BIOGEN INC.
Form 10-K
February 02, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number: 0-19311
BIOGEN INC.
(Exact name of registrant as specified in its charter)

| Delaware | 33-0112644 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

225 Binney Street, Cambridge, Massachusetts 02142
(617) 679-2000
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)
Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, $0.0005 par value | The Nasdaq Global Select Market |

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No x
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 x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| Large accelerated filer x | Accelerated filer o | Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o |
|---|---|---|---|

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x
The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at

which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $52,843,669,823.

As of January 27, 2017, the registrant had 215,951,945 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the "Safe Harbor" provisions of the Act. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of revenues, contingent payments, milestone, royalty and other payments under licensing, collaboration or acquisition agreements, tax positions and contingencies, collectability of receivables, pre-approval inventory, cost of sales, research and development costs, compensation and other selling, general and administrative expenses, amortization of intangible assets, foreign currency exchange risk, estimated fair value of assets and liabilities, and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete;
- the spin off of our hemophilia business, including its anticipated benefits, costs and tax treatment;
- the anticipated amount and timing of payments under the Settlement and License Agreement with Forward Pharma A/S (Forward Pharma) and the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary intellectual property rights under our agreement with Forward Pharma;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- the costs and timing of potential clinical trials, filing and approvals, and the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- the drivers for growing our business, including our plans and intent to commit resources relating to business development opportunities and research and development programs;
- potential costs and expenses incurred in connection with corporate restructurings and to execute business transformation and optimization initiatives;
- our manufacturing capacity, use of third-party contract manufacturing organizations and plans and timing relating to the expansion of our manufacturing capabilities, including anticipated investments and activities in new manufacturing facilities;
- the expected financial impact of ceasing manufacturing activities and vacating our biologics manufacturing facility in Cambridge, MA and warehouse space in Somerville, MA;
- the potential impact on our results of operations and liquidity of the United Kingdom's (U.K.'s) intent to voluntarily depart from the European Union (E.U.);
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs to constrain the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- our ability to finance our operations and business initiatives and obtain funding for such activities; and
- the impact of new laws and accounting standards.

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These forward-looking statements involve risks and uncertainties, including those that are described in the "Risk Factors" section of this report and elsewhere in this report, that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

- "Biogen," the "company," "we," "us" and "our" refer to Biogen Inc. and its consolidated subsidiaries;
- "RITUXAN" refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan);
- "ELOCTATE" refers to both ELOCTATE (the trade name for Antihemophilic Factor (Recombinant), Fc Fusion Protein in the U.S., Canada and Japan) and ELOCTA (the trade name for Antihemophilic Factor (Recombinant), Fc Fusion Protein in the E.U.); and
- "ANGIOMAX" refers to both ANGIOMAX (the trade name for bivalirudin in the U.S., Canada and Latin America) and ANGIOX (the trade name for bivalirudin in Europe).

NOTE REGARDING TRADEMARKS

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PART I

Item 1. Business

Overview

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to people living with serious neurological, rare and autoimmune diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), FUMADERM for the treatment of severe plaque psoriasis and SPINRAZA for the treatment of spinal muscular atrophy (SMA). We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group (Roche Group).

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within areas of our scientific, manufacturing and technical capabilities. For nearly two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as the development of next generation therapies for MS, with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (ALS), and are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy.

Our innovative drug development and commercialization activities are complemented by our biosimilar therapies that expand access to medicines and reduce the cost burden for healthcare systems. We are leveraging our manufacturing capabilities and know-how to develop, manufacture and market biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics). Under this agreement, we are currently manufacturing and commercializing two anti-tumor necrosis factor (TNF) biosimilars in certain European Union (E.U.) countries.

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Key Developments

During 2016 we had a number of key developments affecting our business.

Corporate Matters

Hemophilia Spin-Off

In May 2016 we announced our intention to spin off our hemophilia business, Bioverativ Inc. (Bioverativ), as an independent, publicly traded company. Bioverativ will focus on the discovery, development and commercialization of therapies for treatment of hemophilia and other blood disorders, including ELOCTATE for the treatment of hemophilia A and ALPROLIX for the treatment of hemophilia B. Bioverativ will also assume all of our rights and obligations under our collaboration agreement with Swedish Orphan Biovitrum AB (Sobi) and our collaboration and license agreement with Sangamo Biosciences Inc. (Sangamo).

On February 1, 2017, we completed the distribution of all the then outstanding shares of common stock of Bioverativ to Biogen stockholders, who received one share of Bioverativ common stock for every two shares of Biogen common stock. As a result of the distribution, Bioverativ is now an independent public company whose shares of common stock are trading under the symbol "BIVV" on the Nasdaq Global Select Market.

The financial results of Bioverativ are included in our consolidated results of operations and financial position in our audited consolidated financial statements for the periods presented in this Form 10-K. The financial results of Bioverativ will be excluded from our consolidated results of operations and financial position commencing February 1, 2017. For additional information regarding the separation of Bioverativ, please read Note 26, Subsequent Events to our consolidated financial statements included in this report.

Management Changes

During 2016 we appointed several new executives, each of whom has significant experience in the biopharmaceutical industry and is a leader in his or her functional area. These include Michel Vounatsos, Chief Executive Officer, Michael D. Ehlers, Executive Vice President, Research and Development and Paul McKenzie, Executive Vice President, Pharmaceutical Operations and Technology. For additional information related to these and our other Executive Officers, please read "Our Executive Officers" included in this report.

Cost Saving Initiatives

In 2016 we initiated cost saving measures intended to realign our organizational structure in anticipation of the changes in roles and workforce resulting from our decision to spin off our hemophilia business, as well as to achieve further targeted cost reductions.

In December 2016 after an evaluation of our manufacturing capacity and needs, we ceased manufacturing at our Cambridge, MA manufacturing facility and subleased our rights to this facility to Brammer Bio MA, LLC (Brammer). In addition to the sublease, Brammer purchased certain leasehold improvements and other assets at this facility and agreed to provide certain manufacturing and other transition and support services to us.

TECFIDERA Settlement and License Agreement

In January 2017 we agreed to enter into a settlement and license agreement with Forward Pharma A/S (Forward Pharma). The settlement and license agreement provides us an irrevocable license to all intellectual property owned by Forward Pharma and results in the termination of the German Infringement Litigation. Under the terms of the settlement and license agreement with Forward Pharma, we agreed to pay Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016 we recognized a pre-tax charge of $454.8 million related to this matter. For more information on the settlement and license agreement please read Note 21, Commitments and Contingencies to our consolidated financial statements included in this report.

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Product/Pipeline Developments

Multiple Sclerosis

TYSABRI (natalizumab)

- In June 2016 the European Commission (EC) approved a variation to the marketing authorization of TYSABRI, which extended its indication to include relapsing-remitting MS patients with highly active disease activity despite a full and adequate course of treatment with at least one disease modifying therapy. TYSABRI was previously indicated only for patients who had failed to respond to beta-interferon or glatiramer acetate in the E.U.

ZINBRYTA (daclizumab)

- ZINBRYTA was approved for the treatment of relapsing forms of MS in the U.S. in May 2016 and the E.U. in July 2016.

Opicinumab (Anti-LINGO-1)

- In June 2016 we reported top-line results from SYNERGY, our Phase 2 trial evaluating opicinumab in people with relapsing forms of MS. Opicinumab did not meet the primary endpoint or its secondary efficacy endpoint. However, based on these results, there was a subset of patients within the study that we believe have potential to benefit from treatment, and we are therefore planning another Phase 2 clinical trial related to opicinumab.

Neurodegeneration

Aducanumab (BIIB037)

- In June 2016 we announced that aducanumab, our investigational treatment for early Alzheimer’s disease, was accepted into the European Medicines Agency's (EMA's) Priority Medicines (PRIME) program. PRIME aims to bring treatments to patients more quickly by enhancing the EMA's support for the development of investigational medicines for diseases without available treatments or in need of better treatment options.

- In September 2016 aducanumab was granted "Fast Track" designation by the U.S. Food and Drug Administration (FDA). The FDA’s Fast Track program supports the development of new treatments for serious conditions with an unmet medical need such as Alzheimer’s disease.

- In September 2016 we announced that efficacy and safety data from an additional interim analysis from our Phase 1b study of aducanumab in early Alzheimer's disease were consistent with results previously reported from the Phase 1b study.

- In December 2016 we presented new data from the Phase 1b study of aducanumab, which included interim results from the titration cohort of the placebo-controlled period of the Phase 1b study as well as data from the first year of the long-term extension. The results supported the ongoing Phase 3 studies of aducanumab for early Alzheimer’s disease.

Rare Diseases

SPINRAZA (nusinersen)

- In August 2016 we and Ionis Pharmaceuticals, Inc. (Ionis) announced that SPINRAZA met the primary endpoint for the interim analysis of ENDEAR, the Phase 3 trial evaluating SPINRAZA in infantile-onset (consistent with Type 1) SMA. Based on these results, we exercised our option under our collaboration agreement with Ionis to assume development and commercialization of SPINRAZA, and paid Ionis a $75.0 million license fee in connection with our option exercise.

- In September 2016 we completed the rolling submission of a New Drug Application (NDA) to the FDA for the approval of SPINRAZA, and in October 2016 we filed a marketing authorization application (MAA) with the EMA, which had already granted Accelerated Assessment status to SPINRAZA. These applications have been accepted for review by the applicable regulatory authorities.

- In October 2016 we dosed our first patient in our infantile-onset SMA Expanded Access Program to provide patient access to SPINRAZA.

- In November 2016 we and Ionis announced that SPINRAZA met the primary endpoint for the interim analysis of CHERISH, the Phase 3 trial evaluating SPINRAZA in later-onset (consistent with Type 2) SMA. The analysis found that children receiving SPINRAZA experienced a highly statistically significant improvement in motor function compared to those who did not receive treatment. SPINRAZA demonstrated a favorable safety profile in the study.

- In December 2016 SPINRAZA was approved by the FDA for the treatment of SMA in pediatric and adult patients in the U.S. The FDA also issued us a rare pediatric disease priority review voucher with the approval of SPINRAZA, which confers priority review to a subsequent drug application that would not otherwise qualify for priority review.

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Biosimilars (Samsung Bioepis - Biogen's Joint Venture with Samsung Biologics)

BENEPALI

- In January 2016 the EC approved Samsung Bioepis' MAA for BENEPALI, an etanercept biosimilar referencing ENBREL, for marketing in the E.U. Under our agreement with Samsung Bioepis, we are manufacturing and commercializing BENEPALI in specified E.U. countries.

FLIXABI

- In May 2016 the EC approved Samsung Bioepis' MAA for FLIXABI, an infliximab biosimilar candidate referencing REMICADE, for marketing in the E.U. Under our agreement with Samsung Bioepis, we are manufacturing and commercializing FLIXABI in specified E.U. countries.

Adalimumab (SB5)

- In July 2016 the EMA accepted Samsung Bioepis' MAA for SB5, an adalimumab biosimilar candidate referencing HUMIRA.

Genentech Relationships

GAZYVA (obinutuzumab)

- In February 2016 the Roche Group announced that the FDA approved GAZYVA plus bendamustine chemotherapy followed by GAZYVA alone as a new treatment for people with follicular lymphoma who did not respond to a RITUXAN-containing regiment, or whose follicular lymphoma returned after such treatment.

- In May 2016 the Roche Group announced positive results from the Phase 3 GALLIUM study, which investigated the efficacy and safety of GAZYVA in combination with chemotherapy followed by maintenance with GAZYVA alone, compared to RITUXAN in combination with chemotherapy followed by maintenance with RITUXAN alone in previously untreated patients with follicular lymphoma. Results from pre-planned interim analysis showed that GAZYVA-based treatment significantly reduced the risk of disease worsening or death compared to RITUXAN-based treatment.

- In July 2016 the Roche Group announced that the Phase 3 GOYA study evaluating GAZYVA plus CHOP chemotherapy in people with previously untreated diffuse large B-cell lymphoma did not meet its primary endpoint of significantly reducing the risk of disease worsening or death compared to RITUXAN plus CHOP chemotherapy. Adverse events with GAZYVA and RITUXAN were consistent with those seen in previous clinical trials when each was combined with various chemotherapies.

OCREVUS (ocrelizumab)

- In June 2016 the Roche Group announced that the EMA validated its MAA of OCREVUS for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS) in the E.U. The FDA has also accepted for review the Roche Group's Biologics License Application (BLA) for OCREVUS for the treatment of RMS and PPMS.

RITUXAN (rituximab)

- In November 2016 Genentech announced the FDA accepted its BLA for a subcutaneous formulation of RITUXAN.

Discontinued Programs

- During 2016 we discontinued development of amiselimod (MT-1303) under our agreement with Mitsubishi Tanabe Pharma Corporation, and IONIS-DMPK$_{Rx}$ under one of our collaboration agreements with Ionis. Additionally, we terminated our collaboration agreements with Rodin Therapeutics, Inc. and Ataxion Inc.

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Marketed Products

The following graphs show our revenues by product and revenues from anti-CD20 therapeutic programs and geography as a percentage of revenue for the years ended December 31, 2016, 2015 and 2014.

(1) Interferon includes AVONEX and PLEGRIDY

(2) Other includes ZINBRYTA, FAMPYRA, ELOCTATE, ALPROLIX, FUMADERM, SPINRAZA, BENEPALI and FLIXABI

Product sales for TECFIDERA, AVONEX and TYSABRI and anti-CD20 therapeutic programs for RITUXAN each accounted for more than 10% of our total revenue for the years ended December 31, 2016, 2015 and 2014. For additional financial information about our product and other revenues and geographic areas in which we operate, please read Note 24, Segment Information to our consolidated financial statements, Item 6. Selected Financial Data and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations included in this report. A discussion of the risks attendant to our operations is set forth in the “Risk Factors” section of this report.

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Multiple Sclerosis

We develop, manufacture and market a number of products designed to treat patients with MS. MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active relapsing MS experience an uneven pattern of disease progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning.

Our MS products and major markets include:

| Product | Indication | Collaborator | Major Markets |
|---|---|---|---|
| | Relapsing forms of MS in the U.S.<br><br>Relapsing-remitting MS (RRMS) in the E.U. | None | U.S.<br>France<br>Germany<br>Italy<br>Spain<br>United Kingdom |
| | Relapsing forms of MS | None | U.S.<br>France<br>Germany<br>Italy<br>Spain<br>United Kingdom |
| | Relapsing forms of MS in the U.S.<br><br>RRMS in the E.U. | None | U.S.<br>France<br>Germany<br>Italy<br>Spain<br>United Kingdom |
| | Relapsing forms of MS<br><br>Crohn's disease in the U.S. | None | U.S.<br>France<br>Germany<br>Italy<br>Spain<br>United Kingdom |
| | Relapsing forms of MS | AbbVie Inc. (AbbVie) | U.S.<br>Germany |
| | Walking ability for patients with MS | Acorda Therapeutics, Inc. (Acorda) | France<br>Germany<br>Spain |

Spinal Muscular Atrophy

SMA is characterized by loss of motor neurons in the spinal cord and lower brain stem, resulting in severe and progressive muscular atrophy and weakness. Ultimately, individuals with the most severe type of SMA can become paralyzed and have difficulty performing the basic functions of life, like breathing and swallowing. Due to a loss of, or defect in the SMN1 gene, people with SMA do not produce enough survival motor neuron (SMN) protein, which is

critical for the maintenance of motor neurons. The severity of SMA correlates with the amount of SMN protein. People with Type 1 SMA, the most severe life-threatening form, produce very little SMN protein and do not achieve the ability to sit without support or live beyond two years without respiratory support. People with Type 2 and Type 3 produce greater amounts of SMN protein and have less severe, but still life-altering, forms of SMA.

In December 2016 the FDA approved SPINRAZA for the treatment of SMA in pediatric and adult patients. We are currently in the early stages of commercial launch in the U.S.

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Our products for SMA and major markets include:

| Product | Indication | Collaborator | Major Markets |
|---|---|---|---|
| | Spinal muscular atrophy | Ionis | U.S. |

Other

| Product | Indication | Collaborator | Major Markets |
|---|---|---|---|
| | Moderate to severe plaque psoriasis | None | Germany |

Biosimilars

Biosimilars are a group of biologic medicines that are similar to currently available biologic therapies known as originators. Under our agreement with Samsung Bioepis, we manufacture and commercialize two anti-TNF biosimilars in certain countries in the E.U.: BENEPALI, an etanercept biosimilar referencing ENBREL and FLIXABI, an infliximab biosimilar referencing REMICADE:

| Product | Indication | Major Markets |
|---|---|---|
| | Moderate to severe rheumatoid arthritis<br>Progressive psoriatic arthritis<br>Axial spondyloarthritis<br>Moderate to severe plaque psoriasis | Denmark<br>Germany<br>Netherlands<br>Norway<br>United Kingdom |
| | Rheumatoid arthritis<br>Moderate to severe Crohn's disease<br>Severe ulcerative colitis<br>Severe ankylosing spondylitis<br>Psoriatic arthritis<br>Moderate to severe plaque psoriasis | Germany<br>Netherlands<br>United Kingdom |

Genentech Relationships

We have a collaboration agreement with Genentech that entitles us to certain business and financial rights with respect to RITUXAN, GAZYVA and other anti-CD20 product candidates. Current products include:

| Product | Indication | Major Markets |
|---|---|---|
| | Non-Hodgkin's lymphoma<br>CLL<br>Rheumatoid arthritis<br>Two forms of ANCA-associated vasculitis | U.S.<br>Canada |
| | In combination with chlorambucil for previously untreated CLL<br>Follicular lymphoma | U.S. |

For information about our anti-CD20 therapeutic programs and related agreements with Genentech, please read Note 1, Summary of Significant Accounting Policies and Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Patient Support and Access

We interact with patients, advocacy organizations and healthcare societies in order to gain insights into unmet needs. The insights gained from these engagements help us support patients with services, programs and applications that are designed to help patients lead better lives. Among other things, we provide customer service and other related programs for our products, such as disease and product specific websites, insurance research services, financial assistance programs, and the facilitation of the procurement of our marketed products.

We are dedicated to helping patients obtain access to our therapies. Our patient representatives have access to a comprehensive suite of financial assistance tools. With those tools, we help patients understand their insurance coverage and, if needed, help patients compare and select new insurance options and programs. In the U.S., we have established programs that provide co-pay assistance or free marketed product for qualified uninsured or underinsured patients, based on specific eligibility criteria. We also provide charitable contributions to independent charitable organizations that assist patients with out-of-pocket expenses associated with their therapy.

Marketing and Distribution

Sales Force and Marketing

We promote our products worldwide, including in the U.S., most of the major countries of the E.U. and Japan, primarily through our own sales forces and marketing groups. In some countries, particularly in areas where we continue to expand into new geographic areas, we partner with third parties. We co-promote ZINBRYTA with AbbVie in the U.S., E.U. and Canadian territories.

We focus our sales and marketing efforts on specialist physicians in private practice or at major medical centers. We use customary pharmaceutical company practices to market our products and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, direct mail, public relations and other methods.

Distribution Arrangements

We distribute our products in the U.S. principally through wholesale distributors of pharmaceutical products, mail order specialty distributors or shipping service providers. In other countries, the distribution of our products varies from country to country, including through wholesale distributors of pharmaceutical products and third-party distribution partners who are responsible for most marketing and distribution activities.

AbbVie distributes ZINBRYTA in the U.S., and we distribute ZINBRYTA in ex-U.S. markets.

RITUXAN and GAZYVA are marketed and distributed by the Roche Group and its sublicensees.

Our product sales to two wholesale distributors, AmerisourceBergen and McKesson, each accounted for more than 10% of our total revenues for the years ended December 31, 2016, 2015 and 2014, and on a combined basis, accounted for approximately 60% of our gross product revenues for such years, respectively. For additional information, please read Note 1, Summary of Significant Accounting Policies to our consolidated financial statements included in this report.

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Patents and Other Proprietary Rights

Patents are important to obtaining and protecting exclusive rights in our products and product candidates. We regularly seek patent protection in the U.S. and in selected countries outside the U.S. for inventions originating from our research and development efforts. In addition, we license rights to various patents and patent applications.

U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest application was filed; however, U.S. patents that issue on applications filed before June 8, 1995 may be effective until 17 years from the issue date, if that is later than the 20 year date. In some cases, the patent term may be extended to recapture a portion of the term lost during regulatory review of the claimed therapeutic or, in the case of the U.S., because of U.S. Patent and Trademark Office (USPTO) delays in prosecuting the application. Specifically, in the U.S., under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, a patent that covers an FDA-approved drug may be eligible for patent term extension (for up to five years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. The duration and extension of the term of foreign patents varies, in accordance with local law. For example, supplementary protection certificates (SPCs) on some of our products have been granted in a number of European countries, compensating in part for delays in obtaining marketing approval.

Regulatory exclusivity, which may consist of regulatory data protection and market protection, also can provide meaningful protection for our products. Regulatory data protection provides to the holder of a drug or biologic marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it created at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. After the applicable set period of time, third parties are then permitted to rely upon our data to file for approval of their abbreviated applications for, and to market (subject to any applicable market protection), their generic drugs and biosimilars referencing our data. Market protection provides to the holder of a drug or biologic marketing authorization the exclusive right to commercialize its product for a set period of

time, thereby preventing the commercialization of another product containing the same active ingredient(s) during that period. Although the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory exclusivity to innovative pharmaceutical products, implementation and enforcement varies widely from country to country.

