may be unable to obtain any desired additional financing on terms favorable to it, if at all. If AbbVie loses its investment grade credit rating or adequate

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

AbbVie depends on information technology and a failure of those systems could adversely affect AbbVie's business. AbbVie relies on sophisticated software applications and complex information technology systems to operate its business. These systems are potentially vulnerable to malicious intrusion, random attack, loss of data privacy, disruption, degradation or breakdown. Data privacy or security breaches by employees or others may result in the failure of critical business operations or may cause sensitive data, including intellectual property, trade secrets or personal information belonging to AbbVie, its patients, customers or business partners, to be exposed to unauthorized persons or to the public. Although AbbVie has invested in the protection of its data and information technology and also monitors its systems on an ongoing basis, there can be no assurance that these efforts will prevent breakdowns or breaches in AbbVie's information technology systems that could adversely affect AbbVie's business. Such adverse consequences could include loss of revenue, or the loss of critical or sensitive information from AbbVie's or third-party providers' databases or IT systems and could also result in legal, financial, reputational or business harm to AbbVie and potentially substantial remediation costs.

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

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

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

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

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

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



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

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

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

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

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

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

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

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





CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

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

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\*Leased property.

In addition to the above, AbbVie has other manufacturing facilities worldwide. AbbVie believes its facilities are suitable and provide adequate production capacity. There are no material encumbrances on AbbVie's owned properties.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## EXECUTIVE OFFICERS OF THE REGISTRANT

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

Name	Age	Position
Richard A. Gonzalez	65	Chairman of the Board and Chief Executive Officer
Carlos Alban	56	Vice Chairman, Chief Commercial Officer
Laura J. Schumacher	55	Vice Chairman, External Affairs and Chief Legal Officer
Michael E. Severino, M.D.*	53	Vice Chairman and President
William J. Chase	51	Executive Vice President, Finance and Administration
Henry O. Gosebruch*	46	Executive Vice President and Chief Strategy Officer
Timothy J. Richmond	52	Executive Vice President, Chief Human Resources Officer
Azita Saleki-Gerhardt, Ph.D.	55	Executive Vice President, Operations
Nicholas Donoghoe, M.D.*	38	Senior Vice President, Enterprise Innovation
Robert A. Michael*	48	Senior Vice President, Chief Financial Officer
Jeffrey R. Stewart*	50	Senior Vice President, U.S. Commercial Operations
Brian L. Durkin*	58	Vice President, Controller

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Dr. Severino was first appointed as a corporate officer in June 2014; Mr. Gosebruch was first appointed as a corporate officer in December 2015; Dr. Donoghoe was first appointed as a corporate officer in January 2019; Mr. \*Michael was first appointed as a corporate officer in December 2015; Mr. Stewart was first appointed as a corporate officer in December 2018; and Mr. Durkin was first appointed as a corporate officer in October 2018.

Mr. Gonzalez is the Chairman and Chief Executive Officer of AbbVie. He served as Abbott's Executive Vice President of the Pharmaceutical Products Group from July 2010 to December 2012, and was responsible for Abbott's worldwide pharmaceutical business, including commercial operations, research and development, and manufacturing. He 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.

Mr. Alban is AbbVie's Vice Chairman, Chief Commercial Officer, responsible for global commercial operations of the company, including the Pharmacocyclics commercial functions. He previously served as Executive Vice President, Commercial Operations from 2013 to 2018. He served as Abbott's Senior Vice President, Proprietary Pharmaceutical Products, Global Commercial Operations from 2011 to 2012, as Senior Vice President, International Pharmaceuticals from 2009 to 2011, as Vice President, Western Europe and Canada from 2007 to 2009, and as Vice President, European Operations from 2006 to 2007. Mr. Alban joined Abbott in 1986.

Ms. Schumacher is AbbVie's Vice Chairman, External Affairs and Chief Legal Officer, responsible for legal, ethics and compliance, corporate governance, corporate aviation, and all externally-facing functions including health economics outcomes research, government affairs, corporate responsibility, brand and communications. Prior to her current appointment in 2018, she served as AbbVie's Executive Vice President, External Affairs, General Counsel and Corporate Secretary. Prior to AbbVie's separation from Abbott, Ms. Schumacher served as Executive Vice President, General Counsel and Corporate Secretary from 2007 to 2012. Both at Abbott and AbbVie, Ms. Schumacher also led Licensing and Acquisition and Ventures and Early Stage Collaborations. At Abbott, Ms. Schumacher was also responsible for its Office of Ethics and Compliance. Ms. Schumacher joined Abbott in 1990. She serves on the board of General Dynamics Corporation.

Dr. Severino is AbbVie's Vice Chairman and President, responsible for research and development, human resources, operations, and the corporate strategy office. He served as Executive Vice President, Research and Development and Chief Scientific Officer from 2014 to 2018. Dr. Severino served at Amgen Inc. as Senior Vice President, Global Development and Corporate Chief Medical Officer from 2012 to 2014, as Vice President, Global Development from 2010 to 2012 and as Vice President, Therapeutic Area Head, General Medicine and Inflammation Global Clinical

Development from 2007 to 2012. He joined AbbVie in 2014.

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Mr. Chase is AbbVie's Executive Vice President, Finance and Administration, responsible for all financial and administrative functions of the company. He previously served as Executive Vice President, Chief Financial Officer from 2013 to 2018. He served as Abbott's Vice President, Licensing and Acquisitions from 2010 to 2012, as Vice President, Treasurer from 2007 to 2010, and as Divisional Vice President, Controller of Abbott International from 2004 to 2007. Mr. Chase joined Abbott in 1989.

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

Mr. Richmond is AbbVie's Executive Vice President, Chief Human Resources Officer. He served as Senior Vice President, Human Resources from 2013 to 2018. Mr. Richmond 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 Executive Vice President, Operations. She served as Senior Vice President, Operations from 2013 to 2018. Dr. Saleki-Gerhardt 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. She serves on the board of Entegris Inc.

Dr. Donoghoe is AbbVie's Senior Vice President, Enterprise Innovation. He previously served as a Partner at McKinsey & Company, leading the firm's West Coast pharma and biotechnology practice. Dr. Donoghoe joined the firm in 2007 and supported multiple successful launches in therapeutic areas such as oncology, immunology, and primary care. He joined AbbVie in 2019.

Mr. Michael is AbbVie's Senior Vice President, Chief Financial Officer. Mr. Michael previously served as Vice President, Controller from March 2017 to October 2018. He became an AbbVie officer in 2015 and served as AbbVie's Vice President, Treasurer from 2015 to 2016, as Vice President, Controller, Commercial Operations from 2013 to 2015 and Vice President, Financial Planning and Analysis from 2012 to 2013. At Abbott, Mr. Michael served as Division Controller, Nutrition Supply Chain from 2010 to 2012. Mr. Michael joined Abbott in 1993.

Mr. Stewart is AbbVie's Senior Vice President, U.S. Commercial Operations. Mr. Stewart previously served as AbbVie's President, Commercial Operations from 2013 to 2018. Prior to AbbVie's separation from Abbott, he served as Vice President, Abbott Proprietary Pharmaceutical Division, United States. Mr. Stewart joined Abbott in 1992.

Mr. Durkin is AbbVie's Vice President, Controller. Mr. Durkin previously served as Vice President, Internal Audit from 2016 to 2018. Prior to joining AbbVie, he served as Vice President of Finance and Division Controller for Abbott's Vision Care business from 2009 to 2016 and Controller Pharmaceutical Research and Development from 2005 to 2009. Mr. Durkin joined Abbott in 1986.

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

PART II

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

Principal Market

The principal market for AbbVie's common stock is the New York Stock Exchange (Symbol: ABBV). AbbVie's common stock is also listed on the Chicago Stock Exchange and traded on various regional and electronic exchanges.

Stockholders

There were 48,516 stockholders of record of AbbVie common stock as of January 31, 2019.

Dividends

On November 2, 2018, AbbVie's board of directors declared an increase in the quarterly cash dividend from \$0.96 per share to \$1.07 per share, payable on February 15, 2019 to stockholders of record as of January 15, 2019. The timing, declaration, amount of and payment of any dividends by AbbVie in the future is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by its board of directors. Moreover, if AbbVie determines to pay any dividend in the future, there can be no assurance that it will continue to pay such dividends or the amount of such dividends.

Performance Graph

The following graph compares the cumulative total returns of AbbVie, the S&P 500 Index and the NYSE Arca Pharmaceuticals Index for the period from December 31, 2013 through December 31, 2018. This graph assumes \$100 was invested in AbbVie common stock and each index on December 31, 2013 and also assumes the reinvestment of dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2018 - October 31, 2018	4,246	<sup>(1)</sup> \$ 88.24	<sup>(1)</sup> —	\$1,500,000,050
November 1, 2018 - November 30, 2018	17,119,956 <sup>(1)</sup>	\$ 87.62	<sup>(1)</sup> 17,118,625	\$8,924
December 1, 2018 - December 31, 2018	8,546,698	<sup>(1)</sup> \$ 87.89	<sup>(1)</sup> 8,533,255	\$4,250,016,122 <sup>(2)</sup>
Total	25,670,900 <sup>(1)</sup>	\$ 87.71	<sup>(1)</sup> 25,651,880	\$4,250,016,122 <sup>(2)</sup>

In addition to AbbVie shares repurchased on the open market under a publicly announced program, if any, these 1. shares also included the shares purchased on the open market for the benefit of participants in the AbbVie Employee Stock Purchase Plan – 4,246 in October; 1,331 in November; and 13,443 in December.

These shares do not include the shares surrendered to AbbVie to satisfy minimum tax withholding obligations in connection with the vesting or exercise of stock-based awards.

On December 13, 2018, AbbVie's board of directors authorized a \$5.0 billion increase to the existing stock repurchase program. The company's stock repurchase authorization permits purchases of AbbVie shares from time 2. to time in open-market or private transactions at management's discretion. The program has no time limit and can be discontinued at any time.

## ITEM 6. SELECTED FINANCIAL DATA

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

as of and for the years ended December 31 (in millions, except per share data)	2018	2017	2016	2015	2014
Statement of earnings data					
Net revenues	\$32,753	\$28,216	\$25,638	\$22,859	\$19,960
Net earnings	5,687	5,309	5,953	5,144	1,774
Basic earnings per share	\$3.67	\$3.31	\$3.65	\$3.15	\$1.11
Diluted earnings per share	\$3.66	\$3.30	\$3.63	\$3.13	\$1.10
Cash dividends declared per common share	\$3.95	\$2.63	\$2.35	\$2.10	\$1.75
Weighted-average basic shares outstanding	1,541	1,596	1,622	1,625	1,595
Weighted-average diluted shares outstanding	1,546	1,603	1,631	1,637	1,610
Balance sheet data					
Total assets <sup>(a)(b)</sup>	\$59,352	\$70,786	\$66,099	\$53,050	\$27,513
Long-term debt and lease obligations <sup>(a)(b)(c)</sup>	36,611	36,968	36,465	31,265	14,552

In May 2015, AbbVie acquired Pharmacyclics for approximately \$20.8 billion, including cash consideration of \$12.4 billion and equity consideration of approximately 128 million shares of AbbVie common stock valued at (a) \$8.4 billion. In connection with the acquisition, AbbVie issued \$16.7 billion aggregate principal amount of unsecured senior notes, of which approximately \$11.5 billion was used to finance the acquisition and approximately \$5.0 billion was used to finance an accelerated share repurchase (ASR) program.

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

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



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

The following is a discussion and analysis of the financial condition of AbbVie Inc. (AbbVie or the company) as of December 31, 2018 and 2017 and results of operations for each of the three years in the period ended December 31, 2018. This commentary should be read in conjunction with the consolidated financial statements and accompanying notes appearing in Item 8, "Financial Statements and Supplementary Data."

### EXECUTIVE OVERVIEW

#### Company Overview

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

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

#### 2018 Financial Results

AbbVie's strategy has focused on delivering strong financial results, advancing and investing in its pipeline and returning value to shareholders while ensuring a strong, sustainable growth business over the long term. The company's financial performance in 2018 included delivering worldwide net revenues of \$32.8 billion, operating earnings of \$6.4 billion, diluted earnings per share of \$3.66 and cash flows from operations of \$13.4 billion.

Worldwide net revenues grew by 16%, or 15% on a constant currency basis, driven primarily by revenue growth related to MAVYRET, IMBRUVICA and VENCLEXTA, and the continued strength of HUMIRA.

Diluted earnings per share in 2018 was \$3.66 and included the following after-tax costs: (i) a Stemcentrx-related impairment charge of \$4.1 billion net of the related fair value adjustment to contingent consideration liabilities; (ii) \$1.1 billion of intangible asset amortization; (iii) \$500 million as a result of a collaboration agreement extension with Calico Life Sciences LLC (Calico); (iv) \$424 million for acquired in-process research and development (IPR&D); (v) \$478 million for the change in fair value of contingent consideration liabilities excluding the fair value adjustment associated with the Stemcentrx-related impairment; (vi) litigation reserve charges of \$282 million; (vii) charitable contributions of \$271 million as part of AbbVie's previously announced plan to make contributions to U.S. not-for-profit organizations in 2018; and (viii) milestone payments of \$137 million. 2018 financial results were also impacted by U.S. tax reform and the timing of the new legislation's phase in on certain subsidiaries. Additionally, financial results reflected continued added funding to support all stages of AbbVie's emerging pipeline assets and continued investment in AbbVie's growth brands.

In November 2018, AbbVie's board of directors declared a quarterly cash dividend of \$1.07 per share of common stock payable in February 2019. This reflected an increase of approximately 11.5% over the previous quarterly dividend of \$0.96 per share of common stock.



## 2019 Strategic Objectives

AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including: (i) growing revenues by diversifying revenue streams, driving late-stage pipeline assets to the market and ensuring strong commercial execution of new product launches; (ii) continued investment and expansion in its pipeline in support of opportunities in immunology, oncology and neuroscience, with additional targeted investment in cystic fibrosis and women's health as well as continued investment in key on-market products; (iii) expanding operating margins; and (iv) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in the next twelve months.

AbbVie expects to achieve its strategic objectives through:

• Hematologic oncology revenue growth from both IMBRUVICA and VENCLEXTA.

• The strong execution of new product launches across multiple therapeutic areas.

• HUMIRA U.S. sales growth by driving biologic penetration across disease categories and maintaining market leadership.

• Effective management of HUMIRA international biosimilar erosion.

The favorable impact of pipeline products and indications recently approved or currently under regulatory review where approval is expected in 2019. These products are described in greater detail in the section labeled "Research and Development" included as part of this Item 7.

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

### Research and Development

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

AbbVie's pipeline currently includes more than 60 compounds or indications in clinical development individually or under collaboration or license agreements and is focused on such important medical specialties as immunology, oncology and neuroscience along with targeted investments in cystic fibrosis and women's health. Of these programs, more than 30 are in mid- and late-stage development.

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

### Significant Programs and Developments

#### Immunology

##### Upadacitinib

In January 2018, the U.S. Food and Drug Administration (FDA) granted breakthrough therapy designation for upadacitinib, an investigational oral JAK1-selective inhibitor, in adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy.

In April 2018, AbbVie announced that top-line results from the Phase 3 SELECT-COMPARE clinical trial evaluating upadacitinib met all primary and ranked secondary endpoints in patients with moderate to severe rheumatoid arthritis (RA) who are on a stable background of methotrexate and who have an inadequate response. The safety profile of upadacitinib was consistent with previously reported clinical trials and no new safety signals were detected.



In June 2018, AbbVie announced that top-line results from the Phase 3 SELECT-EARLY clinical trial evaluating upadacitinib versus methotrexate in adult patients with moderate to severe RA who were methotrexate-naïve met all primary and ranked secondary endpoints. The safety profile of upadacitinib was consistent with previously reported clinical trials and no new safety signals were detected.

In July 2018, AbbVie initiated two Phase 3 clinical trials to evaluate the efficacy and safety of upadacitinib in subjects with moderate to severe atopic dermatitis.

In September 2018, AbbVie initiated a Phase 3 clinical trial to evaluate the efficacy and safety of upadacitinib in subjects with moderate to severe ulcerative colitis.

In December 2018, AbbVie submitted a New Drug Application (NDA) to the FDA and a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for upadacitinib for the treatment of adult patients with moderate to severe RA.

#### Risankizumab

In January 2018, AbbVie initiated two Phase 3 clinical trials to evaluate the efficacy and safety of risankizumab, an investigational interleukin-23 (IL-23) inhibitor, versus placebo during induction therapy in subjects with moderately to severely active Crohn's disease.

In February 2018, AbbVie announced that top-line results from two Phase 3 clinical trials evaluating risankizumab with 12-week dosing compared to ustekinumab met ranked additional secondary endpoints for the treatment of patients with moderate to severe chronic plaque psoriasis. The initial results from these clinical trials were previously announced in October 2017. The safety profile was consistent with all previously reported studies, and there were no new safety signals detected across the two studies.

In April 2018, AbbVie submitted a Biologics License Application (BLA) to the FDA and an MAA to the EMA for risankizumab for the treatment of plaque psoriasis in adults.

In May 2018, AbbVie initiated a Phase 2b/3 clinical trial to evaluate the efficacy and safety of risankizumab versus placebo in subjects with moderately to severely active ulcerative colitis.

#### Oncology

##### IMBRUVICA

In April 2018, AbbVie initiated a Phase 3 clinical trial to evaluate the safety and efficacy of IMBRUVICA in combination with VENCLEXTA versus chlorambucil plus GAZYVA (obinutuzumab) for the first-line treatment of subjects with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

In May 2018, AbbVie announced that results from the Phase 3 iLLUMINATE study evaluating IMBRUVICA in combination with GAZYVA in previously untreated CLL/SLL met its primary endpoint. In December 2018, AbbVie announced additional results from the Phase 3 iLLUMINATE study that demonstrated significantly prolonged progression-free survival (PFS).

In June 2018, AbbVie announced that results from an interim analysis of the Phase 3 iNOVATE study evaluating IMBRUVICA plus Rituxan (rituximab) in previously untreated and relapsed/refractory (R/R) patients with Waldenström's macroglobulinemia (WM) met its primary endpoint.

In July 2018, AbbVie announced that results from a Phase 3 study evaluating the addition of IMBRUVICA to a chemotherapy regimen consisting of five different agents used in combination did not meet its primary endpoint in a subset of untreated diffuse large B-cell lymphoma patients identified to have the non-germinal center B-cell or activated B-cell subtypes of this disease.

In August 2018, the FDA approved IMBRUVICA, in combination with Rituxan, for the treatment of adult patients with WM.

In December 2018, AbbVie announced that results from an interim analysis of the Phase 3 ECOG1912E study evaluating IMBRUVICA in combination with Rituxan versus the chemoimmunotherapy FCR (fludarabine, cyclophosphamide and rituximab) in previously untreated and younger CLL patients met its primary endpoint.

In January 2019, AbbVie announced an update on the Phase 3 RESOLVE study evaluating IMBRUVICA in combination with nab-paclitaxel and gemcitabine versus nab-paclitaxel and gemcitabine combination in patients



with metastatic pancreatic adenocarcinoma. Results showed the study did not meet its primary endpoint of improving PFS or overall survival (OS) benefit among the study population. Safety data collected from the study were consistent with the existing safety information for the study therapies.

In January 2019, the FDA approved IMBRUVICA, in combination with GAZYVA, for adult patients with previously untreated CLL/SLL.

#### VENCLEXTA

In January 2018, AbbVie submitted an sNDA to the FDA for VENCLEXTA monotherapy in patients with CLL who are refractory to or have relapsed B-cell receptor pathway inhibitors.

In June 2018, the FDA approved VENCLEXTA in combination with Rituxan for the treatment of patients with CLL/SLL, with or without 17p deletion, who have received at least one prior therapy. VENCLEXTA plus Rituxan is the first oral-based, chemotherapy-free combination in CLL that allows patients an option for fixed treatment duration.

In September 2018, the FDA expanded the label for VENCLEXTA in combination with Rituxan to include information about patients with previously-treated CLL who achieved minimal residual disease (MRD)-negativity in the Phase 3 MURANO trial.

In October 2018, the European Commission approved the type-II variation application for VENCLEXTA in combination with Rituxan for the treatment of patients with R/R CLL who have received at least one prior therapy. In November, AbbVie received notification from the European Commission that conditions of the original conditional marketing authorisation have been fulfilled, granting VENCLEXTA official receipt of approval.

In October 2018, AbbVie announced that the results from the Phase 3 CLL14 study comparing the efficacy and safety of VENCLEXTA plus obinutuzumab versus obinutuzumab plus chlorambucil in previously untreated patients with CLL and coexisting medical conditions met its primary endpoint.

In November 2018, the FDA granted accelerated approval for VENCLEXTA in combination with azacitidine, or decitabine, or low dose cytarabine (LDAC) for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. This indication is approved under accelerated approval based on response rates. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

#### Rova-T

In March 2018, AbbVie announced top-line results from the Phase 2 TRINITY study evaluating rovalpituzumab tesirine (Rova-T) for third-line R/R small cell lung cancer (SCLC). Although Rova-T demonstrated single agent responses in advanced SCLC patients, after consulting with the FDA, based on the magnitude of effect across multiple parameters in this single-arm study, the company will not seek accelerated approval for Rova-T in third-line R/R SCLC.

In December 2018, AbbVie announced the decision to stop enrollment for the TAHOE trial, a Phase 3 study evaluating Rova-T as a second-line therapy for advanced SCLC. An Independent Data Monitoring Committee recommended stopping enrollment in TAHOE due to shorter overall survival in the Rova-T arm compared with the topotecan control arm. AbbVie will continue its ongoing Phase 3 study of Rova-T in first-line SCLC.

#### Other

In November 2018, Bristol-Myers Squibb Company (BMS) announced that the FDA expanded the label for Empliciti in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies. BMS and AbbVie are co-developing Empliciti, with BMS solely responsible for commercial activities.

### Virology/Liver Disease

In November 2018, AbbVie presented EXPEDITION 8 data at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), in which 8 weeks of MAVYRET in treatment naïve, cirrhotic patients was safe and effective with no virologic failures reported.

### Neuroscience

In March 2018, Biogen and AbbVie announced the voluntary worldwide withdrawal of marketing authorizations for ZINBRYTA, a prescription medicine used to treat adults with relapsing forms of multiple sclerosis.

### Other

In February 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-I study evaluating elagolix, an investigational, orally administered gonadotropin-releasing hormone (GnRH) antagonist, being investigated in combination with low-dose hormone (add-back) therapy for uterine fibroids met its primary efficacy endpoint and all ranked secondary endpoints.

In March 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-II study evaluating elagolix in combination with low-dose hormone (add-back) therapy for uterine fibroids met its primary efficacy endpoint and all ranked secondary endpoints.

In July 2018, the FDA approved ORILISSA (elagolix) for the management of moderate to severe pain associated with endometriosis.

In August 2018, AbbVie announced that top-line results from the Phase 3 ELARIS UF-EXTEND study evaluating elagolix in combination with low-dose hormone (add-back) therapy for uterine fibroids were consistent with findings observed in the ELARIS UF-I and ELARIS UF-II Phase 3 studies.

In October 2018, AbbVie announced that it will assume full development and commercial responsibility for its collaboration with Galapagos to discover and develop new therapies to treat cystic fibrosis (CF). Under a revised agreement, AbbVie will assume full development and commercial responsibility over the investigational program comprising several clinical and pre-clinical compounds originally discovered and developed jointly by AbbVie and Galapagos. Galapagos will not pursue further research and development in CF, but is eligible for future milestones and royalties on commercialized programs.