We also rely upon other forms of unpatented confidential information to remain competitive. We protect such information principally through confidentiality agreements with our employees, consultants, outside scientific collaborators, scientists whose research we sponsor and other advisers. In the case of our employees, these agreements also provide, in compliance with relevant law, that inventions and other intellectual property conceived by such employees during their employment shall be our exclusive property.

Our trademarks are important to us and are generally covered by trademark applications or registrations in the USPTO and the patent or trademark offices of other countries. We also use trademarks licensed from third parties, such as the trademark FAMPYRA which we license from Acorda. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Our Patent Portfolio

The following table describes our patents in the U.S. and Europe that we currently consider of primary importance to our marketed products, including the territory, patent number, general subject matter and expected expiration dates. Except as otherwise noted, the expected expiration dates include any granted patent term extensions and issued SPCs. In some instances, there are later-expiring patents relating to our products directed to, among other things, particular forms or compositions, methods of manufacturing, or use of the drug in the treatment of particular diseases or conditions. We also continue to pursue additional patents and patent term extensions in the U.S. and other territories covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table.

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| Product | Territory | Patent No. | General Subject Matter | Patent Expiration[1] |
|---|---|---|---|---|
| TECFIDERA | U.S. | 7,619,001 | Methods of treatment | 2018 |
| | U.S. | 7,803,840 | Methods of treatment | 2018 |
| | U.S. | 8,399,514 | Methods of treatment | 2028 |
| | U.S. | 8,524,773 | Methods of treatment | 2018 |
| | U.S. | 6,509,376 | Formulations of dialkyl fumarates for use in the treatment of autoimmune diseases | 2019 |
| | U.S. | 8,759,393 | Formulations | 2019 |
| | U.S. | 7,320,999 | Methods of treatment | 2020 |
| | Europe | 1131065 | Formulations of dialkyl fumarates and their use for treating autoimmune diseases | 2019[2] |
| | Europe | 2137537 | Methods of use | 2028[3] |
| AVONEX and PLEGRIDY | U.S. | 7,588,755 | Use of recombinant beta interferon for immunomodulation | 2026 |
| PLEGRIDY | U.S. | 7,446,173 | Polymer conjugates of interferon beta-1a | 2022 |
| | U.S. | 8,524,660 | Methods of treatment | 2023 |
| | U.S. | 8,017,733 | Polymer conjugates of interferon beta-1a | 2025 |
| | Europe | 1656952 | Polymer conjugates of interferon-beta-1a and uses thereof | 2019 |
| | Europe | 1476181 | Polymer conjugates of interferon-beta-1a and uses thereof | 2023 |
| TYSABRI | U.S. | 5,840,299 | Humanized immunoglobulins; nucleic acids; pharmaceutical compositions; methods of use | 2017 |
| | U.S. | 6,602,503 | Humanized recombinant antibodies; nucleic acids and host cells; processes for production; therapeutic compositions; methods of use | 2020 |
| | U.S. | 7,807,167 | Methods of treatment | 2023 |
| | U.S. | 9,493,567 | Methods of treatment | 2027 |
| | Europe | 0804237 | Humanized immunoglobulins; nucleic acids; pharmaceutical compositions; medical uses | 2020[4] |
| | Europe | 1485127 | Methods of use | 2023 |
| FAMPYRA | Europe | 1732548 | Sustained-release aminopyridine compositions for increasing walking speed in patients with MS | 2025[5] |
| | Europe | 23775536 | Sustained-release aminopyridine compositions for treating MS | 2025[6] |
| ZINBRYTA | U.S. | 8,454,965 | Methods of treatment | 2024 |
| | U.S. | 7,258,859 | Methods of treatment | 2024 |
| | U.S. | 9,340,619 | Daclizumab HYP compositions | 2032 |
| | Europe | 1539200 | Anti-IL-2-receptor antibody for use in a method of treating a subject with MS | 2023 |
| SPINRAZA | U.S. | 6,166,197 | Oligomeric Compounds Having Pyrimidine Nucleotide(s) | 2017 |
| | U.S. | 6,210,892 | Alteration of Cellular Behavior By Antisense Modulation of MRNA Processing | 2018 |
| | U.S. | 7,101,993 | Oligonucleotides Containing 2’-O-Modified Purines | 2023 |
| | U.S. | 7,838,657 | SMA Treatment Via Targeting of SMN2 Splice Site Inhibitory Sequences | 2027 |
| | U.S. | 8,110,560 | SMA Treatment Via Targeting of SMN2 Splice Site Inhibitory Sequences | 2025 |
| | U.S. | 8,361,977 | Compositions And Methods For Modulation of SMN2 Splicing | 2030 |
| | U.S. | 8,980,853 | | 2030 |

| | | | |
|---|---|---|---|
| | | Compositions And Methods For Modulation of SMN2 Splicing | |
| Europe | 1910395 | Compositions And Methods For Modulation of SMN2 Splicing | 2026 |
| Europe | 2548560 | Compositions And Methods For Modulation of SMN2 Splicing | 2026 |

Footnotes follow on next page.

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(1) In addition to patent protection, certain of our products are entitled to regulatory exclusivity in the U.S. and the E.U. expected until the dates set forth below:

| Product | Territory | Expected Expiration |
|---|---|---|
| TECFIDERA | U.S. | 2018 |
| | E.U. | 2024 |
| PLEGRIDY | U.S. | 2026 |
| | E.U. | 2024 |
| TYSABRI | U.S. | 2016 |
| | E.U. | 2016 |
| FAMPYRA | E.U. | 2021 |
| ZINBRYTA | U.S. | 2028 |
| | E.U. | * |
| SPINRAZA | U.S. | 2023 |

*ZINBRYTA was not designated a new active substance at the time of its approval in the E.U. and is not automatically entitled to regulatory exclusivity. Regulatory exclusivity may, however, be available for independent development of known active substances. We intend to assert the protection of its data on this basis.

(2) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2024.

(3) This patent was revoked in a European opposition. This decision is being appealed. The patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2029.

(4) Reflects SPCs granted in most European countries.

(5) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2026.

(6) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2026.

The existence of patents does not guarantee our right to practice the patented technology or commercialize the patented product. Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes, such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our patents, regulatory exclusivities or other proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patents, regulatory exclusivities and other proprietary rights covering our products by manufacturers of generics and biosimilars. A discussion of certain risks and uncertainties that may affect our patent position, regulatory exclusivities and other proprietary rights is set forth in the “Risk Factors” section of this report, and a discussion of legal proceedings related to certain patents described above is set forth in Note 20, Litigation to our consolidated financial statements included in this report.

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Competition

Competition in the biopharmaceutical industry is intense and comes from many sources, including specialized biotechnology firms and large pharmaceutical companies. Many of our competitors are working to develop products similar to those we are developing or already market and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Certain of these companies have substantially greater financial, marketing and research and development resources than we do.

We believe that competition and leadership in the industry is based on managerial and technological excellence and innovation as well as establishing patent and other proprietary positions through research and development. The achievement of a leadership position also depends largely upon our ability to maximize the approval, acceptance and use of products resulting from research and the availability of adequate financial resources to fund facilities, equipment, personnel, clinical testing, manufacturing and marketing. Another key aspect of remaining competitive within the industry is recruiting and retaining leading scientists and technicians. We believe that we have been successful in attracting and retaining skilled and experienced scientific personnel.

Competition among products approved for sale may be based, among other things, on patent position, product efficacy, safety, convenience/delivery devices, reliability, availability and price. In addition, early entry of a new pharmaceutical product into the market may have important advantages in gaining product acceptance and market share. Accordingly, the relative speed with which we can develop products, complete the testing and approval process and supply commercial quantities of products will have a significant impact on our competitive position.

The introduction of new products or technologies, including the development of new processes or technologies by competitors or new information about existing products or technologies, may result in increased competition for our marketed products or pricing pressure on our marketed products. It is also possible that the development of new or improved treatment options or standards of care or cures for the diseases our products treat could reduce or eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. We may also face increased competitive pressures as a result of generics and the emergence of biosimilars in the U.S. and E.U. If a generic or biosimilar version of one of our products were approved, it could reduce our sales of that product.

Additional information about the competition that our marketed products face is set forth below.

Multiple Sclerosis

TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and ZINBRYTA each compete with one or more of the following products:

| Competing Product | Competitor |
|---|---|
| AUBAGIO (teriflunomide) | Sanofi |
| BETASERON/BETAFERON (interferon-beta-1b) | Bayer Group |
| COPAXONE (glatiramer acetate) | Teva Pharmaceuticals Industries Ltd. |
| EXTAVIA (interferon-beta-1b) | Novartis AG |
| GLATOPA (glatiramer acetate) | Sandoz, a division of Novartis AG |
| GILENYA (fingolimod) | Novartis AG |
| LEMTRADA (alemtuzumab) | Sanofi |
| REBIF (interferon-beta-1) | Merck KGaA (and co-promoted with Pfizer Inc. in the U.S.) |

FAMPYRA is indicated as a treatment to improve walking in adult patients with MS who have walking disability and is the first treatment that addresses this unmet medical need with demonstrated efficacy in people with all types of MS. FAMPYRA is currently the only therapy approved to improve walking in patients with MS.

Competition in the MS market is intense. Along with us, a number of companies are working to develop additional treatments for MS that may in the future compete with our MS products. One such product candidate is OCREVUS, a potential treatment for RMS and PPMS being developed by Genentech. While we have a financial interest in

OCREVUS, future sales of our MS products may be adversely affected by the commercialization of OCREVUS, as well as by other MS products we or our competitors are developing. Future sales may also be negatively impacted by the introduction of generics, prodrugs of existing therapeutics or biosimilars of existing products.

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Spinal Muscular Atrophy

SPINRAZA is the only approved treatment for SMA. We are aware of other products in development that, if successfully developed and approved, may compete with SPINRAZA in the SMA market.

Psoriasis

FUMADERM competes with several different types of therapies in the psoriasis market within Germany, including oral systemics such as methotrexate and cyclosporine.

Biosimilars

BENEPALI and FLIXABI, the two biosimilars we currently manufacture and commercialize in the E.U. for Samsung Bioepis, compete with their applicable reference products, ENBREL and REMICADE, respectively, as well as other biosimilars of those reference products.

Genentech Relationships in Other Indications

RITUXAN and GAZYVA in Oncology

RITUXAN and GAZYVA compete with a number of therapies in the oncology market, including TREANDA (bendamustine HCL), ARZERRA (ofatumumab), IMBRUVICA (ibrutinib) and ZYDELIG (idelalisib).

We also expect that over time GAZYVA will increasingly compete with RITUXAN in the oncology market. In addition, we are aware of other anti-CD20 molecules, including biosimilars, in development that, if successfully developed and approved, may compete with RITUXAN and GAZYVA in the oncology market.

RITUXAN in Rheumatoid Arthritis

RITUXAN competes with several different types of therapies in the rheumatoid arthritis market, including, among others, traditional disease-modifying anti-rheumatic drugs such as steroids, methotrexate and cyclosporine, TNF inhibitors, ORENCIA (abatacept), ACTEMRA (tocilizumab) and XELJANZ (tofacitinib).

We are also aware of other products, including biosimilars, in development that, if successfully developed and approved, may compete with RITUXAN in the rheumatoid arthritis market.

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Research and Development Programs

A commitment to research is fundamental to our mission. Our research efforts are focused on better understanding the underlying biology of diseases so we can discover and deliver treatments that have the potential to make a real difference in the lives of patients with high unmet medical needs. By applying our expertise in biologics and our growing capabilities in small molecule, antisense, gene therapy, gene editing and other technologies, we target specific medical needs where we believe new or better treatments are needed.

We intend to continue committing significant resources to research and development opportunities. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and technologies and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

The table below highlights our current research and development programs that are in clinical trials and the current phase of such programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in the “Risk Factors” section of this report.

| Product Candidate | Collaborator | PHASE 1 | PHASE 2 | PHASE 3 | FILED |
|---|---|---|---|---|---|
| OCREVUS | Genentech (Roche Group) | | | Primary Progressive & Relapsing Multiple Sclerosis | |
| Biosimilar adalimumab | Samsung Bioepis | | | Multiple Immunology Indications in Europe | |
| GAZYVA | Genentech (Roche Group) | | | Front-Line Indolent Non Hodgkin’s Lymphoma | |
| Aducanumab | Neurimmune SubOne AG | | Alzheimer's Disease | | |
| E2609 | Eisai Co., Ltd. (Eisai) | | Alzheimer's Disease | | |
| BIIB074 | None | | | Trigeminal Neuralgia | |
| BIIB074 | None | | | Lumbosacral Radiculopathy | |
| BIIB074 | None | | Erythromelalgia | | |
| BAN2401 | Eisai | | Alzheimer's Disease | | |
| Opicinumab (anti-LINGO-1) | None | | | Multiple Sclerosis | |
| TYSABRI | None | | | Acute Ischemic Stroke | |

| | | |
|---|---|---|
| rAAV-XLRS | AGTC | X-linked Juvenile Retinoschisis |
| BG00011 (STX-100) | None | Idiopathic Pulmonary Fibrosis |
| Dapirolizumab pegol | UCB Pharma | Lupus |
| BIIB059 (Anti-BDCA02) | None | Lupus |
| BIIB061 | None | MS |
| BIIB054 | None | PD* |
| BIIB067 (IONIS-SOD1$_{Rx)}$ | Ionis | ALS** |
| BIIB068 (BTK Inhibitor) | None | A*** |

* Parkinson's Disease
** Amyotrophic Lateral Sclerosis
*** Autoimmune

For information about certain of our agreements with collaborators and other third parties, please read the subsection entitled “Business Relationships” below and Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Late Stage Product Candidates

Additional information about our late stage product candidates, which includes programs in Phase 3 development or in registration stage, is set forth below.

Neurodegeneration

Aducanumab (BIIB037)

- In September 2015 we enrolled our first patient in our two global Phase 3 studies, ENGAGE and EMERGE. ENGAGE and EMERGE will assess the efficacy and safety of aducanumab, our investigational treatment for early Alzheimer's disease, in approximately 2,700 people with early Alzheimer's disease. The studies are identical in design and eligibility criteria. Each study will be conducted in more than 20 countries in North America, Europe and Asia. In October 2015 we announced that we received FDA agreement on a special protocol assessment on the Phase 3 study protocols.

- In June 2016 we announced that aducanumab was accepted into the European Medicines Agency's (EMA's) Priority Medicines (PRIME) program. PRIME aims to bring treatments to patients more quickly by enhancing the EMA's support for the development of investigational medicines for diseases without available treatments or in need of better treatment options.

- In September 2016 aducanumab was granted Fast Track designation by the FDA. The FDA’s Fast Track program supports the development of new treatments for serious conditions with an unmet medical need such as Alzheimer’s disease. We also announced that in a recently completed interim analysis from our Phase 1b study of aducanumab in early Alzheimer's disease efficacy and safety data were consistent with results previously reported.

- In December 2016 we presented new data from the Phase 1b study of aducanumab, which included interim results from the titration cohort of the placebo-controlled period of the Phase 1b study as well as data from the first year of the long-term extension. The results supported the ongoing Phase 3 studies of aducanumab for early Alzheimer’s disease.

E2609

- In October 2016 Eisai announced enrollment has commenced in MISSION AD, a Phase 3 clinical program of the beta secretase cleaving enzyme (BACE) inhibitor E2609 in patients with early Alzheimer's disease in the U.S.

Biosimilars (Samsung Bioepis - Biogen's Joint Venture with Samsung Biologics)

Adalimumab (SB5)

- In July 2016 the EMA accepted Samsung Bioepis' MAA for SB5, an adalimumab biosimilar candidate referencing HUMIRA. If approved by the EC, we will manufacture and commercialize SB5 in specified E.U. countries.

Genentech Relationships

GAZYVA (obinutuzumab)

- The Roche Group is managing GALLIUM, a Phase 3 study examining the efficacy and safety of GAZYVA plus chemotherapy followed by GAZYVA alone for up to two years, as compared head-to-head against RITUXAN plus chemotherapy followed by RITUXAN alone for up to two years. At a pre-planned interim analysis in May 2016, an independent data monitoring committee determined that the study met its primary endpoint early. The results showed GAZYVA-based treatment significantly reduced the risk of disease worsening or death (progression-free survival) compared to RITUXAN-based treatment.

OCREVUS (ocrelizumab)

- In June 2015 the Roche Group announced positive results from two Phase 3 studies evaluating OCREVUS compared with interferon beta-1a in people with relapsing forms of MS. Treatment with OCREVUS compared with interferon beta-1a significantly reduced the annualized relapse rate over a two-year period; significantly reduced the progression of clinical disability; and led to a significant reduction in the number of lesions in the brain as measured by MRI.

- In September 2015 the Roche Group announced positive results from a Phase 3 study evaluating OCREVUS in people with PPMS. Treatment with OCREVUS significantly reduced the progression of clinical disability compared with placebo, as measured by the Expanded Disability Status Scale.

- In June 2016 the Roche Group announced that the EMA validated its MAA of OCREVUS for the treatment of RMS and PPMS in the E.U. The FDA has also accepted for review its BLA for OCREVUS for the treatment of RMS and PPMS, and has granted the application priority review designation. Under our agreement with Genentech, if OCREVUS is approved, we will receive tiered royalty payments on sales of OCREVUS in the U.S.

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Business Relationships

As part of our business strategy, we establish business relationships, including joint ventures and collaborative arrangements with other companies, universities and medical research institutions, to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies, universities and medical research institutions.

Below is a brief description of certain business relationships and collaborations that expand our pipeline and provide us with certain rights to existing and potential new products and technologies. For more information regarding certain of these relationships, including their ongoing financial and accounting impact on our business, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

AbbVie, Inc.

We have a collaboration agreement with AbbVie aimed at advancing the development and commercialization of ZINBRYTA in MS. Under the agreement, we and AbbVie conduct ZINBRYTA co-promotion activities in the U.S., E.U. and Canadian territories, and we are responsible for manufacturing and research and development activities.

Acorda Therapeutics, Inc.

We collaborate with Acorda to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S. We also have responsibility for regulatory activities and the future clinical development of related products in those markets.

Applied Genetic Technologies Corporation

We have a collaboration agreement with Applied Genetic Technologies Corporation (AGTC) to develop gene-based therapies for multiple ophthalmic diseases. The collaboration focuses on the development of a clinical-stage candidate for X-linked Retinoschisis (XLRS) and a preclinical candidate for the treatment of X-linked Retinitis Pigmentosa (XLRP), for which we were granted worldwide commercialization rights. The agreement also provides us with options to early stage discovery programs in two ophthalmic diseases and one non-ophthalmic condition.

Eisai Co., Ltd.

We have a collaboration with Eisai to jointly develop and commercialize E2609 and BAN2401, two Eisai product candidates for the treatment of Alzheimer’s disease. Eisai serves as the global operational and regulatory lead for E2609 and BAN2401 and all costs, including research, development, sales and marketing expenses, are shared equally between us and Eisai. Following marketing approval in major markets, we will co-promote E2609 and BAN2401 with Eisai and share profits equally. In smaller markets, Eisai will distribute these products and pay us a royalty.

The agreement also provides Eisai with options to jointly develop and commercialize two of our candidates for Alzheimer’s disease, aducanumab and an anti-tau monoclonal antibody, upon the exchange or provision of clinical data. Upon exercise of the applicable option, we will execute a separate collaboration agreement with Eisai on terms and conditions that mirror the financial arrangements we have with Eisai with respect to E2609 and BAN2401.

Genentech (Roche Group)

We have a collaboration agreement with Genentech which entitles us to certain financial and other rights with respect to RITUXAN, GAZYVA and other anti-CD20 product candidates. Additionally, under our agreement with Genentech, if OCREVUS is approved, we will receive tiered royalty payments on sales of OCREVUS in the U.S.

Ionis Pharmaceuticals, Inc.

We have an exclusive, worldwide option and collaboration agreement with Ionis relating to the development and commercialization of up to three gene targets, and an exclusive worldwide option and collaboration agreement with Ionis under which both companies are developing and commercializing SPINRAZA for the treatment of SMA.

We also have a six-year research collaboration agreement with Ionis, under which both companies perform discovery level research and will develop and commercialize antisense and other therapeutics for the treatment of neurological disorders.

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Samsung Bioepis

We and Samsung Biologics established a joint venture, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. We also have an agreement with Samsung Bioepis to commercialize, over a 10-year term, three anti-TNF biosimilar product candidates in specified E.U. countries and, in the case of BENEPALI, Japan. Under this agreement, we are manufacturing and commercializing BENEPALI, an etanercept biosimilar referencing ENBREL and FLIXABI, an infliximab biosimilar referencing REMICADE.

In addition to our joint venture and commercialization agreement with Samsung Bioepis, we license certain of our proprietary technology to Samsung Bioepis in connection with Samsung Bioepis' development, manufacture and commercialization of its biosimilar products. We also provide technical development and technology transfer services to Samsung Bioepis, and manufacture clinical and commercial quantities of bulk drug substance of Samsung Bioepis' biosimilar products.