## RESULTS OF OPERATIONS

### Net Revenues

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

	2018	2017	2016	Percent change			
				At actual currency rates		At constant currency rates	
for the years ended (dollars in millions)	2018	2017	2016	2018	2017	2018	2017
United States	\$21,524	\$18,251	\$15,947	17.9%	14.4%	17.9%	14.4%
International	11,229	9,965	9,691	12.8%	2.8%	10.4%	2.1%
Net revenues	\$32,753	\$28,216	\$25,638	16.1%	10.1%	15.2%	9.8%



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The following table details AbbVie's worldwide net revenues:

years ended December 31 (dollars in millions)				Percent change		At constant currency rates			
	2018	2017	2016	2018	2017	2018	2017		
Immunology									
HUMIRA									
United States	\$13,685	\$12,361	\$10,432	10.7	% 18.5	% 10.7	% 18.5	%	
International	6,251	6,066	5,646	3.1	% 7.4	% 0.6	% 6.7	%	
Total	\$19,936	\$18,427	\$16,078	8.2	% 14.6	% 7.4	% 14.4	%	
Hematologic Oncology									
IMBRUVICA									
United States	\$2,968	\$2,144	\$1,580	38.4	% 35.8	% 38.4	% 35.8	%	
Collaboration revenues	622	429	252	45.0	% 70.0	% 45.0	% 70.0	%	
Total	\$3,590	\$2,573	\$1,832	39.5	% 40.5	% 39.5	% 40.5	%	
VENCLEXTA									
United States	\$247	\$89	\$17	>100.0%	>100.0%	>100.0%	>100.0%		
International	97	33	1	>100.0%	>100.0%	>100.0%	>100.0%		
Total	\$344	\$122	\$18	>100.0%	>100.0%	>100.0%	>100.0%		
HCV									
MAVYRET									
United States	\$1,614	\$277	\$—	>100.0%	n/m	>100.0%	n/m		
International	1,824	213	—	>100.0%	n/m	>100.0%	n/m		
Total	\$3,438	\$490	\$—	>100.0%	n/m	>100.0%	n/m		
VIEKIRA									
United States	\$3	\$61	\$342	(96.7)	)% (82.8)	)% (96.7)	)% (82.8)	)%	
International	175	723	1,180	(75.6)	)% (38.7)	)% (74.8)	)% (38.6)	)%	
Total	\$178	\$784	\$1,522	(77.2)	)% (48.6)	)% (76.5)	)% (48.5)	)%	
Other Key Products									
Creon									
United States	\$928	\$831	\$730	11.7	% 13.9	% 11.7	% 13.9	%	
Lupron									
United States	\$726	\$669	\$663	8.6	% 0.8	% 8.6	% 0.8	%	
International	166	160	158	3.4	% 1.4	% 4.7	% 0.5	%	
Total	\$892	\$829	\$821	7.6	% 0.9	% 7.9	% 0.7	%	
Synthroid									
United States	\$776	\$781	\$763	(0.6)	)% 2.3	% (0.6)	)% 2.3	%	
Synagis									
International	\$726	\$738	\$730	(1.6)	)% 1.2	% (2.8)	)% 0.6	%	
AndroGel									
United States	\$469	\$577	\$675	(18.8)	)% (14.5)	)% (18.8)	)% (14.5)	)%	
Duodopa									
United States	\$80	\$61	\$37	31.4	% 66.1	% 31.4	% 66.1	%	
International	350	294	256	19.1	% 14.6	% 14.8	% 13.1	%	
Total	\$430	\$355	\$293	21.2	% 21.1	% 17.7	% 19.8	%	
Sevoflurane									
United States	\$74	\$78	\$80	(6.2)	)% (2.1)	)% (6.2)	)% (2.1)	)%	

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International	317	332	348	(4.4	)%	(4.6	)%	(4.3	)%	(3.7	)%
Total	\$391	\$410	\$428	(4.7	)%	(4.1	)%	(4.6	)%	(3.4	)%
Kaletra											
United States	\$55	\$71	\$116	(22.1	)%	(38.6	)%	(22.1	)%	(38.6	)%
International	281	352	433	(20.2	)%	(18.8	)%	(20.1	)%	(21.1	)%
Total	\$336	\$423	\$549	(20.5	)%	(22.9	)%	(20.4	)%	(24.7	)%
All other	\$319	\$876	\$1,199	(63.6	)%	(26.9	)%	(71.9	)%	(27.9	)%
Total net revenues	\$32,753	\$28,216	\$25,638	16.1	%	10.1	%	15.2	%	9.8	%

n/m – Not meaningful

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The following discussion and analysis of AbbVie's net revenues by product is presented on a constant currency basis. Global HUMIRA sales increased 7% in 2018 and 14% in 2017. The sales increases in 2018 and 2017 were driven primarily by market growth across therapeutic categories and geographies as well as favorable pricing in certain geographies. In the United States, HUMIRA sales increased 11% in 2018 and 18% in 2017. The sales increase in 2018 and 2017 was driven by market growth across all indications and favorable pricing. Internationally, HUMIRA revenues increased 1% in 2018 and 7% in 2017. The sales increase in 2018 was driven primarily by market growth across indications partially offset by direct biosimilar competition in Europe following the expiration of the European Union composition of matter patent for adalimumab in October 2018. Due to the entry of biosimilar competition, AbbVie expects international HUMIRA net revenues to decline in 2019. Biosimilar competition for HUMIRA is not expected in the United States until 2023. AbbVie continues to pursue strategies intended to further differentiate HUMIRA from competing products and add to the sustainability of HUMIRA.

Net revenues for IMBRUVICA represent product revenues in the United States and collaboration revenues outside of the United States related to AbbVie's 50% share of IMBRUVICA profit. AbbVie's global IMBRUVICA revenues increased 39% in 2018 and 40% in 2017 as a result of continued penetration of IMBRUVICA as a first-line treatment for patients with CLL as well as favorable pricing.

Net revenues for VENCLEXTA increased by more than 100% in 2018 primarily due to market share gains following FDA and EMA approvals of VENCLEXTA in combination with Rituxan for certain patients with R/R CLL.

Global MAVYRET sales increased by more than 100% in 2018 as a result of market share gains following the FDA and EMA approvals of MAVYRET in the second half of 2017 as well as further geographic expansion in 2018.

Global VIEKIRA sales decreased by 76% in 2018 and 49% in 2017 primarily due to lower market share following the launch of MAVYRET.

Net revenues for Creon increased 12% in 2018 and 14% in 2017, driven primarily by continued market growth, higher market share and favorable pricing. Creon maintains market leadership in the pancreatic enzyme market.

AndroGel net revenues decreased 19% in 2018 and 14% in 2017 primarily due to market contraction and the entry of generic competition for the AndroGel 1.62% formulation in October 2018. AbbVie expects net revenues for AndroGel to continue to decline in 2019.

Net revenues for Duodopa increased 18% in 2018 and 20% in 2017, primarily as a result of market penetration.

#### Gross Margin

	2018	2017	2016	Percent change 2018 2017
years ended December 31 (dollars in millions)				
Gross margin	\$25,035	\$21,174	\$19,806	18% 7%
as a percent of net revenues	76	% 75	% 77	%

Gross margin as a percentage of net revenues in 2018 increased from 2017 primarily due to the reduction of HUMIRA royalty expense and a 2017 intangible asset impairment charge of \$354 million partially offset by the IMBRUVICA profit sharing arrangement.

Gross margin as a percentage of net revenues in 2017 decreased from 2016 primarily due to an intangible asset impairment charge of \$354 million in 2017, as well as the unfavorable impacts of higher intangible asset amortization and the IMBRUVICA profit sharing arrangement. These drivers were partially offset by lower amortization of the fair market value step-up of acquisition-date inventory of Pharmacyclics as well as favorable changes in product mix and operational efficiencies.

#### Selling, General and Administrative

	2018	2017	2016	Percent change 2018 2017
years ended December 31 (dollars in millions)				
Selling, general and administrative	\$7,399	\$6,295	\$5,881	18% 7%
as a percent of net revenues	23	% 22	% 23	%

Selling, general and administrative (SG&A) expenses as a percentage of net revenues in 2018 increased from 2017 primarily due to the unfavorable impacts of new product launch expenses and charitable contributions of \$350 million

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select U.S. not-for-profit organizations in 2018 as part of AbbVie's previously announced plan partially offset by continued leverage from revenue growth.

SG&A expense percentage in 2017 decreased from 2016. SG&A expense percentage in 2017 was favorably impacted by continued leverage from revenue growth partially offset by litigation reserves charges that increased by \$370 million in 2017 compared to the prior year and new product launch expenses.

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

years ended December 31 (dollars in millions)				Percent change	
	2018	2017	2016	2018	2017
Research and development	\$10,329	\$5,007	\$4,385	>100%	14 %
as a percent of net revenues	32	% 18	% 17	%	
Acquired in-process research and development	\$424	\$327	\$200	30	% 64 %

Research and Development (R&D) expenses in 2018 increased from 2017 principally due to a \$5.1 billion intangible asset impairment charge related to IPR&D acquired as part of the 2016 Stemcentrx acquisition following the decision to stop enrollment in the TAHOE trial. The impairment was primarily due to lower probabilities of success of achieving regulatory approval across Rova-T and other early-stage assets obtained in the acquisition. The remaining increase reflected greater funding to support all stages of the company's pipeline assets. See Note 7 to the Consolidated Financial Statements for additional information regarding the impairment charge.

R&D expenses in 2017 increased from 2016 principally due to increased funding to support all stages of the company's pipeline assets, the impact of the post-acquisition R&D expenses of Stemcentrx and Boehringer Ingelheim (BI) compounds and an increase in development milestones of \$63 million. These factors were partially offset by a decrease in acquisition related costs of \$135 million.

Acquired IPR&D expenses reflect upfront payments related to various collaborations. There were no individually significant transactions or cash flows during 2018. Acquired IPR&D expense in 2017 included a charge of \$205 million as a result of entering into a global strategic collaboration with Alector, Inc. (Alector) to develop and commercialize medicines to treat Alzheimer's disease and other neurodegenerative disorders. There were no individually significant transactions or cash flows during 2016. See Note 5 to the Consolidated Financial Statements for additional information regarding the Alector agreement.

#### Other Operating Expenses

Other operating expenses in 2018 included a \$500 million charge related to the extension of the previously announced Calico collaboration to discover, develop and bring to market new therapies for patients with age-related diseases, including neurodegeneration and cancer.

#### Other Non-Operating Expenses

years ended December 31 (in millions)	2018	2017	2016
Interest expense	\$1,348	\$1,150	\$1,047
Interest income	(204 )	(146 )	(82 )
Interest expense, net	\$1,144	\$1,004	\$965

Net foreign exchange loss	\$24	\$348	\$303
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Other expense, net	18	466	188
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Interest expense in 2018 increased compared to 2017 primarily due to the unfavorable impact of higher interest rates on the company's debt obligations and a higher average outstanding debt balance during 2018. Interest expense in 2017 increased compared to 2016 due to a full year of expense associated with the May 2016 issuance of \$7.8 billion aggregate principal amount of senior notes which were issued primarily to finance the acquisition of Stemcentrx and to repay an outstanding term loan.

Interest income in 2018 increased compared to 2017 primarily due to higher interest rates. Interest income in 2017 increased compared to 2016 primarily due to growth in the company's investment securities.



Net foreign exchange loss in 2017 included \$316 million of historical currency translation losses that were reclassified from accumulated other comprehensive income (AOCI) related to the liquidation of certain foreign entities following the enactment of U.S. tax reform. Net foreign exchange loss in 2016 included losses totaling \$298 million related to the devaluation of AbbVie's net monetary assets denominated in the Venezuelan bolivar. See Note 10 to the Consolidated Financial Statements for additional information regarding the Venezuelan devaluation.

Other expense, net included charges related to the change in fair value of the BI and Stemcentrx contingent consideration liabilities of \$49 million in 2018, \$626 million in 2017 and \$228 million in 2016. The fair value of contingent consideration liabilities is impacted by the passage of time and multiple other inputs, including the probability of success of achieving regulatory/commercial milestones, discount rates, the estimated amount of future sales of the acquired products still in development and other market-based factors. In 2018, the BI contingent consideration liability increased due to the passage of time and higher estimated future sales partially offset by the effect of rising interest rates. The increase in the BI contingent consideration liability was primarily offset by a \$428 million decrease in the Stemcentrx contingent consideration liability recorded during the fourth quarter of 2018 due to a reduction in probabilities of success of achieving regulatory approval across Rova-T and other early-stage assets obtained in the acquisition. In 2017, the change in fair value represented mainly higher probabilities of success, the passage of time and declining interest rates. In 2016, the change in fair value represented mainly the passage of time, as increases to the BI contingent consideration liability due to higher probabilities of success were fully offset by the effects of rising interest rates and changes in other market-based assumptions. See Note 5 to the Consolidated Financial Statements for additional information regarding the acquisitions of Stemcentrx and BI compounds. Other expense, net for 2017 also included realized gains on available-for-sale investment securities of \$90 million.

#### Income Tax Expense

The effective income tax rate was negative 9% in 2018, was 31% in 2017 and was 24% in 2016. The effective tax rate in each period differed from the statutory tax rate principally due to the allocation of the company's taxable earnings among jurisdictions, the benefit from foreign operations which reflects the impact of lower income tax rates in locations outside the United States, tax incentives in Puerto Rico and other foreign tax jurisdictions, and business development activities. The effective tax rate for 2018 reflects the impact of the effective date of provisions of the Tax Cuts and Jobs Act (the Act) related to the earnings from certain foreign subsidiaries and the effects of Stemcentrx intangible impairment related expenses. Given these factors, the effective income tax rate may change significantly in future periods.

The effective tax rate in 2017 included tax expense of \$4.5 billion on the one-time mandatory repatriation of previously untaxed earnings of foreign subsidiaries, partially offset by a \$3.6 billion net tax benefit for the remeasurement of deferred taxes related to the Act and foreign tax law changes.

The Act significantly changed the U.S. corporate tax system. The Act reduced the U.S. federal corporate tax rate from 35% to 21% and created a territorial tax system that included new taxes on certain foreign sourced earnings. See Note 13 to the Consolidated Financial Statements for additional information regarding the Act.

The effective tax rate in 2016 included additional expense of \$187 million related to the recognition of the tax effect of regulations issued by the Internal Revenue Service on December 7, 2016 that changed the determination of the U.S. taxability of foreign currency gains and losses related to certain foreign operations.

#### FINANCIAL POSITION, LIQUIDITY AND CAPITAL RESOURCES

years ended December 31 (in millions) 2018 2017 2016

Cash flows from:

Operating activities	\$13,427	\$9,960	\$7,041
Investing activities	(1,006 )	(274 )	(6,074 )
Financing activities	(14,396 )	(5,512 )	(3,928 )

Operating cash flows in 2018 increased from 2017 primarily due to improved results of operations from revenue growth and a decrease in income tax payments. Operating cash flows in 2017 increased from 2016 primarily due to improved results of operations resulting from revenue growth, an improvement in operating earnings and a decrease in income tax payments. Realized excess tax benefits associated with stock-based compensation totaled \$78 million in 2018 and \$71 million in 2017 and were presented within operating cash flows as a result of the adoption of a new

accounting pronouncement. Prior to the adoption of the new accounting pronouncement, realized excess benefits of \$55 million in 2016 were presented within cash flows from financing activities. Operating cash flows also reflected AbbVie's contributions to its defined benefit plans of \$873 million in 2018, \$246 million in 2017 and \$273 million in 2016.



Investing cash flows in 2018 included payments made for other acquisitions and investments of \$736 million and capital expenditures of \$638 million, partially offset by net sales and maturities of investment securities totaling \$368 million. Investing cash flows in 2017 included capital expenditures of \$529 million and payments made for other acquisitions and investments of \$308 million, partially offset by net sales and maturities of investment securities totaling \$563 million. Investing cash flows in 2016 primarily included \$1.9 billion of cash consideration paid to acquire Stemcentrx in June 2016, a \$595 million upfront payment to acquire certain rights from BI in April 2016, net purchases of investment securities totaling \$3.0 billion and capital expenditures of \$479 million.

In 2018, 2017 and 2016, the company issued and redeemed commercial paper. The balance of commercial paper outstanding was \$699 million as of December 31, 2018 and \$400 million as of December 31, 2017. AbbVie may issue additional commercial paper or retire commercial paper to meet liquidity requirements as needed.

Financing cash flows in 2018 also included proceeds from the issuance of a \$3.0 billion 364-day term loan credit agreement (term loan) entered into in May 2018. In June 2018, the company drew on this term loan and as of December 31, 2018, \$3.0 billion was outstanding and was included in short-term borrowings on the consolidated balance sheet. Borrowings under the term loan bear interest at one month LIBOR plus applicable margin. The term loan may be prepaid without penalty upon prior notice and contains customary covenants, all of which the company was in compliance with as of December 31, 2018. In September 2018, the company issued \$6.0 billion aggregate principal amount of unsecured senior notes. Of the \$5.9 billion net proceeds, \$2.0 billion was used to repay the company's outstanding three-year term loan credit agreement in September 2018 and \$1.0 billion was used to repay the aggregate principal amount of 2.00% senior notes at maturity in November 2018. The company intends to use the remaining proceeds to repay term loan obligations in 2019 as they become due. Financing cash flows in 2018 also included the May 2018 repayment of \$3.0 billion aggregate principal amount of the company's 1.80% senior notes at maturity.

In November 2016, the company issued €3.6 billion aggregate principal amount of unsecured senior Euro notes. The company used the proceeds to redeem \$4.0 billion aggregate principal amount of 1.75% senior notes that were due to mature in November 2017. In May 2016, the company issued \$7.8 billion aggregate principal amount of senior notes. Approximately \$2.0 billion of the net proceeds were used to repay an outstanding term loan that was due to mature in November 2016, approximately \$1.9 billion of the net proceeds were used to finance the acquisition of Stemcentrx and approximately \$3.8 billion of the net proceeds were used to finance an accelerated share repurchase (ASR). See Note 12 to the Consolidated Financial Statements for additional information on the 2016 ASR transaction.

Cash dividend payments totaled \$5.6 billion in 2018, \$4.1 billion in 2017 and \$3.7 billion in 2016. The increase in cash dividend payments was primarily driven by an increase in the dividend rate. On November 2, 2018, AbbVie announced that its board of directors declared an increase in the company's quarterly cash dividend from \$0.96 per share to \$1.07 per share beginning with the dividend payable on February 15, 2019 to stockholders of record as of January 15, 2019. This reflects an increase of approximately 11.5% over the previous quarterly rate. The timing, declaration, amount of and payment of any dividends by AbbVie in the future is within the discretion of its board of directors and will depend upon many factors, including AbbVie's financial condition, earnings, capital requirements of its operating subsidiaries, covenants associated with certain of AbbVie's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets and other factors deemed relevant by its board of directors.

On February 15, 2018, AbbVie's board of directors authorized a new \$10.0 billion stock repurchase program, which superseded AbbVie's previous stock repurchase program. On December 13, 2018, AbbVie's board of directors authorized a \$5.0 billion increase to the existing \$10.0 billion stock repurchase program. The new stock repurchase authorization permits purchases of AbbVie shares from time to time in open-market or private transactions at management's discretion. The program has no time limit and can be discontinued at any time. Under this authorization, AbbVie repurchased approximately 109 million shares for \$10.7 billion in 2018. AbbVie cash-settled \$201 million of its December 2018 open market purchases in January 2019. AbbVie's remaining stock repurchase authorization was \$4.3 billion as of December 31, 2018.

Under previous stock repurchase programs, AbbVie made open market share repurchases of approximately 11 million shares for \$1.3 billion in 2018, approximately 13 million shares for \$1.0 billion in 2017 and approximately 34 million

shares for \$2.1 billion in 2016. AbbVie cash-settled \$285 million of its December 2016 open market purchases in January 2017 and cash-settled \$300 million of its December 2015 open market purchases in January 2016. In 2018, AbbVie paid \$100 million of contingent consideration to BI related to BLA and MAA acceptance milestones. \$78 million of these payments were included in financing cash flows and \$22 million of the payments were included in operating cash flows. In 2017, AbbVie paid \$305 million of contingent consideration to BI related to a Phase 3 enrollment milestone. \$268 million of this milestone was included in financing cash flows and \$37 million was included in operating cash flows.

Cash and equivalents were impacted by net unfavorable exchange rate changes totaling \$39 million in 2018, net favorable exchange rate changes totaling \$29 million in 2017 and net unfavorable exchange rate changes totaling \$338 million in 2016. The unfavorable exchange rate changes in 2018 were primarily due to the weakening of the Euro and other foreign currencies on the translation of the company's Euro-denominated assets and cash denominated in foreign currencies. The favorable exchange rate changes in 2017 were primarily due to the strengthening of the Euro and other foreign currencies on the translation of the company's Euro-denominated assets and cash denominated in foreign currencies. The unfavorable exchange rate changes in 2016 were primarily due to the devaluation of AbbVie's net monetary assets denominated in the Venezuelan bolivar.

#### Credit Risk

AbbVie monitors economic conditions, the creditworthiness of customers and government regulations and funding, both domestically and abroad. AbbVie regularly communicates with its customers regarding the status of receivable balances, including their payment plans and obtains positive confirmation of the validity of the receivables. AbbVie establishes an allowance against accounts receivable when it is probable they will not be collected. Global economic conditions and customer-specific factors may require the company to periodically re-evaluate the collectability of its receivables and the company could potentially incur credit losses. AbbVie may also utilize factoring arrangements to mitigate credit risk, although the receivables included in such arrangements have historically not been a significant amount of total outstanding receivables.

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

##### Credit Facility

In August 2018, AbbVie replaced its existing revolving credit facility with a new \$3.0 billion five-year revolving credit facility. The revolving credit facility enables the company to borrow funds on an unsecured basis at variable interest rates and contains various covenants. At December 31, 2018, the company was in compliance with all its credit facility covenants. Commitment fees under the credit facility were insignificant. No amounts were outstanding under the credit facility as of December 31, 2018 and 2017.

##### 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

There were no changes in the company's credit ratings during 2018. Unfavorable changes to the ratings may have an adverse impact on future financing arrangements; however, they would not affect the company's ability to draw on its credit facility and would not result in an acceleration of scheduled maturities of any of the company's outstanding debt obligations.

##### Contractual Obligations

The following table summarizes AbbVie's estimated contractual obligations as of December 31, 2018:

(in millions)	Total	Less than one year	One to three years	Three to five years	More than five years
Short-term borrowings	\$3,699	\$3,699	\$—	\$—	\$—
Long-term debt and capital lease obligations, including current portion	37,360	1,612	6,808	6,370	22,570
Interest on long-term debt <sup>(a)</sup>	17,204	1,433	2,613	2,024	11,134
Future minimum non-cancelable operating lease commitments	809	116	205	145	343
Purchase obligations and other <sup>(b)</sup>	1,843	1,710	110	21	2

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Other long-term liabilities <sup>(c) (d) (e) (f)</sup>	9,994	736	1,392	1,478	6,388
Total	\$70,909	\$9,306	\$11,128	\$10,038	\$40,437

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- Includes estimated future interest payments on long-term debt and capital lease obligations. Interest payments on debt are calculated for future periods using forecasted interest rates in effect at the end of 2018. 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, 2018. See Note 9 to the Consolidated Financial Statements for additional information regarding the company's debt instruments and Note 10 for additional information on the interest rate swap agreements outstanding at December 31, 2018.
- (a) Includes the company's significant unconditional purchase obligations. These commitments do not exceed the company's projected requirements and are made in the normal course of business.
- Amounts less than one year includes a voluntary contribution of \$150 million that AbbVie made to its principal domestic defined benefit plan subsequent to December 31, 2018. Amounts otherwise exclude pension and other post-employment benefits and related deferred compensation cash outflows. Timing of future funding is uncertain and dependent on future movements in interest rates and investment returns, changes in laws and regulations and other variables. Also included in this amount are components of other long-term liabilities including restructuring. See Note 8 to the Consolidated Financial Statements for additional information on restructuring and Note 11 for additional information on the pension and other post-employment benefit plans.
- (c) Excludes liabilities associated with the company's unrecognized tax benefits as it is not possible to reliably estimate the timing of the future cash outflows related to these liabilities. See Note 13 to the Consolidated Financial Statements for additional information on these unrecognized tax benefits.
- Includes \$4.5 billion of contingent consideration liabilities primarily related to the acquisition of BI compounds which are recorded at fair value on the consolidated balance sheet. Potential contingent consideration payments that exceed the fair value recorded on the consolidated balance sheet are not included in the table of contractual obligations. See Notes 5 and 10 to the Consolidated Financial Statements for additional information regarding these liabilities.
- (e) Includes a one-time transition tax liability on a mandatory deemed repatriation of previously untaxed earnings of foreign subsidiaries resulting from U.S. tax reform enacted in 2017. The one-time transition tax is generally payable in eight annual installments. See Note 13 to the Consolidated Financial Statements for additional information regarding these tax liabilities.
- (f)

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

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

#### Revenue Recognition

AbbVie recognizes revenue when control of promised goods or services is transferred to the company's customers, in an amount that reflects the consideration AbbVie expects to be entitled to in exchange for those goods or services. Sales, value add and other taxes collected concurrent with revenue-producing activities are excluded from revenue. AbbVie generates revenue primarily from product sales. For the majority of sales, the company transfers control, invoices the customer and recognizes revenue upon shipment to the customer.