University of Pennsylvania

We have a collaboration and alliance with the University of Pennsylvania to advance gene therapy and gene editing technologies. The collaboration will primarily focus on the development of therapeutic approaches that target the eye, skeletal muscle and the central nervous system. The alliance is also expected to focus on the research and validation of next-generation gene transfer technology using adeno-associated virus gene delivery vectors and exploring the expanded use of genome editing technology as a potential therapeutic platform.

Regulatory

Our current and contemplated activities and the products, technologies and processes that result from such activities are subject to substantial government regulation.

Regulation of Pharmaceuticals

Product Approval and Post-Approval Regulation in the U.S.

APPROVAL PROCESS

Before new pharmaceutical products may be sold in the U.S., preclinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. With limited exceptions, the FDA requires companies to register both pre-approval and post-approval clinical trials and disclose clinical trial results in public databases. Failure to register a trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties. Clinical trial programs must establish efficacy, determine an appropriate dose and dosing regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. The results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a BLA or a NDA. In response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval.

Product development and receipt of regulatory approval takes a number of years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, potential safety signals observed in preclinical or clinical tests, and the risks and benefits of the product as demonstrated in clinical trials. The FDA has substantial discretion in the product approval process, and it is impossible to predict with any certainty whether and when the FDA will grant marketing approval. The agency may require the sponsor of a BLA or NDA to conduct additional clinical studies or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense. Furthermore, even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the existing pre-clinical or clinical data.

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The FDA has developed four distinct approaches intended to make therapeutically important drugs available as rapidly as possible, especially when the drugs are the first available treatment or have advantages over existing treatments: accelerated approval, fast track, breakthrough therapy and priority review.

- Accelerated Approval: The FDA may grant “accelerated approval” status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. Under the agency's accelerated approval regulations, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it may require certain post-marketing restrictions as necessary to assure safe use. In addition, for products approved under accelerated approval, sponsors may be required to submit all copies of their promotional materials, including advertisements, to the FDA at least thirty days prior to initial dissemination. The FDA may withdraw approval under accelerated approval after a hearing if, for instance, post-marketing studies fail to verify any clinical benefit, it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use, or if a sponsor fails to comply with the conditions of the accelerated approval.
- Fast Track Status: The FDA may grant "fast track" status to products that treat a serious condition and have data demonstrating the potential to address an unmet medical need or a drug that has been designated as a qualified infectious disease product.

- Breakthrough Therapy: The FDA may grant “breakthrough therapy” status to drugs designed to treat, alone or in combination with another drug or drugs, a serious or life-threatening disease or condition and for which preliminary clinical evidence suggests a substantial improvement over existing therapies. Such drugs need not address an unmet need, but are nevertheless eligible for expedited review if they offer the potential for an improvement. Breakthrough therapy status entitles the sponsor to earlier and more frequent meetings with the FDA regarding the development of nonclinical and clinical data and permits the FDA to offer product development or regulatory advice for the purpose of shortening the time to product approval. Breakthrough therapy status does not guarantee that a product will be developed or reviewed more quickly and does not ensure FDA approval.
- Priority Review: Priority Review only applies to applications (original or efficacy supplement) for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority Review may also be granted for any supplement that proposes a labeling change due to studies completed in response to a written request from FDA for pediatric studies, for an application for a drug that has been designated as a qualified infectious disease product, or any application or supplement for a drug submitted with a priority review voucher.

POST-MARKETING STUDIES

Regardless of the approval pathway employed, the FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. If a sponsor fails to conduct the required studies, the agency may withdraw its approval. In addition, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it can mandate post-marketing restrictions as necessary to assure safe use. In such a case, the sponsor may be required to establish rigorous systems to assure use of the product under safe conditions. These systems are usually referred to as Risk Evaluation and Mitigation Strategies (REMS). The FDA can impose financial penalties for failing to comply with certain post-marketing commitments, including REMS. In addition, any changes to an approved REMS must be reviewed and approved by the FDA prior to implementation.

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ADVERSE EVENT REPORTING

We monitor information on side effects and adverse events reported during clinical studies and after marketing approval and report such information and events to regulatory agencies. Non-compliance with the FDA's safety reporting requirements may result in civil or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials), or suspend or withdraw approval of the product. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

APPROVAL OF CHANGES TO AN APPROVED PRODUCT

If we seek to make certain types of changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, the FDA will need to review and approve such changes in advance. In the case of a new indication, we are required to demonstrate with additional clinical data that the product is safe and effective for a use other than that initially approved. FDA regulatory review may result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

REGULATION OF PRODUCT ADVERTISING AND PROMOTION

The FDA regulates all advertising and promotion activities and communications for products under its jurisdiction both before and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. However, physicians may prescribe legally available drugs for uses that are not described in the drug's labeling. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the government.

Regulation of Combination Products

Combination products are defined by the FDA to include products comprising two or more regulated components (e.g., a biologic and a device). Biologics and devices each have their own regulatory requirements, and combination products may have additional requirements. Some of our marketed products meet this definition and are regulated under this framework and similar regulations outside the U.S., and we expect that some of our pipeline product candidates may be evaluated for regulatory approval under this framework as well.

Product Approval and Post-Approval Regulation Outside the U.S.

We market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, for example, where a substantial part of our ex-U.S. efforts are focused, there are several tracks for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing application is similar to the NDA or BLA in the U.S. and is evaluated by the Committee for Medicinal Products for Human Use (CHMP), the expert scientific committee of the EMA. If the CHMP determines that the marketing application fulfills the requirements for quality, safety, and efficacy, it will submit a favorable opinion to the EC. The CHMP opinion is not binding, but is typically adopted by the EC. A marketing application approved by the EC is valid in all member states. The centralized procedure is required for all biological products, orphan medicinal products, and new treatments for neurodegenerative disorders, and it is available for certain other products, including those which constitute a significant therapeutic, scientific or technical innovation.

In addition to the centralized procedure, Europe also has:

- a nationalized procedure, which requires a separate application to and approval determination by each country;
- a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and

- a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision.

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Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection, and evaluation of adverse events post-approval, including national authorities, the EMA, the EC, and the marketing authorization holder. In some regions, it is possible to receive an "accelerated" review whereby the national regulatory authority will commit to truncated review timelines for products that meet specific medical needs.

Good Manufacturing Practices

Regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing and testing of pharmaceutical and biologic products prior to approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required. We also must adhere to current Good Manufacturing Practices (cGMP) and product-specific regulations enforced by regulatory agencies following product approval. The FDA, the EMA and other regulatory agencies also conduct periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions or remedies against us, including significant financial penalties and the suspension of our manufacturing operations.

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected (commonly referred to as current Good Clinical Practices (cGCP)). Regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites, contract research organizations (CROs), and institutional review boards. If our studies fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third parties, including CROs, to carry out many of our clinical trial-related activities. Failure of such third parties to comply with cGCP can likewise result in rejection of our clinical trial data or other sanctions.

Approval of Biosimilars

The Patient Protection and Affordable Care Act (PPACA) amended the Public Health Service Act (PHSA) to authorize the FDA to approve biological products, referred to as biosimilars or follow-on biologics, that are shown to be highly similar to previously approved biological products based upon potentially abbreviated data packages. The biosimilar must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product, and only minor differences in clinically inactive components are allowable in biosimilars products. The approval pathway for biosimilars does, however, grant a biologics manufacturer a 12-year period of exclusivity from the date of approval of its biological product before biosimilar competition can be introduced. There is uncertainty, however, as the approval framework for biosimilars originally was enacted as part of the PPACA. In 2017, there are likely to be federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. If the PPACA is repealed, substantially modified or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation.

Biosimilars legislation has also been in place in the E.U. since 2003. In December 2012 guidelines issued by the EMA for approving biosimilars of marketed monoclonal antibody products became effective. In the E.U., biosimilars have been approved under a specialized pathway of centralized procedures. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the clinical trial data of an innovator product to which the biosimilar has been demonstrated to be "similar". In many cases, this allows biosimilars to be brought to market without conducting the full complement of clinical trials typically required for novel biologic drugs.

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Orphan Drug Act

Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years following marketing approval, except in certain very limited circumstances, such as if the later product is shown to be clinically superior to the orphan product. Legislation similar to the U.S. Orphan Drug Act has been enacted in other countries to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases. In the E.U., medicinal products intended for diagnosis, prevention or treatment of life-threatening or very serious diseases affecting less than five in 10,000 people receive 10-year market exclusivity, protocol assistance and access to the centralized procedure for marketing authorization. SPINRAZA has been granted orphan drug designation in the U.S., E.U. and Japan.

Regulation Pertaining to Pricing and Reimbursement

In both domestic and foreign markets, sales of our products depend, in part, on the availability and amount of reimbursement by third-party payors, including governments, private health plans and other organizations. Substantial uncertainty exists regarding the pricing reimbursement of our products, and drug prices continue to receive significant scrutiny. Governments may regulate coverage, reimbursement and pricing of our products to control cost or affect utilization of our products. Challenges to our pricing strategies, by either government or private stakeholders, could harm our business. The U.S. and foreign governments have enacted and regularly consider additional reform measures that affect health care coverage and costs. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. Other payors, including managed care organizations, health insurers, pharmacy benefit managers, government health administration authorities and private health insurers, seek price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value.

Within the U.S.

Medicaid: Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate is established by law and is adjusted upward if average manufacture price (AMP) increases more than inflation (measured by the Consumer Price Index - Urban). The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services (CMS). The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

- Medicare: Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. In addition, clotting factors for hemophilia are typically paid under Medicare Part B. Medicare Part B pays for such drugs under a payment methodology based on the average sales price (ASP) of the drugs. Manufacturers, including us, are required to provide ASP information to the CMS on a quarterly basis. The manufacturer-submitted information is used to calculate Medicare payment rates. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.
- Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S.

government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with

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manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers, including us, are required to provide to CMS a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

- Federal Agency Discounted Pricing: Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration (VA), Department of Defense, Coast Guard and Public Health Service (PHS). Coverage under Medicaid, Medicare and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the VA, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties.
- 340B Discounted Pricing: To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend significant discounts to certain covered entities that purchase products under Section 340B of the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics, hemophilia treatment centers and other entities that receive certain types of grants under the PHSA. For all of our products, we must agree to charge a price that will not exceed the amount determined under statute (the “ceiling price”) when we sell outpatient drugs to these covered entities. In addition, we may, but are not required to, offer these covered entities a price lower than the 340B ceiling price. The 340B discount formula is based on AMP and is generally similar to the level of rebates calculated under the Medicaid Drug Rebate Program.

Outside the U.S.

Outside the U.S., the E.U. represents a major market. Within the E.U., our products are paid for by a variety of payors, with governments being the primary source of payment. Governments may determine or influence reimbursement of products. Governments may also set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). Budgetary pressures in many E.U. countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing.

Regulation Pertaining to Sales and Marketing

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. There is therefore a possibility that our practices might be challenged under the anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). In the U.S., federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under

the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

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Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include federal “sunshine” provisions. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

The laws to which we are subject also include the U.K. Bribery Act 2010 (Bribery Act) which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

NIH Guidelines

We seek to conduct research at our U.S. facilities in compliance with the current U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). By local ordinance, we are required to, among other things, comply with the NIH Guidelines in relation to our facilities in RTP, North Carolina and are required to operate pursuant to certain permits.

Other Laws

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to data privacy and protection, safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights may be subject to national or international antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Environmental Matters

We strive to comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our operations or competitive position.

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Manufacturing

We are committed to ensuring an uninterrupted supply of medicines to patients around the world. To that end, we continually review our manufacturing capacity, capabilities, processes and facilities. We believe that our manufacturing facilities, together with the third-party contract manufacturing organizations we outsource to, currently provide sufficient capacity for our products and the contract manufacturing services we provide to Samsung Bioepis, our joint venture that develops, manufactures and markets biosimilars, and other strategic contract manufacturing partners. In light of the development of our pipeline, we are expanding our production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which is expected to be operational by the end of the decade.

Manufacturing Facilities

Our drug substance manufacturing facilities include:

| Facility | Drug Substance Manufactured |
|---|---|
| RTP, North Carolina | ALPROLIX<br>AVONEX<br>ELOCTATE<br>PLEGRIDY<br>TYSABRI<br>ZINBRYTA<br>Other* |
| Hillerød, Denmark | TYSABRI<br>Biosimilars |

* Other includes products manufactured for contract manufacturing partners

In addition to our drug substance manufacturing facilities, we have a drug product manufacturing facility and supporting infrastructure in RTP, North Carolina. This parenteral facility adds capabilities and capacity for filling biologics into vials.

We also lease from Eisai an oral solid dose products manufacturing facility in RTP, North Carolina, where we manufacture TECFIDERA and other oral solid dose products, including products for Eisai. This facility supplements our outsourced small molecule manufacturing capabilities. Under our lease arrangement, Eisai may provide us with packaging services for oral solid dose products. In August 2015 we agreed to purchase this facility following the expiration of our current three-year lease in the third quarter of 2018 and Eisai's completion of certain activities.

For a period of time following the spin-off of Bioverativ, we agreed to manufacture and supply, exclusively for Bioverativ, drug substance, drug product and finished goods with respect to ELOCTATE and ALPROLIX and pipeline product candidates.

Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN and GAZYVA and has sourced the manufacture of certain bulk RITUXAN and GAZYVA requirements to a third party, Acorda Therapeutics supplies FAMPYRA to us pursuant to its supply agreement with Alkermes, Inc. and Ionis supplies the active pharmaceutical ingredient (API) for SPINRAZA.

Third-Party Suppliers and Manufacturers

We principally use third parties to manufacture the API, except as noted above for SPINRAZA, and, to a lesser extent, the final product for our small molecule products and product candidates, including TECFIDERA and FUMADERM and the final drug product for our large molecule products and product candidates, including SPINRAZA.

We source all of our fill-finish and the majority of final product assembly and storage operations for our products, along with a substantial part of our packaging operations, to a concentrated group of third-party contract manufacturing organizations. We have internal label and packaging capability for clinical and commercial products at our Hillerød facility. Raw materials, delivery devices, such as syringes and auto-injectors, and other supplies required for the production of our products and product candidates are procured from various third-party suppliers and manufacturers in quantities adequate to meet our needs. Continuity of supply of such raw materials, devices and

supplies is assured using a strategy of dual sourcing where possible or by a risk-based inventory strategy. Our third-party service providers, suppliers and manufacturers may be subject to routine cGMP inspections by the FDA or comparable agencies in other jurisdictions and undergo assessment and certification by our quality management group.

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Our Employees

As of December 31, 2016, we had approximately 7,400 employees worldwide.

Our Executive Officers (as of February 2, 2017)

| Officer | Current Position | Age | Year Joined Biogen |
|---|---|---|---|
| Michel Vounatsos | Chief Executive Officer | 55 | 2016 |
| Susan H. Alexander | Executive Vice President, Chief Legal Officer and Corporate Secretary | 60 | 2006 |
| Paul J. Clancy | Executive Vice President, Finance and Chief Financial Officer | 55 | 2001 |
| Gregory F. Covino | Vice President, Finance and Chief Accounting Officer | 51 | 2012 |
| Michael D. Ehlers | Executive Vice President, Research and Development | 48 | 2016 |
| Paul McKenzie | Executive Vice President, Pharmaceutical Operations and Technology | 51 | 2016 |
| Kenneth DiPietro | Executive Vice President, Human Resources | 58 | 2012 |
| Adriana (Andi) Karaboutis | Executive Vice President, Technology, Business Solutions and Corporate Affairs | 54 | 2014 |
| Alfred W. Sandrock, Jr., M.D., Ph.D. | Chief Medical Officer and Executive Vice President of Neurology Discovery and Development | 59 | 1998 |

Michel Vounatsos

Experience

Mr. Vounatsos has served as our Chief Executive Officer since January 2017. Prior to that, from April 2016 to December 2016, Mr. Vounatsos served as our Executive Vice President and Chief Commercial Officer. Prior to joining Biogen, Mr. Vounatsos spent 20 years at Merck where he most recently served as President, Primary Care, Customer Business Line. In this role, he led Merck's global primary care business unit, a role which encompassed Merck's cardiology-metabolic, general medicine, women's health and biosimilars groups and developed and instituted a strategic framework for enhancing the company's relationships with key constituents, including the most significant providers, payers and retailers and the world's largest governments. Mr. Vounatsos previously held leadership positions across Europe and in China for Merck. Prior to that, Mr. Vounatsos held management positions at Ciba-Geigy.

Education

- Universite Victor Segalen, Bordeaux II, France, C.S.C.T. Certificate in Medicine
- HEC School of Management - Paris, M.B.A.

Susan H. Alexander

Experience

Ms. Alexander has served as our Executive Vice President, Chief Legal Officer and Corporate Secretary since December 2011. Prior to that, from 2006 to December 2011, Ms. Alexander served as our Executive Vice President, General Counsel and Corporate Secretary. From 2003 to January 2006, Ms. Alexander served as the Senior Vice President, General Counsel and Corporate Secretary of PAREXEL International Corporation, a biopharmaceutical services company. From 2001 to 2003, Ms. Alexander served as General Counsel of IONA Technologies, a software company. From 1995 to 2001, Ms. Alexander served as Counsel at Cabot Corporation, a specialty chemicals and performance materials company. Prior to that, Ms. Alexander was a partner at the law firms of Hinckley, Allen & Snyder and Fine & Ambrogne.

Public Company Boards

- Board of Directors of Invacare Corporation, a medical and healthcare product company

Education
- Wellesley College, B.A
- Boston University School of Law, J.D.

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Paul J. Clancy

Experience

Mr. Clancy has served as our Executive Vice President, Finance and Chief Financial Officer since August 2007. Mr. Clancy joined Biogen, Inc. in 2001 and has held several senior executive positions with us, including Vice President of Business Planning, Portfolio Management and U.S. Marketing, and Senior Vice President of Finance with responsibilities for leading the Treasury, Tax, Investor Relations and Business Planning groups. Prior to that, he spent 13 years at PepsiCo, a food and beverage company, serving in a range of financial and general management positions.

Public Company Boards

- Board of Directors of Agios Pharmaceuticals, Inc., a biopharmaceutical company
- Board of Directors of Incyte Corporation, a biopharmaceutical company

Education

- Babson College, B.S. in Finance
- Columbia University, M.B.A.

Gregory F. Covino

Experience

Mr. Covino has served as our Vice President, Finance and Chief Accounting Officer since April 2012. Prior to that, Mr. Covino served at Boston Scientific Corporation, a medical device company, as Vice President, Corporate Analysis and Control since March 2010, having responsibility for the company's internal audit function, and as Vice President, Finance, International from February 2008 to March 2010, having responsibility for the financial activities of the company's international division. Prior to that, Mr. Covino held several finance positions at Hubbell Incorporated, an electrical products company, including Vice President, Chief Accounting Officer and Controller from 2002 to January 2008, Interim Chief Financial Officer from 2004 to 2005, and Director, Corporate Accounting from 1999 to 2002.

Education

- Bryant University, B.S. in Business Administration

Michael D. Ehlers

Experience

Dr. Ehlers has served as our Executive Vice President, Head of R&D since May 2016. Prior to joining Biogen, Dr. Ehlers served in leadership positions at Pfizer, Inc., including Senior Vice President & Head BioTherapeutics R&D and Chief Scientific Officer, Neuroscience & Pain. Prior to that, Dr. Ehlers was the George Barth Geller Professor of Neurobiology and an Investigator of the Howard Hughes Medical Institute at Duke University Medical Center. He is the recipient of numerous awards including the Eppendorf & Science Prize in Neurobiology, the John J. Abel Award in Pharmacology, the Society for Neuroscience Young Investigator Award, a National Institute of Mental

Health MERIT Award, the National Alliance for Schizophrenia and Depression Distinguished Investigator Award, and the Massachusetts Medical Society Honored Business Leader Award. In 2013, Dr. Ehlers became the 11th recipient of the Thudichum Medal of the Biochemical Society of the United Kingdom. Past recipients include two Nobel laureates. Dr. Ehlers has authored over 100 scientific papers, has served on the Editorial Boards of Annual Reviews in Medicine, Annual Reviews in Pharmacology and Toxicology, the Journal of Neuroscience, the Journal of Biological Chemistry, the Journal of Molecular and Cellular Neuroscience, and has sat on advisory committees of the National Institutes of Health.

Outside Affiliations

- PhRMA Foundation Basic Pharmacology Advisory Committee
- Janelia Research Institute Advisory Committee
- McKnight Endowment Fund for Neuroscience Board
- World Economic Forum Global Agenda Council on Brain Research

Education

- California Institute of Technology, B.S. Chemistry
- The John Hopkins University School of Medicine, M.D.
- The John Hopkins University School of Medicine, Ph.D. Neuroscience

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Paul McKenzie

Experience

Dr. McKenzie has served as our Executive Vice President, Pharmaceutical Operations and Technology since July 2016. Prior to that, from February 2016 to June 2016, he served as our Senior Vice President for Global Biologics Manufacturing & Technical Operations. Prior to joining Biogen, since 2008, Dr. McKenzie held a number of positions of increasing responsibility at Johnson & Johnson (J&J), including Vice President of R&D for J&J's Ethicon business where he led the manufacturing and technical operations team responsible for internal and external manufacturing of Janssen's pharmaceutical portfolio. He also ran global Development for Janssen R&D, helping to manage pipeline activities from discovery through clinical development and commercialization. Prior to J&J, Dr. McKenzie also held various R&D and manufacturing positions at Bristol-Myers Squibb and Merck & Co.