## Rebates

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

Rebate and chargeback accruals are accounted for as variable consideration and are recorded as a reduction to revenue in the period the related product is sold. Rebates and chargebacks totaled \$16.4 billion in 2018, \$12.9 billion in 2017 and \$10.8 billion in 2016. Rebate amounts are typically based upon the volume of purchases using contractual or statutory prices, which may vary by product and by payer. For each type of rebate, the factors used in the calculations of the accrual for that rebate include the identification of the products subject to the rebate, the applicable price terms and the estimated lag time between sale and payment of the rebate, which can be significant.

In order to establish its rebate and chargeback accruals, the company uses both internal and external data to estimate the level of inventory in the distribution channel and the rebate claims processing lag time for each type of rebate. To estimate the rebate percentage or net price, the company tracks sales by product and by customer or payer. The company evaluates inventory data reported by wholesalers, available prescription volume information, product pricing, historical experience and other factors in order to determine the adequacy of its reserves. AbbVie regularly monitors its reserves and records adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the reserve is appropriate. Historically, adjustments to rebate accruals have not been material to net earnings.

The following table is an analysis of the three largest rebate accruals and chargeback allowances, which comprise approximately 91% of the total consolidated rebate and chargebacks recorded as reductions to revenues in 2018. Remaining rebate provisions charged against gross revenues are not significant in the determination of operating earnings.

(in millions)	Medicaid and Medicare Rebates	Managed Care Rebates	Wholesaler Chargebacks
Balance at December 31, 2015	\$ 1,032	\$ 920	\$ 363
Provisions	2,606	3,146	3,987
Payments	(2,471 )	(2,899 )	(3,967 )
Balance at December 31, 2016	1,167	1,167	383
Provisions	2,909	3,990	5,026
Payments	(2,736 )	(3,962 )	(4,887 )
Balance at December 31, 2017	1,340	1,195	522
Provisions	3,493	4,729	6,659
Payments	(3,188 )	(4,485 )	(6,525 )
Balance at December 31, 2018	\$ 1,645	\$ 1,439	\$ 656

## Cash Discounts and Product Returns

Cash discounts and product returns, which totaled \$1.6 billion in 2018, \$1.3 billion in 2017 and \$964 million in 2016, are accounted for as variable consideration and are recorded as a reduction to revenue in the same period the related product is sold. The reserve for cash discounts is readily determinable because the company's experience of payment history is fairly consistent. Product returns can be reliably estimated based on the company's historical return experience.

## Pension and Other Post-Employment Benefits

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





The discount rate is selected based on current market rates on high-quality, fixed-income investments at December 31 each year. AbbVie employs a yield-curve approach for countries where a robust bond market exists. The yield curve is developed using high-quality bonds. The yield-curve approach reflects the plans' specific cash flows (i.e. duration) in calculating the benefit obligations by applying the corresponding individual spot rates along the yield curve.

Beginning in 2016, AbbVie also reflected the plans' specific cash flows and applied them to the corresponding individual spot rates along the yield curve in calculating the service cost and interest cost portions of expense. For other countries, AbbVie reviews various indices such as corporate bond and government bond benchmarks to estimate the discount rate. AbbVie's assumed discount rates have a significant effect on the amounts reported for defined benefit pension and other post-employment plans as of December 31, 2018. A 50 basis point change in the assumed discount rate would have had the following effects on AbbVie's calculation of net periodic benefit costs in 2019 and projected benefit obligations as of December 31, 2018:

	50 basis point	
(in millions) (brackets denote a reduction)	Increase	Decrease
Defined benefit plans		
Service and interest cost	\$(54)	\$ 64
Projected benefit obligation	(512)	578
Other post-employment plans		
Service and interest cost	\$(2)	\$ 4
Projected benefit obligation	(47)	54

The expected long-term rate of return is based on the asset allocation, historical performance and the current view of expected future returns. AbbVie considers these inputs with a long-term focus to avoid short-term market influences.

The current long-term rate of return on plan assets for each plan is supported by the historical performance of the trust's actual and target asset allocation. AbbVie's assumed expected long-term rate of return has a significant effect on the amounts reported for defined benefit pension plans as of December 31, 2018 and will be used in the calculation of net periodic benefit cost in 2019. A one percentage point change in assumed expected long-term rate of return on plan assets would increase or decrease the net period benefit cost of these plans in 2019 by \$62 million.

The health care cost trend rate is selected by reviewing historical trends and current views on projected future health care cost increases. The current health care cost trend rate is supported by the historical trend experience of each plan. Assumed health care cost trend rates have a significant effect on the amounts reported for health care plans as of December 31, 2018 and will be used in the calculation of net periodic benefit cost in 2019. A one percentage point change in assumed health care cost trend rates would have the following effects on AbbVie's calculation of net periodic benefit costs in 2019 and the projected benefit obligation as of December 31, 2018:

	One percentage point	
(in millions) (brackets denote a reduction)	Increase	Decrease
Service and interest cost	\$ 17	\$(9)
Projected benefit obligation	110	(87)
Income Taxes		

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

#### Litigation

The company is subject to contingencies, such as various claims, legal proceedings and investigations regarding product liability, intellectual property, commercial, securities and other matters that arise in the normal course of business. See Note 14 to the Consolidated Financial Statements for additional information. Loss contingency

provisions are recorded for probable losses at management's best estimate of a loss, or when a best estimate cannot be made, a minimum loss contingency amount within a probable range is recorded. Accordingly, AbbVie is often initially unable to develop a best estimate of loss and therefore, the minimum amount, which could be zero, is recorded. As information becomes known, either the minimum

loss amount is increased, resulting in additional loss provisions, or a best estimate can be made, also resulting in additional loss provisions. Occasionally, a best estimate amount is changed to a lower amount when events result in an expectation of a more favorable outcome than previously expected.

#### Valuation of Goodwill and Intangible Assets

AbbVie has acquired and may continue to acquire significant intangible assets in connection with business combinations that AbbVie records at fair value. Transactions involving the purchase or sale of intangible assets occur with some frequency between companies in the pharmaceuticals industry and valuations are usually based on a discounted cash flow analysis incorporating the stage of completion. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, risk, cost of capital, terminal values and market participants. Each of these factors can significantly affect the value of the intangible asset. IPR&D acquired in a business combination is capitalized as an indefinite-lived intangible asset until regulatory approval is obtained, at which time it is accounted for as a definite-lived asset and amortized over its estimated useful life, or discontinuation, at which point the intangible asset will be written off. 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 are reviewed for impairment annually or when an event occurs that could result in an impairment. See Note 2 to the Consolidated Financial Statements for further information.

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

For its quantitative impairment tests, the company uses an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, 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. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the assets and could potentially impact the company's results of operations. Actual results may differ from the company's estimates.

#### Contingent Consideration

The fair value measurements of contingent consideration liabilities are determined as of the acquisition date based on significant unobservable inputs, including the discount rate, estimated probabilities and timing of achieving specified development, regulatory and commercial milestones and the estimated amount of future sales of the acquired products still in development. Contingent consideration liabilities are revalued to fair value at each subsequent reporting date until the related contingency is resolved. Changes to the fair value of the contingent consideration liabilities can result from changes to one or a number of inputs, including discount rates, the probabilities of achieving the milestones, the time required to achieve the milestones and estimated future sales. Significant judgment is employed in determining the appropriateness of these inputs. Changes to the inputs described above could have a material impact on the company's financial position and results of operations in any given period. At December 31, 2018, a 50 basis point increase/decrease in the assumed discount rate would have decreased/increased the value of the contingent consideration liabilities by approximately \$160 million. Additionally, at December 31, 2018, a five percentage point increase/decrease in the assumed probability of success across all potential indications would have increased/decreased the value of the contingent consideration liabilities by approximately \$420 million.

#### Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements for additional information on recent accounting pronouncements.

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## 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. See Note 10 to the Consolidated Financial Statements for additional information regarding the company's financial instruments and hedging strategies.

## Foreign Currency Risk

AbbVie's primary net foreign currency exposures are the Euro, Japanese yen and British pound. The following table reflects the total foreign currency forward exchange contracts outstanding at December 31, 2018 and 2017:

(in millions)	2018		2017		
	Contract amount	Weighted average exchange rate	Fair and carrying value receivable/(payable)	Weighted average exchange rate	Fair and carrying value receivable/(payable)
Receive primarily U.S. dollars in exchange for the following currencies:					
Euro	\$6,660	1.157	\$ 68	\$6,366	1.175 \$ (88 )
Japanese yen	1,076	111.5	(12 )	940	112.4 2
British pound	499	1.328	21	760	1.310 (22 )
All other currencies	1,776	n/a	29	1,877	n/a (18 )
Total	\$10,011		\$ 106	\$9,943	\$ (126 )

The company estimates that a 10% 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 \$1.0 billion at December 31, 2018. If realized, this appreciation would negatively affect earnings over the remaining life of the contracts. However, gains and losses on the hedging instruments offset losses and gains on the hedged transactions and reduce the earnings and stockholders' equity volatility relating to foreign exchange. A 10% appreciation is believed to be a reasonably possible near-term change in foreign currencies.

In November 2016, the company issued €3.6 billion aggregate principal amount of unsecured senior Euro notes, which are exposed to foreign currency risk. The company has designated these foreign currency denominated notes as hedges of its net investments in certain foreign subsidiaries and affiliates. As a result, any foreign currency translation gains or losses related to the Euro notes will be included in accumulated other comprehensive income. See Note 9 to the Consolidated Financial Statements for additional information related to the senior Euro note issuance and Note 10 to the Consolidated Financial Statements for additional information related to the net investment hedging program.

## Interest Rate Risk

The company estimates that an increase in interest rates of 100 basis points would adversely impact the fair value of AbbVie's interest rate swap contracts by approximately \$403 million at December 31, 2018. 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 \$2.4 billion at December 31, 2018. A 100 basis point change is believed to be a reasonably possible near-term change in interest rates.

## Market Price Risk

AbbVie's debt securities investment portfolio (the portfolio) is its main exposure to market price risk. The portfolio is subject to changes in fair value as a result of interest rate fluctuations and other market factors. It is AbbVie's policy to mitigate market price risk by maintaining a diversified portfolio that limits the amount of exposure to a particular issuer and security type while placing limits on the amount of time to maturity. AbbVie's investment policy limits investments to investment grade credit ratings. The company estimates that an increase in interest rates of 100 basis points would decrease the fair value of the portfolio by approximately \$16 million as of December 31, 2018. If the portfolio were to be liquidated, the fair value reduction would affect the statement of earnings in the period sold.



ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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AbbVie Inc. and Subsidiaries  
Consolidated Statements of Earnings

years ended December 31 (in millions, except per share data)	2018	2017	2016
Net revenues	\$32,753	\$28,216	\$25,638
Cost of products sold	7,718	7,042	5,832
Selling, general and administrative	7,399	6,295	5,881
Research and development	10,329	5,007	4,385
Acquired in-process research and development	424	327	200
Other expense	500	—	—
Total operating costs and expenses	26,370	18,671	16,298
Operating earnings	6,383	9,545	9,340
Interest expense, net	1,144	1,004	965
Net foreign exchange loss	24	348	303
Other expense, net	18	466	188
Earnings before income taxes	5,197	7,727	7,884
Income tax expense (benefit)	(490 )	2,418	1,931
Net earnings	\$5,687	\$5,309	\$5,953
Per share data			
Basic earnings per share	\$3.67	\$3.31	\$3.65
Diluted earnings per share	\$3.66	\$3.30	\$3.63
Weighted-average basic shares outstanding	1,541	1,596	1,622
Weighted-average diluted shares outstanding	1,546	1,603	1,631

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



AbbVie Inc. and Subsidiaries  
 Consolidated Statements of Comprehensive Income

years ended December 31 (in millions)	2018	2017	2016
Net earnings	\$5,687	\$5,309	\$5,953
Foreign currency translation adjustments, net of tax expense (benefit) of \$(18) in 2018, \$34 in 2017 and \$(31) in 2016	(391 )	996	(165 )
Net investment hedging activities, net of tax expense (benefit) of \$40 in 2018, \$(194) in 2017 and \$79 in 2016	138	(343 )	140
Pension and post-employment benefits, net of tax expense (benefit) of \$35 in 2018, \$(94) in 2017 and \$(75) in 2016	197	(406 )	(135 )
Marketable security activities, net of tax expense (benefit) of \$— in 2018, \$(8) in 2017 and \$(11) in 2016	(10 )	(46 )	(1 )
Cash flow hedging activities, net of tax expense (benefit) of \$23 in 2018, \$(26) in 2017 and \$18 in 2016	313	(342 )	136
Other comprehensive income (loss)	247	(141 )	(25 )
Comprehensive income	\$5,934	\$5,168	\$5,928

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

AbbVie Inc. and Subsidiaries  
Consolidated Balance Sheets

as of December 31 (in millions, except share data)	2018	2017
Assets		
Current assets		
Cash and equivalents	\$7,289	\$9,303
Short-term investments	772	486
Accounts receivable, net	5,384	5,088
Inventories	1,605	1,605
Prepaid expenses and other	1,895	4,741
Total current assets	16,945	21,223
Investments	1,420	2,090
Property and equipment, net	2,883	2,803
Intangible assets, net	21,233	27,559
Goodwill	15,663	15,785
Other assets	1,208	1,326
Total assets	\$59,352	\$70,786
Liabilities and Equity		
Current liabilities		
Short-term borrowings	\$3,699	\$400
Current portion of long-term debt and lease obligations	1,609	6,015
Accounts payable and accrued liabilities	11,931	10,226
Total current liabilities	17,239	16,641
Long-term debt and lease obligations	35,002	30,953
Deferred income taxes	1,067	2,490
Other long-term liabilities	14,490	15,605
Commitments and contingencies		
Stockholders' equity (deficit)		
Common stock, \$0.01 par value, 4,000,000,000 shares authorized, 1,776,510,871 shares issued as of December 31, 2018 and 1,768,738,550 as of December 31, 2017	18	18
Common stock held in treasury, at cost, 297,686,473 shares as of December 31, 2018 and 176,607,525 as of December 31, 2017	(24,108 )	(11,923 )
Additional paid-in-capital	14,756	14,270
Retained earnings	3,368	5,459
Accumulated other comprehensive loss	(2,480 )	(2,727 )
Total stockholders' equity (deficit)	(8,446 )	5,097
Total liabilities and equity	\$59,352	\$70,786

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



AbbVie Inc. and Subsidiaries  
Consolidated Statements of Equity

years ended December 31 (in millions)	Common shares outstanding	Common stock	Treasury stock	Additional paid-in capital	Retained earnings	Accumulated other comprehensive loss	Total
Balance at December 31, 2015	1,610	\$ 17	\$(8,839 )	\$ 13,080	\$ 2,248	\$ (2,561 )	\$ 3,945
Net earnings	—	—	—	—	5,953	—	5,953
Other comprehensive loss, net of tax	—	—	—	—	—	(25 )	(25 )
Dividends declared	—	—	—	—	(3,823 )	—	(3,823 )
Common shares issued to Stemcentrx stockholders	63	—	3,958	(35 )	—	—	3,923
Purchases of treasury stock	(94 )	—	(6,018 )	—	—	—	(6,018 )
Stock-based compensation plans and other	14	1	47	633	—	—	681
Balance at December 31, 2016	1,593	18	(10,852 )	13,678	4,378	(2,586 )	4,636
Net earnings	—	—	—	—	5,309	—	5,309
Other comprehensive loss, net of tax	—	—	—	—	—	(141 )	(141 )
Dividends declared	—	—	—	—	(4,221 )	—	(4,221 )
Purchases of treasury stock	(15 )	—	(1,125 )	—	—	—	(1,125 )
Stock-based compensation plans and other	14	—	54	592	(7 )	—	639
Balance at December 31, 2017	1,592	18	(11,923 )	14,270	5,459	(2,727 )	5,097
Adoption of new accounting standards <sup>(a)</sup>	—	—	—	—	(1,733 )	—	(1,733 )
Net earnings	—	—	—	—	5,687	—	5,687
Other comprehensive income, net of tax	—	—	—	—	—	247	247
Dividends declared	—	—	—	—	(6,045 )	—	(6,045 )
Purchases of treasury stock	(121 )	—	(12,215 )	—	—	—	(12,215 )
Stock-based compensation plans and other	8	—	30	486	—	—	516
Balance at December 31, 2018	1,479	\$ 18	\$(24,108 )	\$ 14,756	\$ 3,368	\$ (2,480 )	\$(8,446)

<sup>(a)</sup> See Note 2 for additional information regarding the cumulative effect of the adoption of accounting standards in 2018.

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

## AbbVie Inc. and Subsidiaries

## Consolidated Statements of Cash Flows

years ended December 31 (in millions) (brackets denote cash outflows)	2018	2017	2016
Cash flows from operating activities			
Net earnings	\$5,687	\$5,309	\$5,953
Adjustments to reconcile net earnings to net cash from operating activities:			
Depreciation	471	425	425
Amortization of intangible assets	1,294	1,076	764
Change in fair value of contingent consideration liabilities	49	626	228
Stock-based compensation	421	365	353
Upfront costs and milestones related to collaborations	1,061	470	280
Devaluation loss related to Venezuela	—	—	298
Intangible asset impairment	5,070	354	39
Impacts related to U.S. tax reform	424	1,242	—
Other, net	76	84	390
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable	(591 )	(391 )	(71 )
Inventories	(226 )	93	(38 )
Prepaid expenses and other assets	(499 )	(118 )	(393 )
Accounts payable and other liabilities	190	425	(1,187 )
Cash flows from operating activities	13,427	9,960	7,041
Cash flows from investing activities			
Acquisition of businesses, net of cash acquired	—	—	(2,495 )
Other acquisitions and investments	(736 )	(308 )	(262 )
Acquisitions of property and equipment	(638 )	(529 )	(479 )
Purchases of investment securities	(1,792 )	(2,230 )	(5,315 )
Sales and maturities of investment securities	2,160	2,793	2,359
Other	—	—	118
Cash flows from investing activities	(1,006 )	(274 )	(6,074 )
Cash flows from financing activities			
Net change in commercial paper borrowings	299	23	(23 )
Proceeds from issuance of other short-term borrowings	3,002	—	—
Proceeds from issuance of long-term debt	5,963	—	11,627
Repayments of long-term debt and lease obligations	(6,035 )	(25 )	(6,010 )
Debt issuance costs	(40 )	—	(69 )
Dividends paid	(5,580 )	(4,107 )	(3,717 )
Purchases of treasury stock	(12,014 )	(1,410 )	(6,033 )
Proceeds from the exercise of stock options	73	254	268
Payments of contingent consideration liabilities	(78 )	(268 )	—
Other, net	14	21	29
Cash flows from financing activities	(14,396 )	(5,512 )	(3,928 )
Effect of exchange rate changes on cash and equivalents	(39 )	29	(338 )
Net change in cash and equivalents	(2,014 )	4,203	(3,299 )
Cash and equivalents, beginning of year	9,303	5,100	8,399
Cash and equivalents, end of year	\$7,289	\$9,303	\$5,100

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Other supplemental information

Interest paid, net of portion capitalized	\$1,215	\$1,099	\$986
Income taxes paid (received)	(35 )	1,696	3,563
Supplemental schedule of non-cash investing and financing activities			
Issuance of common shares associated with acquisitions of businesses	—	—	3,923

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

AbbVie Inc. and Subsidiaries  
Notes to Consolidated Financial Statements  
Note 1 Background

Background

The principal business of AbbVie Inc. (AbbVie or the company) is the discovery, development, manufacture and sale of a broad line of pharmaceutical products. AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to pharmacies and patients. Outside the United States, products are sold primarily to customers or through distributors, depending on the market served.

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

Note 2 Summary of Significant Accounting Policies

Use of Estimates

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

Basis of Consolidation

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

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

Revenue Recognition

AbbVie recognizes revenue when control of promised goods or services is transferred to the company's customers, in an amount that reflects the consideration AbbVie expects to be entitled to in exchange for those goods or services. Sales, value add and other taxes collected concurrent with revenue-producing activities are excluded from revenue. AbbVie generates revenue primarily from product sales. For the majority of sales, the company transfers control, invoices the customer and recognizes revenue upon shipment to the customer. The company recognizes shipping and handling costs as an expense in cost of products sold when the company transfers control to the customer. Payment terms vary depending on the type and location of the customer, are based on customary commercial terms and are generally less than one year. AbbVie does not adjust revenue for the effects of a significant financing component for contracts where AbbVie expects the period between the transfer of the good or service and collection to be one year or less.

Discounts, rebates, sales incentives to customers, returns and certain other adjustments are accounted for as variable consideration. Provisions for variable consideration are based on current pricing, executed contracts, government pricing legislation and historical data and are provided for in the period the related revenues are recorded. Rebate amounts are typically based upon the volume of purchases using contractual or statutory prices, which may vary by product and by payer. For each type of rebate, factors used in the calculation of the accrual include the identification of the products subject to the rebate, the applicable price terms and the estimated lag time between sale and payment

of the rebate, which can be significant. Sales incentives to customers are insignificant.



In addition to revenue from contracts with customers, the company also recognizes certain collaboration revenues. See Note 6 for additional information related to the collaboration with Janssen Biotech, Inc. Additionally, see Note 15 for disaggregation of revenue by product and geography.

#### Research and Development Expenses

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, prior to regulatory approval, the payment obligations are expensed when the milestone results are achieved. Payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized to cost of products sold over the remaining useful life of the related product.

#### Collaborations and Other Arrangements

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

#### Advertising

Costs associated with advertising are expensed as incurred and are included in selling, general and administrative (SG&A) expense in the consolidated statements of earnings. Advertising expenses were \$1.1 billion in 2018, \$846 million in 2017 and \$764 million in 2016.

#### Pension and Other Post-Employment Benefits

AbbVie records annual expenses relating to its defined benefit pension and other post-employment benefit plans based on calculations which utilize various actuarial assumptions, including discount rates, rates of return on assets, 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 gains and losses are deferred in accumulated other comprehensive loss (AOCI), net of tax and are amortized over the remaining service attribution periods of the employees under the corridor method. Differences between the expected long-term return on plan assets and the actual annual return are amortized to net periodic benefit cost over a five-year period.

#### Income Taxes

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

#### Cash and Equivalents

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

#### Investments

Investments consist primarily of time deposits, marketable debt securities, held-to-maturity debt securities and equity securities. Investments in marketable debt 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 AOCI on the consolidated balance sheets until realized, at which time the gains or losses are recognized in earnings. Investments in equity securities that have readily determinable fair values are recorded at fair value. Investments in equity securities that do not have readily

determinable fair values are recorded at cost and are remeasured to fair value based on certain observable price changes or impairment events as they occur. Held-to-

maturity debt securities are recorded at cost. Gains or losses on investments are included in other expense, net in the consolidated statements of earnings.

AbbVie periodically assesses its marketable debt securities for other-than-temporary impairment losses. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below the cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, intent to sell, or whether AbbVie will more likely than not be required to sell the security before recovery of its amortized cost basis. AbbVie also considers industry factors and general market trends. When AbbVie determines that an other-than-temporary decline has occurred, the cost basis of the investment is written down with a charge to other expense, net in the consolidated statements of earnings and an available-for-sale investment's unrealized loss is reclassified from AOCI to other expense, net in the consolidated statements of earnings. Realized gains and losses on sales of investments are computed using the first-in, first-out method adjusted for any other-than-temporary declines in fair value that were recorded in net earnings.

#### Accounts Receivable

Accounts receivable are stated at their net realizable value. The allowance for doubtful accounts 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 for doubtful accounts was \$51 million at December 31, 2018 and \$58 million at December 31, 2017.

#### Inventories

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

as of December 31 (in millions)	2018	2017
Finished goods	\$473	\$610
Work-in-process	862	822
Raw materials	270	173
Inventories	\$1,605	\$1,605

#### Property and Equipment

as of December 31 (in millions)	2018	2017
Land	\$73	\$48
Buildings	1,603	1,428
Equipment	6,362	5,991
Construction in progress	358	604
Property and equipment, gross	8,396	8,071
Less accumulated depreciation	(5,513 )	(5,268 )
Property and equipment, net	\$2,883	\$2,803

Depreciation for property and equipment is recorded on a straight-line basis over the estimated useful lives of the assets. The estimated useful life for buildings ranges from 10 to 50 years. Buildings include leasehold improvements which are amortized over the life of the related facility lease (including any renewal periods, if appropriate) or the asset, whichever is shorter. The estimated useful life for equipment ranges from 2 to 25 years. Equipment includes certain computer software and software development costs incurred in connection with developing or obtaining software for internal use and is amortized over 3 to 10 years. Depreciation expense was \$471 million in 2018, \$425 million in 2017 and \$425 million in 2016. Assets related to capital leases were insignificant at December 31, 2018 and 2017.

#### Litigation and Contingencies

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

accrues for product liability claims on an undiscounted basis. The liabilities are evaluated quarterly and adjusted if necessary as additional information

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becomes available. Receivables for insurance recoveries for product liability claims, if any, are recorded as assets on an undiscounted basis when it is probable that a recovery will be realized.

#### Business Combinations

AbbVie utilizes the acquisition method of accounting for business combinations. This method requires, among other things, that results of operations of acquired companies are included in AbbVie's results of operations beginning on the respective acquisition dates and that assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Any excess of the fair value of consideration transferred over the fair values of the net assets acquired is recognized as goodwill. Contingent consideration liabilities are recognized at the estimated fair value on the acquisition date. Subsequent changes to the fair value of contingent consideration liabilities are recognized in other expense, net in the consolidated statements of earnings. The fair value of assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed twelve months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other business acquisition costs are expensed when incurred.

#### Goodwill and Intangible Assets

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

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

The company tests its goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the company concludes it is more likely than not that the fair value of the reporting unit is less than its carrying amount, a quantitative impairment test is performed. AbbVie tests indefinite-lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the company concludes it is more likely than not that the fair value is less than its carrying amount, a quantitative impairment test is performed. For its quantitative impairment tests, the company uses an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, 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. 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.

#### Acquired In-Process Research and Development

In an asset acquisition, the initial costs of rights to IPR&D projects acquired are expensed as IPR&D in the consolidated statements of earnings unless the project has an alternative future use. These costs include initial payments incurred prior to regulatory approval in connection with research and development collaboration agreements that provide rights to develop, manufacture, market and/or sell pharmaceutical products. In a business combination, the fair value of IPR&D projects acquired 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. R&D costs incurred after the acquisition are expensed as incurred.

Foreign Currency Translation

Foreign subsidiary earnings are translated into U.S. dollars using average exchange rates. The net assets of foreign subsidiaries are translated into U.S. dollars using period-end exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recognized in other comprehensive income (loss) (OCI) in the consolidated statements of comprehensive income. The net assets of subsidiaries in highly inflationary economies are

remeasured as if the functional currency were the reporting currency. The remeasurement is recognized in net foreign exchange loss in the consolidated statements of earnings.

#### Derivatives

All derivative instruments are recognized as either assets or liabilities at fair value on the consolidated balance sheets and are classified as current or long-term based on the scheduled maturity of the instrument.

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 hedged risk are recognized in earnings immediately. 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. If it is determined that a derivative is no longer highly effective as a hedge, the company discontinues hedge accounting prospectively. If a hedged forecasted transaction becomes probable of not occurring, any gains or losses are reclassified from AOCI to earnings. Derivatives that are not designated as hedges are adjusted to fair value through current earnings.

The company also uses derivative instruments or foreign currency denominated debt to hedge its net investments in certain foreign subsidiaries and affiliates. Realized and unrealized gains and losses from these hedges are included in AOCI.

Derivative cash flows, with the exception of net investment hedges, are principally classified in the operating section of the consolidated statements of cash flows, consistent with the underlying hedged item. Cash flows related to net investment hedges are classified in the investing section of the consolidated statements of cash flows.

#### Recent Accounting Pronouncements

##### Recently Adopted Accounting Pronouncements

##### ASU No. 2014-09

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs - Contracts with Customers (Subtopic 340-40). The amendments in this standard superseded most existing revenue recognition requirements. The core principle of the new guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. AbbVie adopted the standard in the first quarter of 2018 using the modified retrospective method. Results for reporting periods beginning after December 31, 2017 have been presented in accordance with the standard, while results for prior periods have not been adjusted and continue to be reported in accordance with AbbVie's historical accounting. The cumulative effect of initially applying the new revenue standard was recognized as an adjustment to the opening balance of retained earnings as of January 1, 2018.

There were no significant changes to the amounts or timing of revenue recognition for product sales, the company's primary revenue stream. For certain licensing arrangements where revenue was previously deferred and recognized over time, revenue is now recognized at the point in time when the license is granted. Additionally, for certain contract manufacturing arrangements where revenue was previously recognized at a point in time at the end of the manufacturing process, revenue is now recognized over time throughout the manufacturing process.

Under the new standard, on January 1, 2018, the company recognized a cumulative-effect adjustment to retained earnings primarily related to certain deferred license revenues that were originally expected to be recognized through early 2020. The adjustment to the consolidated balance sheet included: (i) a \$42 million increase to prepaid expenses and other; (ii) a \$39 million decrease to inventories; (iii) a \$57 million decrease to accounts payable and accrued liabilities; (iv) a \$75 million decrease to other long-term liabilities; (v) a \$22 million increase to deferred income taxes; and (vi) a \$124 million increase to retained earnings. Other cumulative-effect adjustments to the consolidated balance sheet were insignificant.





The impact of adoption on the company's consolidated statements of earnings in 2018 was as follows:

year ended December 31, 2018 (in millions, except per share data)	As Reported	Balances Without Adoption of ASU 2014-09	Effect of Change Higher/(Lower)
Net revenues	\$32,753	\$32,812	\$ (59 )
Cost of products sold	7,718	7,730	(12 )
Income tax benefit	(490 )	(487 )	(3 )
Net earnings	5,687	5,731	(44 )
Diluted earnings per share	\$3.66	\$3.69	\$ (0.03 )

As of December 31, 2018, due to the impact of the adoption of ASU 2014-09, prepaid expenses and other were \$40 million higher, inventories were \$27 million lower, accounts payable and accrued liabilities were \$53 million lower, other long-term liabilities were \$18 million lower, deferred income taxes were \$11 million higher and retained earnings were \$80 million higher on the company's consolidated balance sheet than they would have been had ASU 2014-09 not been adopted. Other impacts to the consolidated balance sheet were insignificant.

ASU No. 2016-01

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The standard requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net earnings. AbbVie adopted the standard in the first quarter of 2018. The adoption did not impact the accounting for AbbVie's investments in debt securities and did not have a material impact on the company's consolidated financial statements.

ASU No. 2016-16

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory. The standard requires entities to recognize the income tax consequences of an intercompany transfer of an asset other than inventory when the transfer occurs. Under previous U.S. GAAP, the income tax consequences of these intercompany asset transfers were deferred until the asset was sold to a third party or otherwise recovered through use. AbbVie adopted the standard in the first quarter of 2018 using the modified retrospective method. As a result, on January 1, 2018, the company recorded a cumulative-effect adjustment to its consolidated balance sheet that included a \$1.9 billion decrease to retained earnings, a \$1.4 billion decrease to prepaid expenses and other and a \$0.5 billion decrease to other assets.

ASU No. 2017-07

In March 2017, the FASB issued ASU No. 2017-07, Compensation - Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost. The standard requires that an employer continue to report the service cost component of net periodic benefit cost in the same income statement line item or items as other employee compensation costs arising from services rendered during the period. The other components of net periodic benefit cost are required to be presented separately outside of income from operations and are not eligible for capitalization. AbbVie adopted the standard in the first quarter of 2018 and applied the income statement classification provisions of this standard retrospectively. As a result, the company reclassified income of \$47 million from operating earnings to non-operating income in 2017 and \$44 million in 2016. Additionally, the company recorded approximately \$34 million of non-operating income in 2018 which would have been recorded in operating earnings under the previous guidance.

ASU No. 2017-12

In August 2017, the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. The standard simplifies the application of hedge accounting and more closely aligns the accounting with an entity's risk management activities. AbbVie elected to early adopt the standard in the first quarter of 2018. The adoption did not have a material impact on the company's consolidated financial statements.



#### Recent Accounting Pronouncements Not Yet Adopted

##### ASU No. 2016-02

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The standard outlines a comprehensive lease accounting model that supersedes the current lease guidance and requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms greater than 12 months. The guidance also changes the definition of a lease and expands the disclosure requirements of lease arrangements. AbbVie has substantially completed its assessment of the new standard as of December 31, 2018. AbbVie will adopt the standard effective in the first quarter of 2019 and will not restate comparative periods upon adoption. AbbVie will elect a package of practical expedients for leases that commenced prior to January 1, 2019 and will not reassess: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases. AbbVie does not expect the adoption will have a material impact on its consolidated statement of earnings. However, the new standard will require AbbVie to establish liabilities and corresponding right-of-use assets on its consolidated balance sheet of approximately \$0.3 billion to \$0.5 billion for operating leases that exist as of the adoption date.

##### ASU No. 2016-13

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326). The standard changes how credit losses are measured for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other financial instruments, the standard requires the use of a new forward-looking "expected credit loss" model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. Additionally, the standard requires new disclosures and will be effective for AbbVie starting with the first quarter of 2020. Early adoption beginning in the first quarter of 2019 is permitted. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact to retained earnings as of the beginning of the fiscal year of adoption. AbbVie is currently assessing the impact and timing of adopting this guidance on its consolidated financial statements.

##### ASU No. 2018-02

In February 2018, the FASB issued ASU No. 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which allows a reclassification from AOCI to retained earnings for stranded tax effects related to adjustments to deferred taxes resulting from the December 2017 enactment of the Tax Cuts and Jobs Act. The standard will be effective for AbbVie starting with the first quarter of 2019. AbbVie is currently assessing the impact of adopting this guidance on its consolidated financial statements.

## Note 3 Supplemental Financial Information

## Interest Expense, Net

years ended December 31 (in millions)	2018	2017	2016
Interest expense	\$1,348	\$1,150	\$1,047
Interest income	(204 )	(146 )	(82 )
Interest expense, net	\$1,144	\$1,004	\$965

## Accounts Payable and Accrued Liabilities

as of December 31 (in millions)	2018	2017
Sales rebates	\$3,939	\$3,069
Dividends payable	1,607	1,143
Accounts payable	1,546	1,474
Salaries, wages and commissions	787	763
Royalty and license arrangements	304	514
Other	3,748	3,263
Accounts payable and accrued liabilities	\$11,931	\$10,226

## Other Long-Term Liabilities

as of December 31 (in millions)	2018	2017
Income taxes payable	\$4,311	\$4,675
Contingent consideration liabilities	4,306	4,266
Liabilities for unrecognized tax benefits	2,726	2,683
Pension and other post-employment benefits	1,840	2,740
Other	1,307	1,241
Other long-term liabilities	\$14,490	\$15,605

## Note 4 Earnings Per Share

AbbVie grants certain restricted stock awards (RSAs) and restricted stock units (RSUs) that are considered to be participating securities. Due to the presence of participating securities, AbbVie calculates earnings per share (EPS) using the more dilutive of the treasury stock or the two-class method. For all periods presented, the two-class method was more dilutive.

The following table summarizes the impact of the two-class method:

(in millions, except per share information)	Years ended December 31,		
	2018	2017	2016
Basic EPS			
Net earnings	\$5,687	\$5,309	\$5,953
Earnings allocated to participating securities	30	26	30
Earnings available to common shareholders	\$5,657	\$5,283	\$5,923
Weighted-average basic shares outstanding	1,541	1,596	1,622
Basic earnings per share	\$3.67	\$3.31	\$3.65

#### Diluted EPS

Net earnings	\$5,687	\$5,309	\$5,953
Earnings allocated to participating securities	30	26	30
Earnings available to common shareholders	\$5,657	\$5,283	\$5,923
Weighted-average shares of common stock outstanding	1,541	1,596	1,622
Effect of dilutive securities	5	7	9
Weighted-average diluted shares outstanding	1,546	1,603	1,631
Diluted earnings per share	\$3.66	\$3.30	\$3.63

As further described in Note 12, AbbVie entered into and executed an accelerated share repurchase agreement (ASR) with a third party financial institution in 2016. For purposes of calculating EPS, AbbVie reflected the ASR as a repurchase of AbbVie common stock.