Education

- University of Pennsylvania, B.S. Chemical Engineering
- Carnegie Mellon University, Ph.D. Chemical Engineering

Kenneth DiPietro

Experience

Mr. DiPietro has served as our Executive Vice President, Human Resources since January 2012. Mr. DiPietro joined Biogen from Lenovo Group, a technology company, where he served as Senior Vice President, Human Resources from 2005 to June 2011. From 2003 to 2005, he served as Corporate Vice President, Human Resources at Microsoft Corporation, a technology company. From 1999 to 2002, Mr. DiPietro worked as Vice President, Human Resources at Dell Inc., a technology company. Prior to that, he spent 17 years at PepsiCo, a food and beverage company, serving in a range of human resource and general management positions.

Public Company Boards

- Board of Directors of InVivo Therapeutics Corporation, a medical device company

Education

- Cornell University, B.S. in Industrial and Labor Relations

Adriana (Andi) Karaboutis

Experience

Ms. Karaboutis has served as our Executive Vice President, Technology, Business Solutions and Corporate Affairs since December 2015 and prior to that served as our Executive Vice President, Technology and Business Solutions since joining Biogen in September 2014. Prior to that, Ms. Karaboutis was Vice President and Global Chief Information Officer of Dell, Inc., where she was responsible for leading a global IT organization focused on powering Dell as an end-to-end technology solutions provider. Prior to joining Dell in 2010, Ms. Karaboutis spent over 20 years at General Motors and Ford Motor Company in various international leadership positions including computer-integrated manufacturing, supply chain operations, and information technology.

Public Company Boards

- Board of Directors of Advance Auto Parts, an automotive aftermarket parts provider

Education

- Wayne State University, B.S. in Computer Science

Alfred W. Sandrock, Jr., M.D., Ph.D.

Experience

Dr. Sandrock has served as our Chief Medical Officer and Executive Vice President of Neurology Discovery and Development since November 2015. Prior to that, Dr. Sandrock served as our Chief Medical Officer and Group Senior Vice President from May 2013 to October 2015, and as our Chief Medical Officer and Senior Vice President of Development Sciences from February 2012 to April 2013. Prior to that, Dr. Sandrock held several senior executive positions since joining us in 1998, including Senior Vice President of Neurology Research and Development and Vice President of Clinical Development, Neurology.

Public Company Boards

- Board of Directors of Neurocrine Biosciences, Inc., a life sciences company

Education

- Stanford University, B.A. in Human Biology
- Harvard Medical School, M.D.
- Harvard University, Ph.D. in Neurobiology
- Massachusetts General Hospital, internship in Medicine, residency and chief residency in Neurology, and clinical fellowship in Neuromuscular Disease and Clinical Neurophysiology (electromyography)

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Available Information

Our principal executive offices are located at 225 Binney Street, Cambridge, MA 02142 and our telephone number is (617) 679-2000. Our website address is www.biogen.com. We make available free of charge through the Investors section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (SEC). We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

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Item 1A. Risk Factors

We are substantially dependent on revenues from our principal products.

Our current revenues depend upon continued sales of our principal products, and, unless we develop or acquire rights to new products and technologies, we may be substantially dependent on sales from our principal products for many years. Further, following the completion of the spin-off of our hemophilia business, our revenues will be further reliant and concentrated on sales of our MS products in an increasingly competitive market, and revenue from sales of our product for spinal muscular atrophy. Any of the following negative developments relating to any of our principal products may adversely affect our revenues and results of operations or could cause a decline in our stock price:

- safety or efficacy issues;
- the introduction or greater acceptance of competing products;
- constraints and additional pressures on product pricing or price increases, including those resulting from governmental or regulatory requirements, increased competition, or changes in, or implementation of, reimbursement policies and practices of payors and other third parties; or
- adverse legal, administrative, regulatory or legislative developments.

SPINRAZA was recently approved by the FDA, and is in the early stages of commercial launch. In addition to risks associated with new product launches and the other factors described in these “Risk Factors”, our ability to successfully commercialize SPINRAZA may be adversely affected due to:

- our limited marketing experience within the spinal muscular atrophy market, which may impact our ability to develop relationships with the associated medical and scientific community;
- the lack of readiness of healthcare providers to treat patients with spinal muscular atrophy;
- the effectiveness of our commercial strategy for marketing SPINRAZA; and
- our ability to maintain a positive reputation among patients, healthcare providers and others in the spinal muscular atrophy community, which may be impacted by pricing and reimbursement decisions relating to SPINRAZA.

If we fail to compete effectively, our business and market position would suffer.

The biopharmaceutical industry and the markets in which we operate are intensely competitive. We compete in the marketing and sale of our products, the development of new products and processes, the acquisition of rights to new products with commercial potential and the hiring and retention of personnel. We compete with biotechnology and pharmaceutical companies that have a greater number of products on the market and in the product pipeline, greater financial and other resources and other technological or competitive advantages. One or more of our competitors may benefit from significantly greater sales and marketing capabilities, may develop products that are accepted more widely than ours or may receive patent protection that dominates, blocks or adversely affects our product development or business.

Our products are also susceptible to competition from generics and biosimilars in many markets. Generic versions of drugs and biosimilars are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of generic or biosimilar versions of our marketed products likely would significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may have an adverse impact on our results of operations.

In the MS market, we face intense competition as the number of products and competitors continues to expand. Due to our significant reliance on sales of our MS products, our business may be harmed if we are unable to successfully compete in the MS market. More specifically, our ability to compete, maintain and grow our share in the MS market may be adversely affected due to a number of factors, including:

- the introduction of more efficacious, safer, less expensive or more convenient alternatives to our MS products, including our own products and products of our collaborators;
- the introduction of lower-cost biosimilars, follow-on products or generic versions of branded MS products sold by our competitors, and the possibility of future competition from generic versions or prodrugs of existing therapeutics or from off-label use by physicians of therapies indicated for other conditions to treat MS patients;

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- patient dynamics, including the size of the patient population and our ability to attract new patients to our therapies;
- damage to physician and patient confidence in any of our MS products or to our sales and reputation as a result of label changes or adverse experiences or events that may occur with patients treated with our MS products;
- inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key international markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our MS products.

Sales of our products depend, to a significant extent, on adequate coverage, pricing and reimbursement from third-party payors, which are subject to increasing and intense pressure from political, social, competitive and other sources. Our inability to maintain adequate coverage, or a reduction in pricing or reimbursement, could have an adverse effect on our business, revenues and results of operations and could cause a decline in our stock price.

Sales of our products are dependent, in large part, on the availability and extent of coverage, pricing and reimbursement from government health administration authorities, private health insurers and other organizations. When a new pharmaceutical product is approved, the availability of government and private reimbursement for that product may be uncertain, as is the pricing and amount for which that product will be reimbursed.

Pricing and reimbursement for our products may be adversely affected by a number of factors, including:

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs; and
- consolidation and increasing assertiveness of payors, including managed care organizations, health insurers, pharmacy benefit managers, government health administration authorities, private health insurers and other organizations, seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value.

Our ability to set the price for our products can vary significantly from country to country and as a result so can the price of our products. Certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the revenue from our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third-party cross-border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Our failure to maintain adequate coverage, pricing, or reimbursement for our products would have an adverse effect on our business, revenues and results of operations, could curtail or eliminate our ability to adequately fund research and development programs for the discovery and commercialization of new products and could cause a decline in our stock price.

Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility, and our results of operations may be adversely impacted.

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Our results of operations may be adversely affected by current and potential future healthcare reforms.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the PPACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. These changes have had and are expected to continue to have a significant impact on our business. In 2017, we may face uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. In recent years, some states have considered legislation and ballot initiatives that would control the prices of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. and laws intended to impose price controls on state drug purchases. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

In the E.U. and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures to reduce health care costs to constrain their overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries to higher-cost countries. These measures have negatively impacted our revenues, and may continue to adversely affect our revenues and results of operations in the future.

Adverse safety events or restrictions on use and safety warnings for our products can negatively affect our business, product sales and stock price.

Adverse safety events involving our marketed products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales or stock price to decline or experience periods of volatility. Restrictions on use or significant safety warnings that may be required to be included in the label of our products, such as the risk of developing progressive multifocal leukoencephalopathy (PML), a serious brain infection, in the label for certain of our products, may significantly reduce expected revenues for those products and require significant expense

and management time.

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If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our business may be harmed.

Our success depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our products and product candidates. The degree of patent protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect. Furthermore, we can provide no assurance that our products will not infringe patents or other intellectual property rights held by third parties.

We also rely on regulatory exclusivity for protection of our products. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect in each of the markets for our products due to challenges, changes or interpretations in the law or otherwise, could affect our revenue for our products or our decision on whether to market our products in a particular country or countries or could otherwise have an adverse impact on our results of operations.

Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory protections covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interference, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

Our long-term success depends upon the successful development of new products and additional indications for existing products.

Our long-term viability and growth will depend upon successful development of additional indications for our existing products as well as successful development of new products and technologies from our research and development activities, our biosimilars joint venture with Samsung Biologics or licenses or acquisitions from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects, result in unexpected adverse events or raise other concerns that may significantly reduce the likelihood of regulatory approval. This may result in terminated programs, significant restrictions on use and safety warnings in an approved label, adverse placement within the treatment paradigm, or significant reduction in the commercial potential of the product candidate.

Clinical trials and the development of biopharmaceutical products is a lengthy and complex process. If we fail to adequately manage our clinical activities, our clinical trials or potential regulatory approvals may be delayed or denied.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete clinical trials in a timely fashion depends in large part on a number of key factors. These factors include protocol design, regulatory and institutional review board approval, patient enrollment rates and compliance with extensive current Good Clinical

Practices. If we or our third-party clinical trial providers or third-party contract research organizations (CROs) do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful.

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We have opened clinical sites and are enrolling patients in a number of countries where our experience is more limited. In most cases, we use the services of third parties to carry out our clinical trial related activities and rely on such parties to accurately report their results. Our reliance on third parties for these activities may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for a substantial portion of our clinical trial related activities and reporting. If this CRO does not adequately perform, many of our trials may be affected. We may need to replace our CROs. Although we believe there are a number of other CROs we could engage to continue these activities, the replacement of an existing CRO may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates.

Successful preclinical work or early stage clinical trials do not ensure success in later stage trials, regulatory approval or commercial viability of a product.

Positive results in a trial may not be replicated in subsequent or confirmatory trials. Additionally, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful or that regulatory approval will be obtained. In addition, even if later stage clinical trials are successful, regulatory authorities may delay or decline approval of our product candidates. Regulatory authorities may disagree with our view of the data, require additional studies or disagree with our trial design or endpoints. Regulatory authorities may also fail to approve the facilities or the processes used to manufacture a product candidate, our dosing or delivery methods or companion devices. Regulatory authorities may grant marketing approval that is more restricted than anticipated. These restrictions may include limiting indications to narrow patient populations and the imposition of safety monitoring, educational requirements and risk evaluation and mitigation strategies. The occurrence of any of these events could result in significant costs and expenses, have an adverse effect on our business, financial condition and results of operations and cause our stock price to decline or experience periods of volatility.

Even if we are able to successfully develop new products or indications, sales of new products or products with additional indications may not meet investor expectations. We may also make a strategic decision to discontinue development of a product or indication if, for example, we believe commercialization will be difficult relative to the standard of care or other opportunities in our pipeline.

Management and key personnel changes may disrupt our operations, and we may have difficulty retaining key personnel or attracting and retaining qualified replacements on a timely basis for management and other key personnel who may leave the Company.

We have experienced changes in management and other key personnel in critical functions across our organization, including our chief executive officer, and heads of research and development and pharmaceutical operations and technology. Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition and results of operations. Further, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs.

Our success is dependent upon our ability to attract and retain qualified management and key personnel in a highly competitive environment. Qualified individuals are in high demand, and we may incur significant costs to attract them, particularly at the executive level. We may face difficulty in attracting and retaining key talent for a number of reasons, such as management changes, the underperformance or discontinuation of one or more late stage programs or recruitment by competitors. We cannot assure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any such personnel will not have a material impact on our financial condition and results of operations.

Manufacturing issues could substantially increase our costs, limit supply of our products and reduce our revenues.

The process of manufacturing our products is complex, highly regulated and subject to numerous risks, including:

- Risk of Product Loss. The manufacturing process for our products is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or

manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.

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Risks of Reliance on Third Parties and Single Source Providers. We rely on third-party suppliers and manufacturers for many aspects of our manufacturing process for our products and product candidates. In some cases, due to the unique manner in which our products are manufactured, we rely on single source providers of several raw materials and manufacturing supplies. These third parties are independent entities subject to their own unique operational and financial risks that are outside of our control. These third parties may not perform their obligations in a timely and

- cost-effective manner or in compliance with applicable regulations, and they may be unable or unwilling to increase production capacity commensurate with demand for our existing or future products. Finding alternative providers could take a significant amount of time and involve significant expense due to the specialized nature of the services and the need to obtain regulatory approval of any significant changes to our suppliers or manufacturing methods. We cannot be certain that we could reach agreement with alternative providers or that the FDA or other regulatory authorities would approve our use of such alternatives.

Global Bulk Supply Risks. We rely on our principal manufacturing facilities for the production of drug substance for

- our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

Risks Relating to Compliance with cGMP. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the

- manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

Any adverse developments affecting our manufacturing operations or the operations of our third-party suppliers and manufacturers may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

We depend on relationships with collaborators and other third-parties for revenue, and the development, regulatory approval, commercialization and marketing of certain products, which are outside of our full control.

We rely on a number of significant collaborative relationships for revenue, and the development, regulatory approval, commercialization and marketing of certain of our products and product candidates. We also outsource to third parties certain aspects of our regulatory affairs and clinical development relating to our products and product candidates. Reliance on collaborative and other third-party relationships subjects us to a number of risks, including:

- we may be unable to control the resources our collaborators or third parties devote to our programs or products;
- disputes may arise under the agreement, including with respect to the achievement and payment of milestones or ownership of rights to technology developed with our collaborators or other third parties, and the underlying contract with our collaborators or other third parties may fail to provide significant protection or may fail to be effectively enforced if the collaborators or third parties fail to perform;
- the interests of our collaborators or third parties may not always be aligned with our interests, such parties may not pursue regulatory approvals or market a product in the same manner or to the same extent that we would, which could adversely affect our revenues;
- third-party relationships and collaborations often require the parties to cooperate, and failure to do so effectively could adversely affect product sales, or the clinical development or regulatory approvals of products under joint control or could result in termination of the research, development or commercialization of product candidates or result in litigation or arbitration; and

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- any failure on the part of our collaborators or other third parties to comply with applicable laws and regulatory requirements in the marketing, sale and maintenance of the marketing authorization of our products or to fulfill any responsibilities our collaborators or other third parties may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings.

Given these risks, there is considerable uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline.

Our business may be adversely affected if we do not successfully execute our growth initiatives.

We anticipate growth through internal development projects, commercial initiatives and external opportunities, which may include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. While we believe we have a number of promising programs in our pipeline, failure of internal development projects to advance or difficulties in executing on our commercial initiatives could impact our current and future growth, resulting in additional reliance on external development opportunities for growth. The availability of high quality, cost-effective development opportunities is limited and competitive, and we are not certain that we will be able to identify candidates that we and our shareholders consider suitable or complete transactions on terms that are acceptable to us and our shareholders. We may fail to complete transactions for other reasons, including if we are unable to obtain desired financing on favorable terms, if at all. Even if we are able to successfully identify and complete acquisitions and other strategic alliances and collaborations, we may face unanticipated costs or liabilities in connection with the transaction or we may not be able to integrate them or take full advantage of them or otherwise realize the benefits that we expect.

Supporting our growth initiatives and the further development of our existing products and potential new products in our pipeline will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing capabilities and other areas of our business. If we do not successfully manage our growth initiatives, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

We may incur operational difficulties or be exposed to claims and liabilities as a result of the separation and distribution of Bioverativ.

On February 1, 2017, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen stockholders in connection with the separation of our hemophilia business. In connection with the distribution, we entered into a separation and distribution agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between the two companies going forward, including with respect to potential tax-related losses associated with the separation and distribution. They also provide for the performance of services by each company for the benefit of the other for a period of time (including under the manufacturing and supply agreement pursuant to which we will manufacture and supply certain products and materials to Bioverativ). There could be significant liability if the separation and distribution is determined to be a taxable transaction. Bioverativ has agreed to indemnify us for certain potential liabilities that may arise, but we cannot guarantee that Bioverativ will be able to satisfy its indemnification obligations.

The separation and distribution agreement provides for indemnification obligations designed to make Bioverativ financially responsible for many liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation. It is possible that a court would disregard the allocation agreed to between us and Bioverativ and require us to assume responsibility for obligations allocated to Bioverativ. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation and distribution agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Bioverativ may be significant. These risks could negatively affect our business, financial condition or results of operations.

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The separation of Bioverativ continues to involve a number of risks, including, among other things, the indemnification risks described above and the potential that management's and our employees' attention will be significantly diverted by the provision of transitional services. Certain of the agreements described above provide for the performance of services by each company for the benefit of the other for a period of time. If Bioverativ is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could incur losses. These arrangements could also lead to disputes over rights to certain shared property and over the allocation of costs and revenues for products and operations. Our inability to effectively manage the separation activities and related events could adversely affect our business, financial condition or results of operations.

We may not achieve some or all of the expected benefits of the separation and distribution, and such events may adversely affect our business.

We may not be able to achieve the full strategic and financial benefits expected to result from the separation and distribution, or such benefits may be delayed or not occur at all. If we fail to achieve some or all of the expected benefits of the separation, or if such benefits are delayed, our business, financial condition, results of operations and the value of our stock could be adversely impacted.

A breakdown or breach of our technology systems could subject us to liability or interrupt the operation of our business.

We are increasingly dependent upon technology systems and data. Our computer systems continue to increase in multitude and complexity due to the growth in our business, making them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy or security breaches by individuals authorized to access our technology systems or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, customers or other business partners, may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. They are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and "hacktivists." Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our technology systems and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security posture. While we continue to build and improve our systems and infrastructure and believe we have taken appropriate security measures to reduce these risks to our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies such as ours have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and

donations to third party charities that provide such assistance. If we, or our vendors or donation recipients, are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

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Regulations governing the health care industry are subject to change, with possibly retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

Violations of governmental regulation may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of accrued amounts. As a global biopharmaceutical company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from country to country, the results of examinations and audits of our tax filings, adjustments to the value of our uncertain tax positions, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations.

In addition, our inability to secure or sustain acceptable arrangements with tax authorities and future changes in the tax laws, among other things, may result in tax obligations in excess of amounts accrued in our financial statements. In the U.S., there are several proposals under consideration to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, penalize certain transfer pricing structures, and reduce or eliminate certain foreign or domestic tax credits or deductions. Our future reported financial results may be adversely affected by tax law changes which restrict or eliminate certain foreign tax credits or our ability to deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

In addition to U.S. tax reform proposals, the adoption of some or all of the recommendations set forth in the Organization for Economic Co-operation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities in the countries in which we operate, could negatively impact our effective tax rate. These recommendations focus on payments from affiliates in high tax jurisdictions to affiliates in lower tax jurisdictions and the activities that give rise to a taxable presence in a particular country.

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Our indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

Our indebtedness, together with our significant contingent liabilities, including milestone and royalty payment obligations, could have important consequences to our business; for example, such obligations could:

- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to access capital markets and incur additional debt in the future;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts, research and development and mergers and acquisitions; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that have less debt.

Our sales and operations are subject to the risks of doing business internationally.

We are increasing our presence in international markets, particularly emerging markets, subjecting us to many risks that could adversely affect our business and revenues, such as:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- collectability of accounts receivable;
- fluctuations in foreign currency exchange rates, in particular the recent strength of the U.S. dollar versus foreign currencies that has adversely impacted our revenues and net income;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability; and
- changes in tax laws and tariffs.

In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. Failure to comply with domestic or foreign laws could result in various adverse consequences, including: possible delay in approval or refusal to approve a product; recalls, seizures or withdrawal of an approved product from the market; disruption in the supply or availability of our products or suspension of export or import privileges; the imposition of civil or criminal sanctions; the prosecution of executives overseeing our international operations; and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

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Our operating results are subject to significant fluctuations.

Our quarterly revenues, expenses and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the risks described in these "Risk Factors" as well as the timing of charges and expenses that we may take. We have recorded, or may be required to record, charges that include:

- the cost of restructurings;
- impairments with respect to investments, fixed assets and long-lived assets, including in-process R&D and other intangible assets;
- inventory write-downs for failed quality specifications, charges for excess or obsolete inventory and charges for inventory write downs relating to product suspensions, expirations or recalls;
- changes in the fair value of contingent consideration;
- bad debt expenses and increased bad debt reserves;
- outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters;
- milestone payments under license and collaboration agreements; and
- payments in connection with acquisitions and other business development activities.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. Although we have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, the U.S. dollar, and the currencies in which we do business will affect our operating results, often in unpredictable ways. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher than expected charges from hedge ineffectiveness or from the termination of a hedge relationship.