Certain shares issuable under stock-based compensation plans were excluded from the computation of EPS because the effect would have been antidilutive. The number of common shares excluded was insignificant for all periods presented.

Note 5 Licensing, Acquisitions and Other Arrangements

#### Acquisition of Stemcentrx

On June 1, 2016, AbbVie acquired all of the outstanding equity interests in Stemcentrx, a privately-held biotechnology company. The transaction expanded AbbVie's oncology pipeline by adding the late-stage asset rovalpituzumab tesirine (Rova-T), four additional early-stage clinical compounds in solid tumor indications and a significant portfolio of pre-clinical assets. Rova-T is currently in registrational trials for small cell lung cancer.

The acquisition of Stemcentrx was accounted for as a business combination using the acquisition method of accounting. The aggregate upfront consideration for the acquisition of Stemcentrx consisted of approximately 62.4 million shares of AbbVie common stock, issued from common stock held in treasury, and cash. AbbVie may make certain contingent payments upon the achievement of defined development and regulatory milestones. As of the acquisition date, the maximum aggregate amount payable for development and regulatory milestones was \$4.0 billion. The acquisition-date fair value of these milestones was \$620 million and was estimated using a combination of probability-weighted discounted cash flow models and Monte Carlo simulation models. The estimate was determined based on significant inputs that are not observable in the market, referred to as Level 3 inputs, as described in more detail in Note 10.

The following table summarizes total consideration:

(in millions)	
Cash	\$1,883
Fair value of AbbVie common stock	3,923

Contingent consideration	620
Total consideration	\$6,426

The following table summarizes fair values of assets acquired and liabilities assumed as of the June 1, 2016 acquisition date:

(in millions)

Assets acquired and liabilities assumed	
Accounts receivable	\$1
Prepaid expenses and other	7
Property and equipment	17
Intangible assets - Indefinite-lived research and development	6,100
Accounts payable and accrued liabilities	(31 )
Deferred income taxes	(1,933 )
Other long-term liabilities	(7 )
Total identifiable net assets	4,154
Goodwill	2,272
Total assets acquired and liabilities assumed	\$6,426

Intangible assets were related to IPR&D for Rova-T, four additional early-stage clinical compounds in solid tumor indications and several additional pre-clinical compounds. The estimated fair value of the acquired IPR&D was determined using the multi-period excess earnings model of the “income approach,” which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. Some of the more significant assumptions inherent in the development of those asset valuations include the estimated annual cash flows for each asset or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and working capital/contributory asset charges), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset’s life cycle, the regulatory approval probabilities, commercial success risks, competitive landscape as well as other factors. See Note 7 for additional information on the 2018 partial impairment of Stemcentrx-related intangible assets.

The goodwill recognized represented expected synergies, including the ability to: (i) leverage the respective strengths of each business; (ii) expand the combined company’s product portfolio; (iii) accelerate AbbVie’s clinical and commercial presence in oncology; and (iv) establish a strong leadership position in oncology. Goodwill was also impacted by the establishment of a deferred tax liability for the acquired identifiable intangible assets which have no tax basis. The goodwill is not deductible for tax purposes.

Following the acquisition date, the operating results of Stemcentrx have been included in the company’s financial statements. AbbVie’s consolidated statement of earnings for the year ended December 31, 2016 included no net revenues and an operating loss of \$165 million associated with Stemcentrx’s operations. This operating loss included \$43 million of post-acquisition stock-based compensation expense for Stemcentrx options and excluded interest expense and certain acquisition costs.

#### Pro Forma Financial Information

The following table presents the unaudited pro forma combined results of operations of AbbVie and Stemcentrx for the year ended December 31, 2016 as if the acquisition of Stemcentrx had occurred on January 1, 2015:

year ended December 31 (in millions, except per share information)	2016
Net revenues	\$25,641
Net earnings	5,907
Basic earnings per share	\$3.58
Diluted earnings per share	\$3.56

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of AbbVie and Stemcentrx. In order to reflect the occurrence of the acquisition on January 1, 2015 as required, the unaudited pro forma financial information includes adjustments to reflect the additional interest expense associated with the issuance of debt to finance the acquisition and the reclassification of acquisition, integration and financing-related costs incurred during the year ended December 31, 2016 to the year ended December 31,



2015. The unaudited pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been had the acquisition been completed on January 1, 2015. In addition, the unaudited pro forma financial information is not a projection of the future results of operations of the combined company nor does it reflect the expected realization of any cost savings or synergies associated with the acquisition.

#### Acquisition of BI 655066 and BI 655064 from Boehringer Ingelheim

On April 1, 2016, AbbVie acquired all rights to risankizumab (BI 655066), an anti-IL-23 monoclonal biologic antibody in Phase 3 development for psoriasis, from Boehringer Ingelheim (BI) pursuant to a global collaboration agreement. AbbVie is also evaluating the potential of this biologic therapy in other indications, including Crohn's disease, psoriatic arthritis and ulcerative colitis. In addition to risankizumab, AbbVie also gained rights to an anti-CD40 antibody, BI 655064, currently in Phase 1 development. BI will retain responsibility for further development of BI 655064, and AbbVie may elect to advance the program after completion of certain clinical achievements. The acquired assets include all patents, data, know-how, third-party agreements, regulatory filings and manufacturing technology related to BI 655066 and BI 655064.

The company concluded that the acquired assets met the definition of a business and accounted for the transaction as a business combination using the acquisition method of accounting. Under the terms of the agreement, AbbVie made an upfront payment of \$595 million. Additionally, \$18 million of payments to BI, pursuant to a contractual obligation to reimburse BI for certain development costs it incurred prior to the acquisition date, were initially deferred. AbbVie may make certain contingent payments upon the achievement of defined development, regulatory and commercial milestones, as well as royalty payments based on net revenues of licensed products. As of the acquisition date, the maximum aggregate amount payable for development and regulatory milestones was approximately \$1.6 billion. The acquisition-date fair value of these milestones was \$606 million. The acquisition-date fair value of contingent royalty payments was \$2.8 billion. The potential contingent consideration payments were estimated by applying a probability-weighted expected payment model for contingent milestone payments and a Monte Carlo simulation model for contingent royalty payments, which were then discounted to present value. The fair value measurements were based on Level 3 inputs.

The following table summarizes total consideration:

(in millions)

Cash	\$595
Deferred consideration payable	18
Contingent consideration	3,365
Total consideration	\$3,978

The following table summarizes fair values of assets acquired as of the April 1, 2016 acquisition date:

(in millions)

Assets acquired	
Identifiable intangible assets - Indefinite-lived research and development	\$3,890
Goodwill	88
Total assets acquired	\$3,978

The estimated fair value of the acquired IPR&D was determined using the multi-period excess earnings model of the "income approach." The goodwill recognized represented expected synergies, including an expansion of the company's immunology product portfolio.

Pro forma results of operations for this acquisition have not been presented because this acquisition was insignificant to AbbVie's consolidated results of operations.

**Other Licensing & Acquisitions Activity**

Excluding the acquisitions above, cash outflows related to other acquisitions and investments totaled \$736 million in 2018, \$308 million in 2017 and \$262 million in 2016. AbbVie recorded acquired IPR&D charges of \$424 million in 2018, \$327 million in 2017 and \$200 million in 2016. Significant arrangements impacting 2018, 2017 and 2016, some of which require contingent milestone payments, are summarized below.

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#### Calico Life Sciences LLC

In June 2018, AbbVie and Calico Life Sciences LLC (Calico) entered into an extension of a collaboration to discover, develop and bring to market new therapies for patients with age-related diseases, including neurodegeneration and cancer. Under the terms of the agreement, AbbVie and Calico will each contribute an additional \$500 million to the collaboration and the term is extended for an additional 3 years. Calico will be responsible for research and early development until 2022 and will advance collaboration projects through Phase 2a through 2027. Following completion of Phase 2a, AbbVie will have the option to exclusively license collaboration compounds. AbbVie will support Calico in its early research and development efforts and, upon exercise, would be responsible for late-stage development and commercial activities. Collaboration costs and profits will be shared equally by both parties post option exercise. During 2018, AbbVie recorded \$500 million in other expense in the consolidated statement of earnings related to its commitments under the agreement.

#### Alector, Inc.

In October 2017, AbbVie entered into a global strategic collaboration with Alector, Inc. (Alector) to develop and commercialize medicines to treat Alzheimer's disease and other neurodegenerative disorders. AbbVie and Alector have agreed to research a portfolio of antibody targets and AbbVie has an option to global development and commercial rights to two targets. The terms of the arrangement included an initial upfront payment of \$205 million, which was expensed to IPR&D in the fourth quarter of 2017. Alector will conduct exploratory research, drug discovery and development for lead programs up to the conclusion of the proof of concept studies. If the option is exercised, AbbVie will lead development and commercialization activities and could make additional payments to Alector of up to \$986 million upon achievement of certain development and regulatory milestones. Alector and AbbVie will co-fund development and commercialization and will share global profits equally.

#### Other Arrangements

In addition to the significant arrangements described above, AbbVie entered into several other arrangements resulting in charges to IPR&D of \$424 million in 2018, \$122 million in 2017 and \$200 million in 2016. In connection with the other individually insignificant early-stage arrangements entered into in 2018, AbbVie could make additional payments of up to \$4.8 billion upon the achievement of certain development, regulatory and commercial milestones. Note 6 Collaboration with Janssen Biotech, Inc.

In December 2011, Pharmacyclics, a wholly-owned subsidiary of AbbVie, entered into a worldwide collaboration and license agreement with Janssen Biotech, Inc. and its affiliates (Janssen), one of the Janssen Pharmaceutical companies of Johnson & Johnson, for the joint development and commercialization of IMBRUVICA, a novel, orally active, selective covalent inhibitor of Bruton's tyrosine kinase (BTK) and certain compounds structurally related to IMBRUVICA, for oncology and other indications, excluding all immune and inflammatory mediated diseases or conditions and all psychiatric or psychological diseases or conditions, in the United States and outside the United States.

The collaboration provides Janssen with an exclusive license to commercialize IMBRUVICA outside of the United States and co-exclusively with AbbVie in the United States. Both parties are responsible for the development, manufacturing and marketing of any products generated as a result of the collaboration. The collaboration has no set duration or specific expiration date and provides for potential future development, regulatory and approval milestone payments of up to \$200 million to AbbVie. The collaboration also includes a cost sharing arrangement for associated collaboration activities. Except in certain cases, Janssen is responsible for approximately 60% of collaboration development costs and AbbVie is responsible for the remaining 40% of collaboration development costs.

In the United States, both parties have co-exclusive rights to commercialize the products; however, AbbVie is the principal in the end-customer product sales. AbbVie and Janssen share pre-tax profits and losses equally from the commercialization of products. Sales of IMBRUVICA are included in AbbVie's net revenues. Janssen's share of profits is included in AbbVie's cost of products sold. Other costs incurred under the collaboration are reported in their respective expense line items, net of Janssen's share.

Outside the United States, Janssen is responsible for and has exclusive rights to commercialize IMBRUVICA. AbbVie and Janssen share pre-tax profits and losses equally from the commercialization of products. AbbVie's share of profits

is included in AbbVie's net revenues. Other costs incurred under the collaboration are reported in their respective expense line items, net of Janssen's share.

The following table shows the profit and cost sharing relationship between Janssen and AbbVie:

years ended December 31 (in millions)	2018	2017	2016
United States - Janssen's share of profits (included in cost of products sold)	\$ 1,372	\$ 1,001	\$ 735
International - AbbVie's share of profits (included in net revenues)	622	429	252
Global - AbbVie's share of other costs (included in respective line items)	326	288	262

AbbVie's receivable from Janssen, included in accounts receivable, net, was \$177 million at December 31, 2018 and \$124 million at December 31, 2017. AbbVie's payable to Janssen, included in accounts payable and accrued liabilities, was \$376 million at December 31, 2018 and \$253 million at December 31, 2017.

Note 7 Goodwill and Intangible Assets

#### Goodwill

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

(in millions)

Balance as of December 31, 2016