Our operating results during any one period do not necessarily suggest the anticipated results of future periods.

We are pursuing opportunities to expand our manufacturing capacity for future clinical and commercial requirements for product candidates, which will result in the incurrence of significant investment with no assurance that such investment will be recouped.

While we believe we currently have sufficient large scale manufacturing capacity to meet our near-term manufacturing requirements, it is probable that we would need additional large scale manufacturing capacity to support future clinical and commercial manufacturing requirements for product candidates in our pipeline, if such candidates are successful and approved. We are building a large scale biologics manufacturing facility in Solothurn, Switzerland and acquired an additional manufacturing facility in Research Triangle Park, North Carolina. Due to the long lead times necessary for the expansion of manufacturing capacity, we expect to incur significant investment to build or expand our facilities or obtain third-party contract manufacturers with no assurance that such investment will be recouped. If we are unable to adequately and timely manufacture and supply our products and product candidates or if we do not fully utilize our manufacturing facilities, our business may be harmed.

Our investment in Samsung Bioepis, and our success in commercializing biosimilars developed by Samsung Bioepis, are subject to risks and uncertainties inherent in the development, manufacture and commercialization of biosimilars.

Our investment in Samsung Bioepis, and our success in commercializing biosimilars developed by Samsung Bioepis, are subject to a number of risks, including:

- Reliance on Third Parties. We are dependent on the efforts of Samsung Bioepis and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If Samsung Bioepis or such other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;
- Regulatory Compliance. Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;

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- Intellectual Property and Regulatory Challenges. Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years;
- Failure to Gain Market and Patient Acceptance. Market success of biosimilar products will be adversely affected if patients, physicians and payers do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- Ability to Provide Adequate Supply. Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet higher than anticipated demand; and
- Competitive Challenges. Biosimilar products face significant competition, including from innovator products and from biosimilar products offered by other companies. In some jurisdictions, local tendering processes may restrict biosimilar products from being marketed and sold in those jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective matter are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area.

Our investments in properties may not be fully realized.

We own or lease real estate primarily consisting of buildings that contain research laboratories, office space and manufacturing operations. For strategic or other operational reasons, we may decide to further consolidate or co-locate certain aspects of our business operations or dispose of one or more of our properties, some of which may be located in markets that are experiencing high vacancy rates and decreasing property values. If we determine that the fair value of any of our owned properties is lower than their book value we may not realize the full investment in these properties and incur significant impairment charges or additional depreciation when the expected useful lives of certain assets have been shortened due to the anticipated closing of facilities. If we decide to fully or partially vacate a leased property, such as ceasing manufacturing at our facility in Cambridge, Massachusetts, we may incur significant cost, including facility closing costs, employee separation and retention expenses, lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements and accelerated depreciation of assets. Any of these events may have an adverse impact on our results of operations.

Our portfolio of marketable securities is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities for investment of our cash. Changes in the value of our portfolio of marketable securities could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

There can be no assurance that we will continue to repurchase stock or that we will repurchase stock at favorable prices.

From time to time our Board of Directors authorizes stock repurchase programs, including most recently a $5.0 billion stock repurchase program in July 2016. The amount and timing of stock repurchases are subject to capital availability and our determination that stock repurchases are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the repurchase of stock. Our ability to repurchase stock will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, results of operations, financial condition and other factors beyond our control that we may deem relevant. A reduction in, or the completion or expiration of, our stock repurchase programs could have a negative effect on our stock price. We can provide no assurance that we will repurchase stock at favorable prices, if at all.

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We may not be able to access the capital and credit markets on terms that are favorable to us.

We may seek access to the capital markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets have experienced extreme volatility and disruption which leads to uncertainty and liquidity issues for both borrowers and investors. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on favorable terms. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our cost of financing and the market price of our securities.

Our business involves environmental risks, which include the cost of compliance and the risk of contamination or injury.

Our business and the business of several of our strategic partners involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with state, federal and foreign standards, there will always be the risk of accidental contamination or injury. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

Manufacturing of our products and product candidates also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, including permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing, distribution and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name. Stolen inventory that is not properly stored or sold through unauthorized channels could adversely impact patient safety, our reputation and our business. In addition, inventory that is stolen from warehouses, plants or while in-transit, and that is subsequently improperly stored and sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Some of our collaboration agreements contain change in control provisions that may discourage a third party from attempting to acquire us.

Some of our collaboration agreements include change in control provisions that could reduce the potential acquisition price an acquirer is willing to pay or discourage a takeover attempt that could be viewed as beneficial to shareholders. Upon a change in control, some of these provisions could trigger reduced milestone, profit or royalty payments to us or give our collaboration partner rights to terminate our collaboration agreement, acquire operational control or force the purchase or sale of the programs that are the subject of the collaboration.

Item 1B. Unresolved Staff Comments

None.

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Item 2. Properties

Below is a summary of our owned and leased properties as of December 31, 2016.

Massachusetts

In Cambridge, Massachusetts, we own approximately 508,000 square feet of real estate space, consisting of a building that houses a research laboratory and a cogeneration plant totaling approximately 263,000 square feet and a building that contains research, development and quality laboratories which total approximately 245,000 square feet.

In addition, we lease a total of approximately 1,250,000 square feet in Massachusetts, which is summarized as follows:

- 893,000 square feet in Cambridge, Massachusetts, which is comprised of a 67,000 square foot biologics manufacturing facility, which is subleased by Brammer, and 826,000 square feet for our corporate headquarters, laboratory and additional office space; and
- 357,000 square feet of office space in Weston, Massachusetts, of which 175,000 square feet has been subleased through the remaining term of our lease agreement.

Our Massachusetts lease agreements expire at various dates through the year 2028.

North Carolina

In RTP, North Carolina, we own approximately 834,000 square feet of real estate space, which is summarized as follows:

- 357,000 square feet of laboratory and office space;
- 175,000 square feet related to a large-scale biologics manufacturing facility;
- 105,000 square feet related to a biologics manufacturing facility;
- 84,000 square feet of warehouse space and utilities;
- 70,000 square feet related to a parenteral fill-finish facility; and
- 43,000 square feet related to a large-scale purification facility.

In addition, we lease 188,000 square feet of a facility in RTP, North Carolina from Eisai to manufacture our and Eisai's oral solid dose products and 40,000 square feet of warehouse space in Durham, North Carolina.

Denmark

We own a large-scale biologics manufacturing facility totaling approximately 228,000 square feet located in Hillerød, Denmark.

We also own approximately 306,000 square feet of additional space, which is summarized as follows:

- 139,000 square feet of warehouse, utilities and support space;
- 70,000 square feet related to a label and packaging facility;
- 50,000 square feet related to a laboratory facility; and
- 47,000 square feet of administrative space.

Switzerland

In December 2015 we acquired land in Solothurn, Switzerland where we are building a biologics manufacturing facility in the Commune of Luterbach over the next several years.

Other International

We lease office space in Zug, Switzerland, our international headquarters, the U.K., Germany, France, Denmark and numerous other countries. Our international lease agreements expire at various dates through the year 2028.

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Item 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2016, please read Note 20, Litigation to our consolidated financial statements included in this report, which is incorporated into this item by reference.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market and Stockholder Information

Our common stock trades on The NASDAQ Global Select Market under the symbol "BIIB." The following table shows the high and low sales price for our common stock as reported by The NASDAQ Global Select Market for each quarter in the years ended December 31, 2016 and 2015:

| | Common Stock Price | | | |
|---|---|---|---|---|
| | 2016 | | 2015 | |
| | High | Low | High | Low |
| First Quarter | $301.02 | $242.07 | $480.18 | $334.40 |
| Second Quarter | $292.69 | $223.02 | $432.88 | $368.88 |
| Third Quarter | $333.65 | $240.07 | $412.24 | $265.00 |
| Fourth Quarter | $329.83 | $268.00 | $311.65 | $254.00 |

As of January 27, 2017, there were approximately 700 stockholders of record of our common stock.

Dividends

We have not paid cash dividends since our inception. While we historically have not paid cash dividends and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, among other things, payment of cash dividends, stock repurchases or acquisitions.

Issuer Purchases of Equity Securities

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. The following table summarizes our common stock repurchase activity under our 2016 Share Repurchase Program during the fourth quarter of 2016:

| Period | Total Number of Shares Purchased (#) | Average Price Paid per Share ($) | Total Number of Shares Purchased as Part of Publicly Announced Programs (#) | Maximum Approximate Dollar Value of Shares That May Yet Be Purchased Under Our Programs ($ in millions) |
|---|---|---|---|---|
| October 2016 | 1,254,818 | 298.71 | 1,254,818 | $ 4,276.3 |
| November 2016 | 939,046 | 294.24 | 939,046 | $ 4,000.0 |
| December 2016 | — | — | — | $ 4,000.0 |
| Total | 2,193,864 | 296.80 | | |

As of December 31, 2016, we repurchased and retired approximately 3.3 million shares of common stock at a cost of $1.0 billion under the 2016 Share Repurchase Program.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of our common stock (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under our share-based compensation plans. The 2011 Share Repurchase Program does not have an expiration date. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program during the year ended December 31, 2016, and have approximately 1.3 million shares remaining available for repurchase under this authorization.

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Stock Performance Graph

The graph below compares the five-year cumulative total stockholder return on our common stock, the S&P 500 Index, the Nasdaq Pharmaceutical Index and the Nasdaq Biotechnology Index assuming the investment of $100.00 on December 31, 2011 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|
| Biogen Inc. | 100.00 | 133.00 | 254.04 | 308.45 | 278.37 | 257.68 |
| NASDAQ Pharmaceutical | 100.00 | 114.32 | 155.11 | 188.95 | 199.22 | 197.05 |
| S&P 500 Index | 100.00 | 116.00 | 153.57 | 174.60 | 177.01 | 198.18 |
| NASDAQ Biotechnology | 100.00 | 132.74 | 220.37 | 296.19 | 331.05 | 260.37 |

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Item 6. Selected Financial Data

BIOGEN INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

Our results of operations are summarized as follows:

| | For the Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| (In millions, except per share amounts) | 2016 (d) (e) | 2015 (d) | 2014 (f) | 2013 (g) | 2012 (h) |
| Results of Operations | | | | | |
| Product revenues, net (a) | $9,817.9 | $9,188.5 | $8,203.4 | $5,542.3 | $4,166.1 |
| Revenues from anti-CD20 therapeutic programs | 1,314.5 | 1,339.2 | 1,195.4 | 1,126.0 | 1,137.9 |
| Other revenues | 316.4 | 236.1 | 304.5 | 263.9 | 212.5 |
| Total revenues | 11,448.8 | 10,763.8 | 9,703.3 | 6,932.2 | 5,516.5 |
| Total cost and expenses | 6,298.4 | 5,872.8 | 5,747.7 | 4,441.6 | 3,707.4 |
| Gain on sale of rights | — | — | 16.8 | 24.9 | 46.8 |
| Income from operations | 5,150.4 | 4,891.0 | 3,972.4 | 2,515.5 | 1,855.9 |
| Other income (expense), net | (217.4) | (123.7) | (25.8) | (34.9) | (0.7) |
| Income before income tax expense and equity in loss of investee, net of tax | 4,933.0 | 4,767.3 | 3,946.6 | 2,480.6 | 1,855.1 |
| Income tax expense | 1,237.3 | 1,161.6 | 989.9 | 601.0 | 470.6 |
| Equity in loss of investee, net of tax | — | 12.5 | 15.1 | 17.2 | 4.5 |
| Net income | 3,695.7 | 3,593.2 | 2,941.6 | 1,862.3 | 1,380.0 |
| Net income (loss) attributable to noncontrolling interests, net of tax | (7.1) | 46.2 | 6.8 | — | — |
| Net income attributable to Biogen Inc. | $3,702.8 | $3,547.0 | $2,934.8 | $1,862.3 | $1,380.0 |
| | | | | | |
| Diluted Earnings Per Share | | | | | |
| Diluted earnings per share attributable to Biogen Inc. | $16.93 | $15.34 | $12.37 | $7.81 | $5.76 |
| Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Inc. | 218.8 | 231.2 | 237.2 | 238.3 | 239.7 |

Our financial condition is summarized as follows:

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 | 2013 | 2012 |
| Financial Condition | | | | | |
| Cash, cash equivalents and marketable securities | $7,724.5 | $6,188.9 | $3,316.0 | $1,848.5 | $3,742.4 |
| Total assets | $22,876.8 | $19,504.8 | $14,314.7 | $11,863.3 | $10,130.1 |
| Notes payable and other financing arrangements, less current portion (b) | $6,512.7 | $6,521.5 | $580.3 | $592.4 | $687.4 |
| Total Biogen Inc. shareholders' equity (c) | $12,140.1 | $9,372.8 | $10,809.0 | $8,620.2 | $6,961.5 |

In addition to the following notes, the financial data included within the tables above should be read in conjunction with our consolidated financial statements and related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this report and our previously filed Form 10-Ks.

(a) Product revenues, net reflect the impact of the following product launches:

- Commercial sales of SPINRAZA began in the fourth quarter of 2016.

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- Under the terms of our collaboration agreement with AbbVie, we began to recognize revenues on sales of ZINBRYTA to third parties in the E.U. in the third quarter of 2016.
- Under the terms of our commercial agreement with Samsung Bioepis, we began to recognize revenues on sales of BENEPALI and FLIXABI to third parties in the E.U. in the first quarter of 2016 and third quarter of 2016, respectively.
- Commercial sales of ALPROLIX commenced in the second quarter of 2014 and commercial sales of ELOCTATE and PLEGRIDY commenced in the third quarter of 2014.
- TECFIDERA began in April 2013.

(b) Notes payable and other financing arrangements reflects the issuance of our senior unsecured notes for an aggregate principal amount of $6.0 billion in September 2015, and the 2013 repayment of our 6.0% notes that were issued in 2008 for an aggregate principal amount of $450.0 million.

(c) Total Biogen Inc.'s shareholders' equity reflects the repurchase of approximately 32.8 million shares of our common stock at a cost of approximately $8.3 billion between 2012 and 2016:

- During 2016 we repurchased and retired approximately 3.3 million shares of our common stock at a cost of $1.0 billion under our 2016 Share Repurchase Program.
- During 2015 we repurchased and retired approximately 16.8 million shares of our common stock at a cost of $5.0 billion under our 2015 Share Repurchase Program.
- During 2014, 2013 and 2012 we repurchased approximately 2.9 million, 2.0 million and 7.8 million shares, respectively of our common stock at a cost of approximately $2.3 billion under our 2011 Share Repurchase Program of which approximately 3.7 million of these shares were retired.

(d) Total cost and expenses for the years ended December 31, 2016 and 2015, include restructuring charges of $33.1 million and $93.4 million, respectively. In addition, total cost and expenses for the year ended December 31, 2016, also include charges to cost of sales totaling $52.4 million of expenses incurred as a result of our determination to vacate and cease manufacturing in our small-scale biologics facility in Cambridge, MA as well as vacate our warehouse in Somerville, MA. Total cost and expenses for year ended December 31, 2016, also include $18.1 million of costs incurred directly related to our separation of our hemophilia business into an independent, publicly traded company.

(e) Total cost and expenses for the year ended December 31, 2016, includes a pre-tax charge of $454.8 million related to the January 2017 settlement and license agreement with Forward Pharma A/S (Forward Pharma).

(f) In June 2014 AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. As a result, we recognized $53.5 million of TYSABRI revenues in the second quarter of 2014 related to the periods beginning February 2013 that were previously deferred.

(g) Our share of revenues from anti-CD20 therapeutic programs reflects charges of $49.7 million in 2013 for damages and interest awarded to Hoechst in Genentech's arbitration with Hoechst for RITUXAN.

(h) Commencing in the second quarter of 2013 product and total revenues include 100% of net revenues related to sales of TYSABRI as a result of our acquisition of all remaining rights to TYSABRI from Elan Pharma International, Ltd (Elan), an affiliate of Elan Corporation, plc. Upon the closing, our collaboration agreement was terminated, and we no longer record collaboration profit sharing expense. We recognized collaboration profit sharing expense of $85.4 million and $317.9 million during the years ended December 31, 2013 and 2012, respectively.

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1 of this report. Certain totals may not sum due to rounding.

Executive Summary

Introduction

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to people living with serious neurological, rare and autoimmune diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), FUMADERM for the treatment of severe plaque psoriasis and SPINRAZA for the treatment of spinal muscular atrophy (SMA). We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma, and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group.

In May 2016 we announced our intention to spin off our hemophilia business, Bioverativ Inc. (Bioverativ), as an independent, publicly traded company. Bioverativ will focus on the discovery, development and commercialization of therapies for the treatment of hemophilia and other blood disorders, including ELOCTATE for the treatment of hemophilia A and ALPROLIX for the treatment of hemophilia B. Bioverativ will also assume all of our rights and obligations under our collaboration agreement with Swedish Orphan Biovitrum AB (Sobi) and our collaboration and license agreement with Sangamo Biosciences Inc. (Sangamo).

On February 1, 2017, we completed the distribution of all the then outstanding shares of common stock of Bioverativ to Biogen stockholders, who received one share of Bioverativ common stock for every two shares of Biogen common stock. As a result of the distribution, Bioverativ is now an independent public company whose shares of common stock are trading under the symbol "BIVV"

on the Nasdaq Global Select Market.

The financial results of Bioverativ are included in our consolidated results of operations and financial position in our audited consolidated financial statements for the periods presented in this Form 10-K. The financial results of Bioverativ will be excluded from our consolidated results of operations and financial position commencing February 1, 2017. For additional information regarding the separation of Bioverativ, please read Note 26, Subsequent Events to our consolidated financial statements included in this report.

Our current revenues depend upon continued sales of our principal products and, unless we develop, acquire rights to, and commercialize new products and technologies, we may be substantially dependent on sales from our principal products for many years. Further, following the completion of the spin-off of our hemophilia business, our revenues will be further reliant and concentrated on sales of our MS products in an increasingly competitive market.

In the longer term, our revenue growth will be dependent upon the successful clinical development, regulatory approval and launch of new commercial products as well as additional indications for our existing products, our ability to obtain and maintain patents and other rights related to our marketed products, assets originating from our research and development efforts and successful execution of external business development opportunities.

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within areas of our scientific, manufacturing and technical capabilities. For nearly two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as, the development of next generation therapies for MS with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (ALS), and are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy.

Our innovative drug development and commercialization activities are complemented by our biosimilar therapies that expand access to medicines and reduce the cost burden for healthcare systems. We are leveraging our manufacturing

capabilities and know-how by developing, manufacturing and marketing

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biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics). Under our commercial agreement with Samsung Bioepis, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the European Union (E.U.).

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were $16.93 for 2016, representing an increase of 10.4% over the same period in 2015.

As described below under “Results of Operations,” our income from operations for the year ended December 31, 2016, reflects the following:

- Total revenues were $11,448.8 million for 2016, representing an increase of 6.4% over the same period in 2015. Product revenues, net totaled $9,817.9 million for 2016, representing an increase of 6.8% over the same period in 2015. This increase was driven by a 9.1% increase in worldwide TECFIDERA revenues, a 52.8% increase in worldwide hemophilia revenues, a 4.1% increase in worldwide TYSABRI revenues and revenues from BENEPALI. These increases are partially offset by a 5.8% decrease in worldwide Interferon revenues. Product revenues, net for 2016, compared to the same period in 2015, were also negatively impacted by a $167.8 million decrease in hedge gains recognized under our foreign currency hedging program in comparative periods.
- Revenues from anti-CD20 therapeutic programs totaled $1,314.5 million for 2016, representing a decrease of 1.8% over the same period in 2015.
- Other revenues totaled $316.4 million for 2016, representing an increase of 34.0% from the same period in 2015. This increase was primarily driven by an increase in other corporate revenues, which includes amounts earned with respect to our contract manufacturing activities.
- Total cost and expenses totaled $6,298.4 million for 2016, representing an increase of 7.2%, compared to the same period in 2015. This increase was driven by a $454.8 million litigation settlement and license charge and a 19.2% increase in cost of sales, which includes a charge of $45.5 million for accelerated depreciation as a result of the determination to cease manufacturing in Cambridge, MA and vacate our biologics manufacturing facility in Cambridge, MA and warehouse space in Somerville, MA. These increases were partially offset by a 7.8% decrease in selling, general and administrative expenses and a decrease in restructuring charges.

We generated $4,522.4 million of net cash flows from operations for 2016, which were primarily driven by earnings. Cash, cash equivalents and marketable securities totaled approximately $7,724.5 million as of December 31, 2016. During the year ended December 31, 2016, we repurchased and retired approximately 3.3 million shares of common stock at a cost of $1.0 billion under our share repurchase programs.

Collaborative and Other Relationships

In May 2016 we entered into a collaboration and alliance with the University of Pennsylvania (UPenn) to advance gene therapy and gene editing technologies. For additional information related to this transaction, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Restructuring and Cost Saving Initiatives

During the third quarter of 2016 we initiated cost saving measures primarily intended to realign our organizational structure due to the changes in roles and workforce resulting from our decision to spin off our hemophilia business, and to achieve further targeted cost reductions.

Additionally, in connection with the transaction to sublease our rights to the manufacturing facility in Cambridge, MA to Brammer Bio MA, LLC (Brammer), certain employees were separated from Biogen.

For additional information related to our restructuring and cost saving initiatives, please read Note 3, Restructuring, Business Transformation and Other Cost Saving Initiatives to our consolidated financial statements included in this report.

Business Environment

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing. In addition, the commercialization of certain of our own approved MS products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing MS products. Our products may also face increased competitive pressures from the introduction of generic versions, prodrugs of existing therapeutics or biosimilars of existing products and other technologies, such as gene therapies and bispecific antibodies.

In addition, sales of our products are dependent, in large part, on the availability and extent of coverage, pricing and reimbursement from government health administration authorities, private health insurers and other organizations. Drug prices are under significant scrutiny in the markets in which our products are prescribed. Drug pricing and other health care costs continue to be subject to intense political and societal pressures.

For additional information related to our competition and pricing risks that could negatively impact our product sales, please read the “Risk Factors” section of this report.

Results of Operations

Revenues

Revenues are summarized as follows:

| | For the Years Ended December 31, | | | % Change | |
|---|---|---|---|---|---|
| (In millions, except percentages) | 2016 | 2015 | 2014 | 2016 compared to 2015 | 2015 compared to 2014 |
| Product Revenues: | | | | | |
| United States | $7,050.4 | $6,545.8 | $5,566.7 | 7.7 % | 17.6 % |
| Rest of world | 2,767.5 | 2,642.7 | 2,636.7 | 4.7 % | 0.2 % |
| Total product revenues | 9,817.9 | 9,188.5 | 8,203.4 | 6.8 % | 12.0 % |
| Revenues from anti-CD20 therapeutic programs | 1,314.5 | 1,339.2 | 1,195.4 | (1.8 )% | 12.0 % |
| Other revenues | 316.4 | 236.1 | 304.5 | 34.0 % | (22.5 )% |
| Total revenues | $11,448.8 | $10,763.8 | $9,703.3 | 6.4 % | 10.9 % |

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Product Revenues

Product revenues are summarized as follows:

| (In millions, except percentages) | For the Years Ended December 31, 2016 | 2015 | 2014 | % Change 2016 compared to 2015 | 2015 compared to 2014 |
|---|---|---|---|---|---|
| Multiple Sclerosis: | | | | | |
| TECFIDERA | $3,968.1 | $3,638.4 | $2,909.2 | 9.1 % | 25.1 % |
| Interferon* | 2,795.2 | 2,968.7 | 3,057.6 | (5.8)% | (2.9)% |
| TYSABRI | 1,963.8 | 1,886.1 | 1,959.5 | 4.1 % | (3.7)% |
| FAMPYRA | 84.9 | 89.7 | 80.2 | (5.4)% | 11.8 % |
| ZINBRYTA | 7.8 | — | — | ** | ** |
| Hemophilia: | | | | | |
| ELOCTATE | 513.2 | 319.7 | 58.4 | 60.5 % | 447.4 % |
| ALPROLIX | 333.7 | 234.5 | 76.0 | 42.3 % | 208.6 % |
| Other product revenues: | | | | | |
| FUMADERM | 45.9 | 51.4 | 62.5 | (10.7)% | (17.8)% |
| SPINRAZA | 4.6 | — | — | ** | ** |
| BENEPALI | 100.6 | — | — | ** | ** |
| FLIXABI | 0.1 | — | — | ** | ** |
| Total product revenues | $9,817.9 | $9,188.5 | $8,203.4 | 6.8 % | 12.0 % |

* Interferon includes AVONEX and PLEGRIDY.

** Percentage not meaningful.

Multiple Sclerosis (MS)

TECFIDERA

For 2016 compared to 2015, the increase in U.S. TECFIDERA revenues was primarily due to price increases, partially offset by higher discounts and allowances and a decrease in unit sales volume of 1%.

For 2015 compared to 2014, the increase in U.S. TECFIDERA revenues was primarily due to increases in unit sales volume of 13% as TECFIDERA penetrated the U.S. market, and increases in gross price partially offset by higher discounts and allowances.

For 2016 compared to 2015, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume of 32% in existing markets and new markets where we continue to launch the product and expand our presence around the world. These increases were partially offset by pricing reductions in certain European countries. Rest of world TECFIDERA revenues for 2016, compared to 2015, were also negatively impacted by a $50.2 million decrease in hedge gains recognized under our foreign currency hedging program in the comparative period.

For 2015 compared to 2014, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume in existing markets and in new markets as we continue to launch the product and expand our presence around the world. These increases were partially offset by pricing reductions in Germany as described below. Rest of world TECFIDERA revenues for 2015, compared to 2014, were also negatively impacted by foreign currency exchange losses totaling $74.1 million. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program totaling $47.5 million.

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Under German legislation related to the pricing of new drug products introduced in the German market, pricing is unregulated for the first 12 months after launch. We launched TECFIDERA in Germany in February 2014 and our unregulated pricing ended in the first quarter of 2015, at which time we began recognizing revenue at the fixed price established through our negotiations with the German regulatory authorities. The negotiated annual price is fixed for three years.

We anticipate relatively stable demand for TECFIDERA in 2017 on a global basis, with patient growth in our international markets offsetting modest patient declines in the U.S. primarily resulting from increasing competition from additional treatments and product candidates for MS, including OCREVUS.

Interferon

AVONEX and PLEGRIDY

For 2016, 2015 and 2014, U.S. AVONEX revenues totaled $1,675.3 million, $1,790.2 million and $1,956.7 million, respectively.

For 2016, 2015 and 2014, U.S. PLEGRIDY revenues totaled $305.0 million, $227.1 million and $27.8 million, respectively.

For 2016 compared to 2015, the decrease in U.S. Interferon revenues was primarily due to an overall decrease in Interferon unit sales volume of 10%, which was attributable to a decrease in AVONEX unit sales volume primarily due to patients transitioning to other oral MS therapies, as well as higher discounts and allowances. These decreases were partially offset by price increases.

For 2015 compared to 2014, the increase in U.S. Interferon revenues was primarily due to gross price increases for AVONEX and an increase in PLEGRIDY unit sales volume as sales of PLEGRIDY began in the U.S. in fourth quarter of 2014. These increases were partially offset by a decrease in AVONEX unit sales volume of 17%, which was attributable in part to patients transitioning to other oral MS therapies, including TECFIDERA.

For 2016, 2015 and 2014 rest of world AVONEX revenues totaled $638.2 million, $840.0 million and $1,056.4 million, respectively.

For 2016, 2015 and 2014, rest of world PLEGRIDY revenues totaled $176.7 million, $111.4 million and $16.7 million, respectively.

For 2016 compared to 2015, the decrease in rest of world Interferon revenues was primarily due to pricing reductions in certain European countries and an overall decrease in AVONEX unit sales volume of 10% due primarily to patients transitioning to other oral MS therapies, including TECFIDERA. Rest of world Interferon revenues for 2016, compared to 2015, were also negatively impacted by a $66.1 million decrease in hedge gains recognized under our hedging program in the comparative period.

For 2015 compared to 2014, the decrease in rest of world Interferon revenues was due to a decrease in AVONEX unit sales volume of 11% primarily in Europe attributable to patients transitioning to other oral MS therapies, including TECFIDERA. These increases were partially offset by an increase in PLEGRIDY unit sales volume as sales of PLEGRIDY began in the E.U. in the third quarter of 2014. Rest of world Interferon revenues for 2015, compared to 2014, were also negatively impacted by foreign currency exchange losses of $153.1 million. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program of $58.4 million.

We expect that overall Interferon revenues will continue to decline as a result of competition from our other products as well as other MS therapies.

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TYSABRI

For 2016 compared to 2015, the increase in U.S. TYSABRI revenues was primarily due to an increase in unit sales volume of 4% and increases in price, partially offset by higher discounts and allowances.

For 2015 compared to 2014, the increase in U.S. TYSABRI revenues was primarily due to an increase in unit sales volume of 4% and increases in gross price, partially offset by higher discounts and allowances.

For 2016 compared to 2015, the slight decrease in rest of world TYSABRI revenues was primarily due to the impact of a $46.1 million decrease in hedge gains recognized under our hedging program in the comparative period. This decrease was partially offset by an increase in unit sales volume of 8%, primarily in Europe.

For 2015 compared to 2014, the decrease in rest of world TYSABRI revenues was due to pricing reductions in some European countries and the prior year recognition of $53.5 million of revenue previously deferred in Italy relating to the pricing agreement with the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) as discussed below.

Rest of world TYSABRI revenues for 2015, compared to 2014, were negatively impacted by foreign currency exchange losses of $136.3 million. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program of $45.9 million.

In the fourth quarter of 2011 Biogen Italia SRL, our Italian subsidiary, received a notice from AIFA that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. In January 2017, we negotiated an agreement in principle with AIFA's Price and Reimbursement Committee to settle all of AIFA's existing claims relating to sales of TYSABRI in excess of the reimbursement limit for the periods from February 2009 through January 2013 for an aggregate repayment of EUR37.4 million. The agreement is subject to ratification by AIFA. If this most recent settlement agreement is accepted, we could recognize approximately EUR42 million in revenue upon resolution of this matter. For information regarding our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 17, Other Consolidated Financial Statement Detail to our consolidated financial statements included in this report.

We anticipate relatively stable demand for TYSABRI in 2017 on a global basis, with patient growth in our international markets offsetting modest patient declines in the U.S. primarily resulting from increasing competition from additional treatments and product candidates for MS, including ZINBRYTA and OCREVUS.

ZINBRYTA

Under the terms of our collaboration agreement with AbbVie, we began to recognize revenues on sales of ZINBRYTA to third parties in the E.U. in the third quarter of 2016.

For additional information on our relationship with AbbVie, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Hemophilia

ELOCTATE

For 2016 compared to 2015, the increase in U.S. ELOCTATE revenues was primarily due to an increase in unit sales volume of 45%.

For 2015 compared to 2014, the increase in U.S. ELOCTATE revenues was primarily due to increases in unit sales volume. Sales of ELOCTATE in the U.S. began in the third quarter of 2014.

For 2016 compared to 2015, the increase in rest of world ELOCTATE revenues was primarily due to an increase in unit sales volume, primarily in Japan.

For 2015 compared to 2014, the increase in rest of world ELOCTATE revenues was primarily due to increases in unit sales volume. Sales of ELOCTATE in Japan began in the first quarter of 2015.

ALPROLIX

For 2016 compared to 2015, the increase in U.S. ALPROLIX revenues was primarily due to an increase in unit sales volume of 28%.

For 2015 compared to 2014, the increase in U.S. ALPROLIX revenues was primarily due to increases in unit sales volume. Sales of ALPROLIX in the U.S. began in the second quarter of 2014.

For 2016 compared to 2015, the increase in rest of world ALPROLIX revenues was primarily due to an increase in unit sales volume, primarily in Japan.

For 2015 compared to 2014, the increase in rest of world ALPROLIX revenues was primarily due to increases in unit sales volume. Sales of ALPROLIX in Japan began in the fourth quarter of 2014.

On February 1, 2017, we completed the distribution of the then outstanding shares of common stock of Bioverativ to Biogen stockholders. As a result of the distribution, Bioverativ will assume discovery, development and commercialization of ELOCTATE and ALPROLIX in the U.S.

For additional information on the transaction to separate from and spin off our hemophilia business as a separate independent public company, please read Note 26, Subsequent Events to our consolidated financial statements included in this report.

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Biosimilars

Under the terms of our commercial agreement with Samsung Bioepis, we began to recognize revenues on sales of BENEPALI and FLIXABI to third parties in the E.U. in the first quarter of 2016 and third quarter of 2016, respectively.

For additional information on our relationship with Samsung Bioepis, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN and GAZYVA operating profits are summarized as follows:

Biogen's Share of Pre-tax Profits in the U.S. for RITUXAN and GAZYVA

The following table provides a summary of amounts comprising our share of pre-tax profits on RITUXAN and GAZYVA in the U.S.:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Product revenues, net | $3,941.8 | $3,847.9 | $3,556.6 |
| Cost and expenses | 744.5 | 673.7 | 771.1 |
| Pre-tax profits in the U.S. | $3,197.3 | $3,174.2 | $2,785.5 |
| Biogen's share of pre-tax profits | $1,249.5 | $1,269.8 | $1,117.1 |

Our share of RITUXAN pre-tax profits in the U.S. decreased to 39% from 40% as GAZYVA was approved by the FDA in follicular lymphoma in February 2016.

For 2016 compared to 2015, the increase in U.S. product revenues was primarily due to an increase in GAZYVA unit sales volume of 41%, an increase in RITUXAN unit sales of 1% and selling price increases, partially offset by higher RITUXAN discounts and allowances.

For 2015 compared to 2014, the increase in U.S. product revenues was primarily due to a 4% increase in RITUXAN unit sales volume and selling price increases, partially offset by higher discounts and allowances.

Collaboration costs and expenses for 2016 compared to 2015 increased primarily due to an increase in RITUXAN product cost of sales.

Collaboration costs and expenses for 2015 compared to 2014 decreased primarily due to the 2014 recognition of $53.9 million of additional Branded Pharmaceutical Drug (BPD) fee expense as well as lower RITUXAN cost of sales, partially offset by higher GAZYVA sales and marketing expenses. During 2014 the Internal Revenue Service issued final regulations related to the BPD fee, which had the effect of changing the recognition of the fee for accounting purposes, from the period in which the fee was paid, to the period when the sale occurs. As a result of these final regulations, we recognized an incremental BPD fee in 2014 for the periods 2013 through the end of the third quarter of 2014. The final regulations did not change the timing of payments.

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For additional information related to our collaboration with Genentech, including information regarding the pre-tax profit sharing formula and its impact on future revenues from anti-CD20 therapeutic programs, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Revenue on Sales in the Rest of World for RITUXAN

Revenue on sales in the rest of world for RITUXAN primarily consists of our share of pre-tax co-promotion profits on RITUXAN in Canada.

For 2016 compared to 2015, and 2015 compared to 2014, revenue on sales in the rest of world for RITUXAN decreased as a result of lower pre-tax co-promotion profits on RITUXAN in Canada.

Other Revenues

Other revenues are summarized as follows:

| | For The Years Ended December 31, | | | % Change | |
|---|---|---|---|---|---|
| (In millions, except percentages) | 2016 | 2015 | 2014 | 2016 compared to 2015 | 2015 compared to 2014 |
| Revenues from collaborative and other relationships | $39.3 | $69.1 | $58.5 | (43.1)% | 18.1 % |
| Other royalty and corporate revenues | 277.1 | 167.0 | 246.0 | 65.9 % | (32.1 )% |
| Total other revenues | $316.4 | $236.1 | $304.5 | 34.0 % | (22.5 )% |

Revenues from Collaborative and Other Relationships

Revenues from collaborative and other relationships include revenues earned under our manufacturing services agreement with Sobi on shipments of ELOCTA and ALPROLIX to Sobi, royalties from Sobi on sales of ELOCTA and ALPROLIX in their territory, which includes substantially all of Europe, Russia and certain markets in Northern Africa and the Middle East (the Sobi Territory), our 50% share of the co-promotion profits or losses of ZINBRYTA in the U.S. with AbbVie and revenues from our technical development and manufacturing services agreements with Samsung Bioepis.

For 2016 compared to 2015, the decrease in revenues from collaborative and other relationships is primarily due to a net overall loss in the collaboration with AbbVie of $21.9 million within the U.S. territory and lower revenues earned under our manufacturing services agreement with Samsung Bioepis, partially offset by an increase in ELOCTA shipments made under our manufacturing services agreement with Sobi.

For 2015 compared to 2014, the increase in revenues from collaborative and other relationships was primarily due to the start of product shipments to Sobi in relation to our collaboration agreement, as well as increased revenues earned under our manufacturing services agreement with Samsung Bioepis.

For additional information on our collaborative and other relationships, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Other Royalty and Corporate Revenues

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Royalty Revenues

We receive royalties from net sales on products related to patents that we have out-licensed. Prior to 2015, our most significant source of royalty revenue had been derived from net worldwide sales of ANGIOMAX, which was out-licensed to The Medicines Company. On December 15, 2014 we ceased recognizing royalty revenues from U.S. sales of ANGIOMAX, contemporaneous with the U.S. patent's expiration.

For 2016 compared to 2015, royalty revenues were relatively consistent.

For 2015 compared to 2014, royalty revenues decreased primarily due to the expiration of U.S. patent rights that gave rise to royalty payments related to ANGIOMAX.

Other Corporate Revenues

Our corporate partner revenues include amounts earned under contract manufacturing agreements.

For 2016 compared to 2015, as well as 2015 compared to 2014, to the increase in other corporate revenues was primarily due to higher contract manufacturing revenues related to drug substance manufacturing provided to a strategic partner.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances, including those associated with the implementation of pricing actions in certain international markets where we operate.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which will have an effect on earnings in the period of adjustment.

Reserves for discounts, contractual adjustments and returns that reduced gross product revenues are summarized as follows:

For the years ended December 31, 2016, 2015 and 2014, reserves for discounts and allowances as a percentage of gross product revenues were 21.3%, 19.3% and 16.6%, respectively.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For 2016 compared to 2015, the increase in discounts was primarily driven by increases in gross selling price, contractual discount rates and volume related to our hemophilia products.

For 2015 compared to 2014, the increase in discounts was primarily driven by our recent product additions, gross price increases and increases in contractual rates

Contractual Adjustments

Contractual adjustments relate to Medicaid and managed care rebates, co-payment assistance (copay), Veterans Administration (VA), Public Health Service (PHS) discounts, specialty pharmacy program fees and other government rebates or applicable allowances.

For 2016 compared to 2015, the increase in contractual adjustments was primarily due to higher Medicaid and other governmental rebates and allowances in the U.S. and managed care rebates, due in part to an increase in gross selling prices.

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For 2015 compared to 2014, the increase in contractual adjustments was primarily due to our recent product additions, higher Medicaid and other governmental rebates and allowances in the U.S. and managed care rebates as a result of an increase in contracted business and gross prices.

Returns

Product return reserves are established for returns made by wholesalers. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to

product expiration. Provisions for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales.

For 2016 compared to 2015, and 2015 compared to 2014, return reserves decreased primarily due to a reduction in return rates based on recent experiences of returned products.

For additional information related to our reserves, please read Note 4, Reserves for Discounts and Allowances to our consolidated financial statements included in this report.

Cost and Expenses

A summary of total cost and expenses is as follows:

| | For the Years Ended December 31, | | | % Change | |
|---|---|---|---|---|---|
| (In millions, except percentages) | 2016 | 2015 | 2014 | 2016 compared to 2015 | 2015 compared to 2014 |
| Cost of sales, excluding amortization of acquired intangible assets | $1,478.7 | $1,240.4 | $1,171.0 | 19.2 % | 5.9 % |
| Research and development | 1,973.3 | 2,012.8 | 1,893.4 | (2.0)% | 6.3 % |
| Selling, general and administrative | 1,947.9 | 2,113.1 | 2,232.3 | (7.8)% | (5.3)% |
| Amortization of acquired intangible assets | 385.6 | 382.6 | 489.8 | 0.8 % | (21.9)% |
| Restructuring charges | 33.1 | 93.4 | — | (64.6)% | ** |
| (Gain) loss on fair value remeasurement of contingent consideration | 14.8 | 30.5 | (38.9) | (51.5)% | (178.4)% |
| Collaboration profit sharing | 10.2 | — | — | ** | ** |
| TECFIDERA litigation settlement and license charges | 454.8 | — | — | ** | ** |
| Total cost and expenses | $6,298.4 | $5,872.8 | $5,747.7 | 7.2 % | 2.2 % |

** Percentage not meaningful.

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Cost of Sales, Excluding Amortization of Acquired Intangible Assets (Cost of Sales)

Product Cost of Sales

For 2016 compared to 2015, the increase in product cost of sales was primarily driven by increased contract manufacturing shipments and higher unit sales volume related to our biosimilars and hemophilia products, partially offset by favorable production costs and mix of products.

Product cost of sales for 2016 also reflects the recognition of $45.5 million of accelerated depreciation as a result of the determination to cease manufacturing in Cambridge, MA and vacate our biologics manufacturing facility in Cambridge, MA and warehouse space in Somerville, MA.

For 2015 compared to 2014, the increase in product cost of sales was primarily driven by increased contract manufacturing production and higher unit sales volume of our marketed products, including newly launched products. Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons totaled $48.2 million, $41.9 million and $50.6 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Royalty Cost of Sales

For 2016 compared to 2015, the increase in royalty cost of sales was primarily driven by the increase in royalty rates payable to Sobi, increased sales of our hemophilia products and higher royalties on sales of AVONEX and PLEGRIDY in the U.S., partially offset by a decrease in TYSABRI royalties due to the expiration of certain third party royalties.

On June 28, 2016, the U.S. Patent and Trademark Office issued to the Japanese Foundation for Cancer Research (JFCR) a patent related to recombinant interferon-beta protein. This patent, U.S. Patent No. 9,376,478, expires in June 2033. This patent was issued following an interference proceeding between JFCR and us. This patent is relevant to AVONEX and PLEGRIDY, and we will pay royalties in the mid-single digits in relation to this patent during the life of the patent.

For 2015 compared to 2014, the increase in royalty cost of sales was primarily driven by the increase in royalties due to Sobi on increased sales of our hemophilia products and an increase in the contractual rate of TYSABRI contingent payments due to Perrigo Company plc (Perrigo), which is based on the expected level of annual worldwide net sales of TYSABRI, partially offset by a decrease in TYSABRI revenues and the expiration of certain third-party royalties related to TYSABRI.

For additional information on our relationship with Sobi, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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Research and Development

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Research and development expense incurred in support of our marketed products includes costs associated with product lifecycle management activities including, if applicable, costs associated with the development of new indications for existing products. Late stage programs are programs in Phase 3 development or in registration stage. Early stage programs are programs in Phase 1 or Phase 2 development. Research and discovery represents costs incurred to support our discovery research and translational science efforts. Other research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as management costs as well as depreciation and other facility-based expenses. Costs are reflected in the development stage based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same year. For several of our programs, the research and development activities are part of our collaborative and other relationships. Our costs reflect our share of the total costs incurred.

For 2016 compared to 2015, the decrease in research and development expense was primarily related to decreases in costs incurred in connection with our early stage programs, marketed products and other research and development costs. These decreases were partially offset by increased costs incurred in connection with our late stage programs and research and discovery.

The decrease in spending associated with our early stage programs for 2016 compared to 2015 was primarily due to the advancement of our aducanumab program for Alzheimer's disease to a late stage program in the third quarter of 2015, decreased costs incurred in connection with opicinumab in MS and the discontinuance of development of anti-TWEAK in lupus nephritis. These decreases were partially offset by increased costs of BIIB074 (formerly known as Raxatrigine) in trigeminal neuralgia (TGN) and increased costs associated with our discontinuance of development of amiselimod in the third quarter of 2016.

The decrease in spending associated with our marketed products for 2016 compared to 2015 was primarily due to the discontinuance of development of TYSABRI and TECFIDERA in secondary primary multiple sclerosis (SPMS) in the third and fourth quarters of 2015, respectively, and decreased costs incurred in connection with our hemophilia products. These decreases were partially offset by the approvals of ZINBRYTA and SPINRAZA in the third and fourth quarters of 2016, respectively.

The increase in spending associated with our late stage programs for 2016 compared to 2015 was primarily driven by costs incurred to advance our aducanumab program for Alzheimer's disease, the increased costs incurred to advance our SPINRAZA program for the treatment of SMA and the advancement of E2609 to a late stage program in the fourth quarter of 2016, partially offset by the approval of ZINBRYTA in the third quarter of 2016.

For 2015 compared to 2014, the increase in research and development expense was primarily related to increases in costs incurred in connection with our late and early stage programs and research and discovery, partially offset by a decrease in milestone and upfront expenses and the positive impact of foreign currency translation of $34.0 million.

The increase in spending associated with our late stage programs for 2015 compared to 2014 was primarily driven by costs incurred to advance our aducanumab program for Alzheimer's disease and the SPINRAZA program for the treatment of SMA, partially offset by a decrease in costs related to ZINBRYTA and the approvals of PLEGRIDY and ELOCTATE in 2014.

The increase in spending associated with our early stage programs for 2015 compared to 2014 was primarily due to costs incurred in connection with our aducanumab program for Alzheimer's disease, which advanced to a late stage program during the third quarter of 2015, the BAN2401 program for Alzheimer’s disease related to our collaboration with Eisai and our BIIB074 program for TGN. These increases were partially offset by a decrease in costs incurred in connection with the SPINRAZA program for the treatment of SMA as the program advanced to a late stage program during the first quarter of 2015.

We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where the drug candidate has the potential to be highly differentiated. Specifically, we intend to continue to invest in our MS pipeline, our aducanumab program, the BAN2401 and E2609 programs and our BIIB074 program.

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Milestone and Upfront Expenses included in Research and Development Expense

Research and development expense for 2016 includes a $75.0 million license fee paid to Ionis as we exercised our option to develop and commercialize SPINRAZA from Ionis, a $50.0 million milestone payment due to Eisai related to the initiation of a Phase 3 trial for E2609 and a $20.0 million upfront milestone paid to the UPenn upon entering into a collaboration and alliance. For additional information about these transactions, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Research and development expense for 2015 includes $60.0 million recorded upon entering into our collaboration with Mitsubishi Tanabe Pharma Corporation (MTPC), $48.1 million recorded upon entering into our collaboration with Applied Genetic Technologies Corporation (AGTC), $30.0 million recorded as milestones in relation to our collaboration agreements with Ionis and $16.0 million paid to AbbVie related to milestones for the development of ZINBRYTA as a result of filing with the FDA and EMA during the year. For additional information about these transactions, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Research and development expense for 2014 includes $139.3 million recorded in connection with our collaboration agreement with Eisai Co., Ltd. (Eisai), $25.0 million recorded as milestones in relation to our collaboration agreements with Ionis and an aggregate of $60.0 million related to upfront payments made to Sangamo and Google Inc. and for other strategic business arrangements.

These payments are classified as research and development expense as the programs they relate to had not achieved regulatory approval as of the payment date.

Selling, General and Administrative

For 2016 compared to 2015, the decrease in selling, general and administrative expenses reflects cost savings in connection with our corporate restructuring, which are described below under the heading "Restructuring Charges," partially offset by an increase in costs associated with developing commercial capabilities for ZINBRYTA and SPINRAZA.

For 2015 compared to 2014, the decrease in selling, general and administrative expenses was driven by a decrease in corporate giving, incentive compensation and the positive impact of foreign currency translation of $87.6 million, partially offset by an increase of $38.9 million of BPD fee expense.

Amortization of Acquired Intangible Assets

Our amortization expense is based on the economic consumption of intangible assets. Our most significant intangible assets are related to our AVONEX and TYSABRI products. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of AVONEX and TYSABRI.

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Our most recent long range planning cycle was completed in the third quarter of 2016. Based upon this analysis, the estimated future amortization of acquired intangible assets is expected to be as follows:

| (In millions) | As of December 31, 2016 |
|---|---|
| 2017 | $ 334.8 |
| 2018 | 312.7 |
| 2019 | 295.2 |
| 2020 | 259.7 |
| 2021 | 242.8 |

We monitor events and expectations regarding product performance. If new information indicates that the assumptions underlying our most recent analysis are substantially different than those utilized in our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenues of the relevant process. The occurrence of an adverse event could substantially increase the amount of amortization expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

For 2016 compared to 2015, the amortization of acquired intangible assets was relatively consistent as our most recent analysis completed during the third quarter of 2016 resulted in no significant net change in our expected rate of amortization for acquired intangible assets.

For 2015 compared to 2014, the decrease in amortization of acquired intangible assets was primarily driven by a decrease in AVONEX revenues during the comparative periods and the impact of higher expected lifetime revenues of AVONEX due to a slower than previously expected adoption of PLEGRIDY. Amortization of acquired intangible assets during 2014 included total impairment charges of $50.9 million related to one of our out-licensed patents and one of our in-process research and development (IPR&D) intangible assets.

For additional information related to the amortization of acquired intangible assets, please read Note 6, Intangible Assets and Goodwill to our consolidated financial statements included in this report.

Impairment of Intangible Assets

We record charges associated with impairments of intangible assets in amortization of intangible assets.

During 2016 we terminated our collaboration agreements with Rodin Therapeutics, Inc. and Ataxion Inc., resulting in impairment losses of $8.7 million and $3.5 million, respectively, related to the IPR&D assets recorded upon entering into the collaboration agreements.

Impairment charges related to our intangible assets during 2015 were insignificant.

During 2014 we recorded a charge of $34.7 million related to the impairment of one of our out-licensed patents to reflect a change in its estimated fair value, due to a change in the underlying competitive market for that product. During 2014 we updated the probabilities of success related to the early stage programs acquired through our recent acquisitions. This change in probability of success, combined with a delay in one of the projects, resulted in an impairment loss of $16.2 million.

For additional information, please read Note 6, Intangible Assets and Goodwill to our consolidated financial statements included in this report.

IPR&D

Overall, the value of our acquired IPR&D assets is dependent upon a number of variables, including estimates of future revenues and the effects of competition, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from a clinical trial phase to the next. We are continually reevaluating our estimates concerning these variables and evaluating industry data regarding the productivity of clinical research and the development process. Changes in our estimates of items may result in a significant change to our valuation of these assets.

The field of developing treatments for forms of neuropathic pain, such as TGN, and idiopathic pulmonary fibrosis (IPF) are highly competitive and can be affected by changes to expected market candidates and changes in timing and

the clinical development of our product candidates. There can be no assurance that we will be able to successfully develop BIIB074 for the treatment of TGN or STX-100 for the treatment of IPF, or other indications or that a successfully developed therapy will be able to secure sufficient pricing in a competitive market. Changes to clinical development plans or life cycle management strategies are evaluated regularly. We review amounts

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capitalized as acquired IPR&D for impairment at least annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Our most recent impairment assessment as of October 31, 2016 resulted in no impairments.

Restructuring, Business Transformation and Other Cost Saving Initiatives

2015 Cost Saving Initiatives

2015 Restructuring Charges

On October 21, 2015, we announced a corporate restructuring, which included the termination of certain pipeline programs and an 11% reduction in workforce. As a result of these initiatives, we reduced our annual run rate of operating expenses by $250 million and reinvested these savings to support the advancement of our high potential pipeline candidates and key commercial activities.

Under this restructuring, cash payments were estimated to total $120 million, of which $15.9 million were related to previously accrued 2015 incentive compensation, resulting in net restructuring charges totaling approximately $102.0 million. These amounts were substantially incurred and paid by the end of 2016.

For the years ended December 31, 2016 and 2015, we recognized total net restructuring charges of $8.0 million and $93.4 million, respectively.

The following table summarizes the charges and spending related to our 2015 restructuring program during 2016:

| (In millions) | Workforce Reduction | Pipeline Programs | Total |
|---|---|---|---|
| Restructuring reserve as of December 31, 2015 | $ 33.7 | $ 3.6 | $37.3 |
| Expense | 4.9 | 5.4 | 10.3 |
| Payment | (31.2) | (9.0) | (40.2) |
| Adjustments to previous estimates, net | (5.2) | 2.9 | (2.3) |
| Restructuring reserve as of December 31, 2016 | $ 2.2 | $ 2.9 | $5.1 |

2016 Organizational Changes and Cost Saving Initiatives

2016 Restructuring Charges

During the third quarter of 2016 we initiated additional cost saving measures primarily intended to realign our organizational structure due to the changes in roles and workforce resulting from our decision to spin off our hemophilia business, and to achieve further targeted cost reductions. For 2016 we recognized charges totaling $17.7 million related to this effort, which are in addition to, and separate from, the 2015 corporate restructuring described above. These amounts, which were substantially incurred and paid by the end of 2016, are primarily related to severance and are reflected in restructuring charges in our consolidated statements of income.

Cambridge, MA Manufacturing Facility

In June 2016 following an evaluation of our current and future manufacturing capabilities and capacity needs, we determined that we intend to vacate and cease manufacturing in our 67,000 square foot small-scale biologics manufacturing facility in Cambridge, MA and also vacate our 46,000 square foot warehouse space in Somerville, MA. In December 2016 we subleased our rights to the manufacturing facility in Cambridge, MA to Brammer. Brammer also purchased from us certain manufacturing equipment, leasehold improvements and other assets in exchange for shares of Brammer common LLC interests and assumed manufacturing operations effective January 1, 2017. In December 2016 we also closed and vacated our warehouse space in Somerville, MA.

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Our departure from these facilities shortened the expected useful lives of certain leasehold improvements and other assets at these facilities. As a result, we recorded additional depreciation expense to reflect the assets' new shorter useful lives. For the year ended December 31, 2016, we recognized approximately $45.5 million of this additional depreciation, which was recorded as cost of sales in our consolidated statement of income.

Under the terms of the agreement, Brammer will also provide manufacturing and other transition and support services to us.

In the fourth quarter of 2016 we recognized charges totaling $7.4 million for severance costs related to certain employees separated from Biogen in connection with this transaction. These amounts will be substantially incurred and paid by the end of the first quarter of 2017 and are reflected in restructuring charges in our consolidated statements of income.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

The consideration for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular factor or factors. We record an obligation for such contingent consideration payments at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of income.

The loss on fair value remeasurement of contingent consideration for 2016 was primarily due to changes in the probability of achieving certain developmental milestones and changes in the discount rate.

The loss on fair value remeasurement of contingent consideration for 2015 was primarily due to changes in the expected timing and probabilities of success related to the achievement of certain developmental milestones and in the discount rate.

The gain on fair value remeasurement of contingent consideration for 2014 was primarily due to an adjustment to the value of our contingent consideration liabilities as we updated the probabilities of success related to the early stage programs acquired through our recent acquisitions. For additional information, please read Note 7, Fair Value Measurements to our consolidated financial statements included in this report.

Collaboration Profit (Loss) Sharing

Collaboration profit (loss) sharing includes our 50% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis and our 50% share of the co-promotion profits or losses in the E.U. and Canada related to our collaboration agreement with AbbVie on the commercialization of ZINBRYTA.

We began to recognize revenues on sales of biosimilars in the first quarter of 2016. For 2016 we recognized net expense of $15.1 million related to our biosimilars commercial agreement with Samsung.

We began to recognize revenues on sales of ZINBRYTA in the E.U. in the third quarter of 2016. For 2016 we also recognized income of $4.9 million to reflect AbbVie's 50% share of net collaboration losses in the E.U. and Canada. For additional information related to these arrangements, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

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TECFIDERA Litigation Settlement and License Charges

In January 2017 we agreed to enter into a settlement and license agreement with Forward Pharma A/S (Forward Pharma) that will provide us an irrevocable license to all intellectual property owned by Forward Pharma and results in the termination of the German Infringement Litigation. Under the terms of the settlement and license agreement with Forward Pharma, we have agreed to pay Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016 we recognized a pre-tax charge of $454.8 million related to this matter. This amount represents the fair value of estimated royalties on our sales of TECFIDERA during the period April 2014 through December 31, 2016. For additional information related to the agreement, please read Note 21, Commitments and Contingencies to our consolidated financial statements included in this report.

Other Income (Expense), Net

For 2016 compared to 2015, the change in other income (expense), net was primarily due to an increase in interest expense as a result of the issuance of our senior unsecured notes in the third quarter of 2015. This increase was partially offset by an increase in interest income on higher yields and cash, cash equivalents and marketable securities balances as well as a decrease in foreign exchange losses recognized during the year ended December 31, 2016, compared to the prior year comparative period.

For 2015 compared to 2014, the change in other income (expense), net was primarily due to an increase in interest expense as a result of the issuance of our senior unsecured notes in the third quarter of 2015, higher foreign exchange losses and a decrease in net gains recognized on the sale of our strategic investments and marketable securities.

For additional information related to our senior unsecured notes, please read Note 11, Indebtedness, to our consolidated financial statements included in this report.

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Income Tax Provision

Our effective tax rate fluctuates from year to year due to the global nature of our operations. The factors that most significantly impact our effective tax rate include variability in the allocation of our taxable earnings among multiple jurisdictions, changes in tax laws, the amount and characterization of our research and development expenses, the levels of certain deductions and credits, acquisitions and licensing transactions.

Our effective tax rate for 2016 compared to 2015 increased primarily due to a net state tax benefit in 2015 of $27.0 million resulting from the remeasurement of one of our uncertain tax positions and a higher relative percentage of our earnings being attributed to the U.S., a higher tax jurisdiction.

Our effective tax rate for 2015 compared to 2014 benefited from lower anticipated taxes on foreign earnings and reflects a $27.0 million benefit from the 2015 remeasurement of one of our uncertain tax positions.

Accounting for Uncertainty in Income Taxes

For more information on our uncertain tax positions and income tax rate reconciliation for 2016, 2015 and 2014, please read Note 16, Income Taxes to our consolidated financial statements included in this report.

Equity in Loss of Investee, Net of Tax

In February 2012 we entered into an agreement with Samsung Biologics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. We account for this investment under the equity method of accounting. We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears.

During 2015 our share of losses exceeded the carrying value of our investment. We therefore suspended recognizing additional losses and will continue to do so unless we commit to providing additional funding.

For 2015 compared to 2014, the decrease in our equity in loss of investee, net of tax, was due to the suspension of equity method investment losses due to our share of losses exceeding the carrying value of our investment in 2015 and a decrease in our ownership interest.

For additional information related to this transaction, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

Noncontrolling Interest

For 2016 compared to 2015, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily related to a $60.0 million milestone payment made to Neurimmune SubOne AG (Neurimmune) in 2015.

For 2015 compared to 2014, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily related to a $60.0 million milestone payment made to Neurimmune, partially offset by increases in research expenses attributable to noncontrolling interests.

For additional information about Neurimmune, please read Note 18, Investments in Variable Interest Entities to our consolidated financial statements included in this report.

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Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

| (In millions, except percentages) | As of December 31, 2016 | 2015 | % Change 2016 compared to 2015 |
|---|---|---|---|
| Financial assets: | | | |
| Cash and cash equivalents | $2,326.5 | $1,308.0 | 77.9 % |
| Marketable securities — current | 2,568.6 | 2,120.5 | 21.1 % |
| Marketable securities — non-current | 2,829.4 | 2,760.4 | 2.5 % |
| Total cash, cash equivalents and marketable securities | $7,724.5 | $6,188.9 | 24.8 % |
| Borrowings: | | | |
| Current portion of notes payable and other financing arrangements | $4.7 | $4.8 | (2.1 )% |
| Notes payable and other financing arrangements | 6,512.7 | 6,521.5 | (0.1 )% |
| Total borrowings | $6,517.4 | $6,526.3 | (0.1 )% |
| Working Capital: | | | |
| Current assets | $8,732.2 | $6,700.3 | 30.3 % |
| Current liabilities | (3,419.9 ) | (2,577.7 ) | 32.7 % |
| Total working capital | $5,312.3 | $4,122.6 | 28.9 % |

For the year ended December 31, 2016, certain significant cash flows were as follows:

- $4.5 billion in net cash flows provided by operating activities;
- $1.0 billion used for share repurchases;
- $1.6 billion in total net payments for income taxes;
- $1.2 billion in contingent payments made to former shareholders of Fumapharm AG and holders of their rights; and
- $616.1 million used for purchases of property, plant and equipment.
- $102.0 million used for upfront and milestone payments to Samsung Bioepis, AbbVie and UPenn; and
- $75.0 million license fee payment made to Ionis.

For the year ended December 31, 2015, certain significant cash flows were as follows:

- $3.7 billion in net cash flows provided by operating activities;
- $5.9 billion in proceeds from the issuance of our senior unsecured notes;
- $5.0 billion used for share repurchases;
- $1.7 billion in total net payments for income taxes;
- $850.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $643.0 million used for purchases of property, plant and equipment, including $104.8 million related to the acquisition of Eisai's drug product manufacturing facility in Research Triangle Park (RTP), North Carolina and $62.5 million related to the acquisition of land in Solothurn, Switzerland;
- $198.8 million net cash paid for the acquisition of Convergence; and
- $244.0 million used for upfront and milestone payments to AGTC, MTPC and Neurimmune.

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Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. We expect to continue funding our current and planned operating requirements principally through our cash flows from operations, as well as our existing cash resources. We believe that our existing funds, when combined with cash generated from operations and our access to additional financing resources, if needed, are sufficient to satisfy our operating, working capital, strategic alliance, milestone payment, capital expenditure and debt service requirements for the foreseeable future. In addition, we may choose to opportunistically return cash to shareholders and pursue other business initiatives, including acquisition and licensing activities. We may, from time to time, also seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources should we identify a significant new opportunity.

The undistributed cumulative foreign earnings of certain of our foreign subsidiaries, exclusive of earnings that would result in little or no net income tax expense under current U.S. tax law or which has already been subject to tax under U.S. tax law, are invested indefinitely outside the U.S.

Of the total cash, cash equivalents and marketable securities at December 31, 2016, approximately $5.5 billion was generated in foreign jurisdictions and is primarily intended for use in our foreign operations or in connection with business development transactions outside of the U.S. In managing our day-to-day liquidity in the U.S., we do not rely on the unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings.

For additional information related to certain risks that could negatively impact our financial position or future results of operations, please read the “Risk Factors” and “Quantitative and Qualitative Disclosures About Market Risk” sections of this report.

Share Repurchase Programs

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. During the year ended December 31, 2016, we repurchased and retired 3.3 million shares of common stock at a cost of $1.0 billion under our 2016 Share Repurchase

Program.

In May 2015 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2015 Share Repurchase Program), which was completed as of December 31, 2015. As of December 31, 2015, we repurchased and retired approximately 16.8 million shares of common stock at a cost of $5.0 billion under our 2015 Share Repurchase Program.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million of our common stock (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under our share-based compensation plans. The 2011 Share Repurchase Program does not have an expiration date. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program during the years ended December 31, 2016 and 2015. During the year ended December 31, 2014, we purchased approximately 2.9 million shares of common stock at a cost of $886.8 million under our 2011 Share Repurchase Program. We have approximately 1.3 million shares remaining available for repurchase under the 2011 Share Repurchase Program.

Cash, Cash Equivalents and Marketable Securities

Until required for another use in our business, we typically invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments and other interest bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type.

The net increase in cash, cash equivalents and marketable securities at December 31, 2016, from December 31, 2015, is primarily due to net cash flows provided by operating activities, partially offset by purchases of our common stock, payments for income taxes, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, the net purchases of property, plant and equipment and upfront and milestone payments related to our

collaboration agreements.

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Borrowings

The following is a summary of our principal indebtedness:

- $550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018;
- $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020;
- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022;
- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025; and
- $1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045.

These senior unsecured notes were issued at a discount and are amortized as additional interest expense over the period from issuance through maturity.

During the third quarter of 2015, we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of December 31, 2016, we had no outstanding borrowings and were in compliance with all covenants

under this facility.

In connection with our 2006 distribution agreement with Fumedica AG (Fumedica), we issued notes totaling 61.4 million Swiss Francs that were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a carrying value of 6.2 million Swiss Francs ($6.0 million) and 8.9 million Swiss Francs ($9.0 million) as of December 31, 2016 and 2015, respectively.

For a summary of the fair values of our outstanding borrowings as of December 31, 2016 and 2015, please read Note 7, Fair Value Measurements to our consolidated financial statements included in this report.

Working Capital

We define working capital as current assets less current liabilities. The increase in working capital at December 31, 2016, from December 31, 2015, reflects an increase in total current assets of $2,031.9 million, partially offset by an increase in current liabilities of $842.2 million. The increase in total current assets was primarily driven by an increase in cash, cash equivalents and marketable securities due to net cash flows provided by operating activities. The increase in total current liabilities primarily resulted from litigation settlement and license charges and an increase in accrued collaboration expenses.

Cash Flows

The following table summarizes our cash flow activity:

| | For the Years Ended December 31, | | | % Change | |
|---|---|---|---|---|---|
| (In millions, except percentages) | 2016 | 2015 | 2014 | 2016 compared to 2015 | 2015 compared to 2014 |
| Net cash flows provided by operating activities | $4,522.4 | $3,716.1 | $2,942.1 | 21.7 % | 26.3 % |
| Net cash flows used in by investing activities | $(2,484.8) | $(4,553.6) | $(1,543.0) | (45.4 )% | 195.1 % |
| Net cash flows provided by (used in) financing activities | $(987.8 ) | $986.4 | $(755.9 ) | (200.1)% | (230.5 )% |

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future.

Operating cash flow is derived by adjusting our net income for:

- Non-cash operating items such as depreciation and amortization, impairment charges and share-based compensation charges;
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and

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- Changes associated with the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For 2016 compared to 2015, the increase in cash provided by operating activities was primarily driven by higher net income, non-cash charges for depreciation and amortization, a comparative increase in accrued expenses and other liabilities, partially offset by a comparative increase in accounts receivable.

For 2015 compared to 2014, the increase in cash provided by operating activities was primarily driven by higher net income and accounts receivable collections, partially offset by income tax payments.

Investing Activities

For 2016 compared to 2015, the decrease in net cash flows used in investing activities was primarily due to a decrease in net purchases of marketable securities and cash paid for the acquisition of Convergence in February 2015, partially offset by an increase in the contingent consideration

related to the Fumapharm AG acquisition.

For 2015 compared to 2014, the increase in net cash flows used in investing activities was primarily due to an increase in net purchases of marketable securities, an increase in the total amount of contingent consideration paid to the former shareholders of Fumapharm AG, an increase in purchases of property, plant and equipment and cash paid for the acquisition of Convergence.

Financing Activities

For 2016 compared to 2015, the decrease in net cash flows provided by financing activities was primarily due to the issuance of our senior unsecured notes issued in the third quarter of 2015, partially offset by a decrease in the purchases of common stock.

For 2015 compared to 2014, the change in net cash flows provided by financing activities was primarily due to the issuance of our 2015 Senior Notes, partially offset by an increase in the amount of common stock we repurchased.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2016, excluding amounts related to uncertain tax positions, funding commitments, contingent development, regulatory and commercial milestone payments, TYSABRI contingent payments and contingent consideration related to our business combinations, as described below.

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| (In millions) | Total | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | After 5 Years |
| Capital leases (1) | $18.7 | $2.0 | $16.7 | $— | $— |
| Non-cancellable operating leases (2), (3) | 549.5 | 66.4 | 108.2 | 98.4 | 276.5 |
| Long-term debt obligations (4) | 10,281.1 | 282.5 | 1,055.1 | 1,939.7 | 7,003.8 |
| Purchase and other obligations (5) | 1,740.1 | 1,598.2 | 88.5 | 43.9 | 9.5 |
| Defined benefit obligation | 74.5 | — | — | — | 74.5 |
| Total contractual obligations | $12,663.9 | $1,949.1 | $1,268.5 | $2,082.0 | $7,364.3 |

(1) During 2015 we amended our existing lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina, where we manufacture our and Eisai's oral solid dose products. Amounts reflected within the table above include the future contractual commitments. For additional information, please read Note 10, Property, Plant and Equipment to our consolidated financial statements included in this report.

(2) We lease properties and equipment for use in our operations. Amounts reflected within the table above detail future minimum rental commitments under non-cancelable operating leases as of December 31 for each of the periods presented. In addition to the minimum rental commitments, these leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

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(3) Obligations are presented net of sublease income expected to be received for the vacated manufacturing facility in Cambridge, MA, the vacated portion of our Weston, Massachusetts facility and other facilities throughout the world. For additional information related to the sublease of the vacated manufacturing facility in Cambridge, MA, please read Note 3, Restructuring, Business Transformation and Other Cost Savings Initiatives to our consolidated financial statements included in this report.

(4) Long-term debt obligations are primarily related to our Senior Notes, including principal and interest payments.

(5) Purchase and other obligations primarily includes our obligations to purchase direct materials, our obligation of $1.25 billion under the litigation settlement and license agreement with Forward Pharma, $176.3 million in contractual commitments for the construction of a biologics manufacturing facility in Solothurn, Switzerland and $13.6 million related to the fair value of net liabilities on derivative contracts. For additional information on the litigation settlement and license agreement with Forward Pharma please read Note 21, Commitments and Contingencies to our consolidated financial statements included in this report.

TYSABRI Contingent Payments

In 2013 we acquired from Elan full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the terms of the acquisition agreement, we are obligated to make contingent payments to Elan of 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo in December 2013. Following that acquisition, we began making these royalty payments to Perrigo.

Contingent Consideration related to Business Combinations

In connection with our acquisitions of Convergence, Stromedix, Inc. (Stromedix) and Biogen International Neuroscience GmbH (BIN), we agreed to make additional payments based upon the achievement of certain milestone events.

As the acquisitions of Convergence, Stromedix and BIN occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately $1.2 billion in remaining milestones

related to these acquisitions. For additional information related to our acquisition of Convergence please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

Fumapharm AG

In 2006 we acquired Fumapharm AG. As part of this acquisition we acquired FUMADERM and TECFIDERA (together, Fumapharm Products). We are required to make contingent payments to former shareholders of Fumapharm AG or holders of their rights based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior twelve month period, as defined in the acquisition agreement.

During 2016 we paid $1.2 billion in contingent payments as we reached the $7.0 billion, $8.0 billion, $9.0 billion and $10.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2015 and the first, second and third quarters of 2016, respectively, and accrued $300.0 million upon reaching $11.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2016.

We will owe an additional $300.0 million contingent payment for every additional $1.0 billion in cumulative sales level of Fumapharm Products reached if the prior 12 months sales of the Fumapharm Products exceed $3.0 billion, until such time as the cumulative sales level reaches $20.0 billion, at which time no further contingent payments shall be due. If the prior 12 months sales of Fumapharm Products are less than $3.0 billion, contingent payments remain payable on a decreasing tiered basis. These payments will be accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm. Any portion of the payment which is tax deductible will be recorded as a reduction to goodwill. Payments are due within 60 days following the end of the quarter in which the applicable cumulative sales level has been reached.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2016, we could make potential future milestone payments to third parties of up to approximately $3.1 billion, including approximately $0.5 billion in development milestones, approximately $0.8 billion in regulatory milestones and approximately $1.8 billion in commercial milestones as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable

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upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2016, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones. We anticipate that we may pay approximately $157.0 million of milestone payments in 2017, provided various development, regulatory or commercial milestones are achieved.

Other Funding Commitments

As of December 31, 2016, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $21.0 million on our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2016. We have approximately $500.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2016.

Tax Related Obligations

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2016, we have approximately $47.8 million of net liabilities associated with uncertain tax positions.

Other Off-Balance Sheet Arrangements

We do not have any relationships with entities often referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We consolidate variable interest entities if we are the primary beneficiary.

Legal Matters

For a discussion of legal matters as of December 31, 2016, please read Note 20, Litigation to our consolidated financial statements included in this report.

Critical Accounting Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenue and expenses. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition and Related Allowances

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; our price to the customer is fixed or determinable; and collectability is reasonably assured. For additional information related to the new accounting standard for revenues from contracts with customers please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements to our consolidated financial statements included in this report.

Product Revenues

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery. Product revenues are recorded net of applicable reserves for discounts and allowances. The timing of distributor orders and shipments can cause variability in earnings.

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Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

In addition to the discounts and rebates described above and classified as a reduction of revenue, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services, which are generally reflected as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services, we classify these payments within selling, general and administrative expenses.

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs consist of:

(i) our share of pre-tax profits and losses in the U.S. for RITUXAN and GAZYVA;

(ii) reimbursement of our selling and development expenses in the U.S. for RITUXAN; and

(iii) revenues on sales in the rest of world for RITUXAN, which consist of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenue on RITUXAN sales outside the U.S. and Canada by the Roche Group and its sublicensees.

Pre-tax co-promotion profits on RITUXAN and GAZYVA are calculated and paid to us by Genentech in the U.S. Pre-tax co-promotion profits on RITUXAN are calculated and paid to us by the Roche Group in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian net sales to third-party customers less applicable costs to manufacture, third-party royalty expenses, distribution, selling and marketing expenses, and joint development expenses incurred by Genentech, the Roche Group and us. We record our share of the pre-tax co-promotion profits on RITUXAN in Canada and royalty revenues on RITUXAN sales outside the U.S. on a cash basis as we do not have the ability to estimate these profits or royalty revenue in the period incurred. Our share of the pre-tax profits on RITUXAN and GAZYVA in the U.S. includes estimates made by Genentech and those estimates are subject to change. Actual results may differ from our estimates.

Concentrations of Credit Risk

The majority of our accounts receivable arise from product sales in the U.S. and Europe and are primarily due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. Credit and economic conditions in the E.U. continue to remain uncertain, which has, from time to time, led to longer collection periods for our accounts receivable and greater collection risk in certain countries.

Where our collections continue to be subject to significant payment delays due to government funding and reimbursement practices and a portion of these receivables are routinely being collected beyond our contractual payment terms and over periods in excess of one year, we have discounted our receivables and reduced related revenues based on the period of time that we estimate those amounts will be paid, to the extent such period exceeds one year, using the country’s market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets.

To date, we have not experienced any significant losses with respect to the collection of our accounts receivable. If economic conditions worsen and/or the financial condition of our customers were to further deteriorate, our risk of collectability may increase, which may result in additional allowances and/or significant bad debts.

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For additional information related to our concentration of credit risk associated with our accounts receivable balances, please read the subsection entitled “Credit Risk” in the “Quantitative and Qualitative Disclosures About Market Risk” section of this report.

Collaborative and Other Relationships

Our development and commercialization arrangements with Sobi and AbbVie represent collaborative arrangements as each party is an active participant and exposed to significant risks and rewards of the arrangements. Where we are the principal on sales transactions with third parties, we recognize revenue, cost of sales and sales and marketing expenses on a gross basis in their respective lines in our consolidated statements of income. Where we are not the principal on sales transactions with third parties, we record our share of the revenues, cost of sales and sales and marketing expenses on a net basis in collaborative and other relationships in our consolidated statements of income.

For additional information related to our collaborations with Sobi and AbbVie, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

Capitalization of Inventory Costs

We capitalize inventory costs associated with our products prior to regulatory approval, when, based on management’s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We consider numerous attributes in evaluating whether the costs to manufacture a particular product should be capitalized as an asset. We assess the regulatory approval process and where the particular product stands in relation to that approval process, including any known safety or efficacy concerns, potential labeling restrictions and other impediments to approval. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or delay commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize. We expense previously capitalized costs related to pre-approval inventory upon a change in such judgment,

due to, among other potential factors, a denial or significant delay of approval by necessary regulatory bodies. All changes in judgment in relation to pre-approval inventory have historically been insignificant.

Acquired Intangible Assets, including In-process Research and Development (IPR&D)

Effective January 1, 2009, when we purchase a business, the acquired IPR&D is measured at fair value, capitalized as an intangible asset and tested for impairment at least annually, as of October 31, until commercialization, after which time the IPR&D is amortized over its estimated useful life. If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

We have acquired, and expect to continue to acquire, intangible assets through the acquisition of biotechnology companies or through the consolidation of variable interest entities. These intangible assets primarily consist of technology associated with human therapeutic products and IPR&D product candidates. When significant identifiable intangible assets are acquired, we generally engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Management will determine the fair value of less significant identifiable intangible assets acquired. Discounted cash flow models are typically used in these valuations, and these models require the use of significant estimates and assumptions including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates.

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If these projects are not successfully developed, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. We believe that the foregoing assumptions used in the IPR&D analysis were reasonable at the time of the respective acquisition. No assurance can be given that the underlying assumptions used to estimate expected project sales, development costs or profitability, or the events associated with such projects, will transpire as estimated.

Certain IPR&D programs have a fair value that is not significantly in excess of carrying value, including our program for the treatment of TGN. Such programs could become impaired if assumptions used in determining the fair value change.

Impairment and Amortization of Long-lived Assets and Accounting for Goodwill

Long-lived Assets Other than Goodwill

Long-lived assets to be held and used include property, plant and equipment as well as intangible assets, including IPR&D and trademarks. Property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

When performing our impairment assessment, we calculate the fair value using the same methodology as described above under "Acquired Intangible Assets, including In-process Research and Development (IPR&D)". If the carrying value of our intangible assets with indefinite lives exceeds its fair value, then the intangible asset is written-down to its fair value.

Our most significant intangible assets are our acquired and in-licensed rights and patents and developed technology. Acquired and in-licensed rights and patents primarily relates to our acquisition of all remaining rights to TYSABRI from Elan. Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. We amortize the intangible assets related to TYSABRI and AVONEX using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of TYSABRI and AVONEX is performed annually during our long range planning cycle, which is generally updated in the third quarter of each year, and whenever events or changes in circumstances

would significantly affect the anticipated lifetime revenues of TYSABRI or AVONEX.

For additional information on the impairment charges related to our long-lived assets during 2016 and 2014, please read Note 6, Intangible Assets and Goodwill to our consolidated financial statements included in this report. Impairment charges related to our long-lived assets during 2015 were insignificant.

Goodwill

Goodwill relates largely to amounts that arose in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003 and amounts that are being paid in connection with the acquisition of Fumapharm AG. Our goodwill balances represent the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting.

We assess our goodwill balance within our single reporting unit annually, as of October 31, and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. We compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of our reporting unit, then we would need to determine the implied fair value of our reporting unit’s goodwill. If the carrying value of our reporting unit’s goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference.

We completed our required annual impairment test in the fourth quarters of 2016, 2015 and 2014, respectively, and determined in each of those periods that the carrying value of goodwill was not impaired. In each year, the fair value of our reporting unit, which includes goodwill, was significantly in excess of the carrying value of our reporting unit.

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Investments, including Fair Value Measures and Impairments

We invest in various types of securities, including short-term and long-term marketable securities, principally corporate notes, government securities including government sponsored enterprise mortgage-backed securities and credit card and auto loan asset-backed securities, in which our excess cash balances are invested.

In accordance with the accounting standard for fair value measurements, we have classified our financial assets as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, yield curves and foreign currency spot rates. Fair values determined by Level 3 inputs utilize unobservable data points for the asset.

As noted in Note 7, Fair Value Measurements to our consolidated financial statements, a majority of our financial assets have been classified as Level 2. These assets have been initially valued at the transaction price and subsequently valued utilizing third-party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. We validate the prices provided by our third-party pricing services by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

Impairment

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security’s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are reflected within earnings as an impairment loss.

Share-Based Compensation

We make certain assumptions in order to value and record expense associated with awards made under our share-based compensation arrangements. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments.

Determining the appropriate valuation model and related assumptions requires judgment, and includes estimating the expected market price of our stock on vesting date and stock price volatility as well as the term of the expected awards. Determining the appropriate amount to expense based on the anticipated achievement of performance targets requires judgment, including forecasting the achievement of future financial targets. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made throughout the term as appropriate. The cumulative impact of any revision is reflected in the period of change.

We also estimate forfeitures over the requisite service period when recognizing share-based compensation expense based on historical rates and forward-looking factors. These estimates are adjusted to the extent that actual forfeitures differ, or are expected to materially differ, from our estimates.

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Contingent Consideration

For acquisitions completed before January 1, 2009, we record contingent consideration resulting from a business combination when the contingency is resolved. For acquisitions completed after January 1, 2009, we record contingent consideration resulting from a business combination at its fair value on the acquisition date. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value as an adjustment to contingent consideration expense in our consolidated statements of income. Changes in the fair value of the contingent consideration obligations can result from changes to one or multiple inputs including adjustments to the discount rates and achievement and timing of any cumulative sales-based and development milestones, or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above, could have a material impact on the amount of contingent consideration expense we record in any given period.

Restructuring Charges

We have made estimates and judgments regarding the amount and timing of our restructuring expense and liability, including current and future period termination benefits, pipeline program termination costs and other exit costs to be incurred when related actions take place. Severance and other related costs are reflected in our consolidated statements of income as a component of total restructuring charges incurred. Actual results may differ from these estimates.

Income Taxes

We prepare and file income tax returns based on our interpretation of each jurisdiction’s tax laws and regulations. In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

All tax effects associated with intercompany transfers of assets within our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through our consolidated statements of income when the asset transferred is sold to a third-party or otherwise recovered through amortization of the asset's remaining economic life. If the asset transferred becomes impaired, for example through the obsolescence of inventory or the discontinuation of a research program, we will expense any remaining deferred charge or prepaid tax. As of December 31, 2016, total deferred charges and prepaid taxes were $989.8 million. For additional information related to the new accounting standard on tax effects associated with intercompany transfers of assets within our consolidated group please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements to our consolidated financial statements included in this report.

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We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished, through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the “more-likely-than-not” threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews, we have no plans to appeal or litigate any aspect of the tax position, and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

We earn a significant amount of our operating income outside the U.S. As a result, a portion of our cash, cash equivalents and marketable securities are held by foreign subsidiaries. We currently do not intend or foresee a need to repatriate these funds. We expect existing domestic cash, cash equivalents, marketable securities and cash flows from operations to continue to be sufficient to fund our domestic operating activities and cash commitments for investing and financing activities for the foreseeable future.

As of December 31, 2016, our non-U.S. subsidiaries’ undistributed foreign earnings included in consolidated retained earnings and other basis differences aggregated to approximately $7.6 billion. All undistributed foreign earnings of non-U.S. subsidiaries, exclusive of earnings that would result in little or no net income tax expense or which were previously taxed under current U.S. tax law, are reinvested indefinitely in operations outside the U.S. This determination is made on a jurisdiction-by-jurisdiction basis and takes into the account the liquidity requirements in both the U.S. and within our foreign subsidiaries.

If we decide to repatriate funds in the future to execute our growth initiatives or to fund any other liquidity needs, the resulting tax consequences would negatively impact our results of operations through a higher effective tax rate and dilution of our earnings. The residual U.S. tax liability, if cumulative amounts were repatriated, would be between $1.8 billion to $2.3 billion as of December 31, 2016.

New Accounting Standards

For a discussion of new accounting standards please read Note 1, Summary of Significant Accounting Principles to our consolidated financial statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market Risk

We are subject to certain risks which may affect our results of operations, cash flows and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements, pricing pressures worldwide and weak economic conditions in the foreign markets in which we operate. We manage the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. We do not enter into financial instruments for trading or speculative purposes. The counter-parties to these contracts are major financial institutions and there is no significant concentration of exposure with any one counter-party.

Foreign Currency Exchange Risk

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. We have operations or maintain distribution relationships in the U.S., Europe, Canada, Asia, Central and South America. In addition, we recognize our share of pre-tax co-promotion profits on RITUXAN in Canada. As a result, our financial position, results of operations and cash flows can be affected by market fluctuations in foreign exchange rates, primarily with respect to the Euro, British pound sterling, Canadian dollar, Swiss franc, Danish krone and Japanese yen.

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While the financial results of our global activities are reported in U.S. dollars, the functional currency for most of our foreign subsidiaries is their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar strengthens versus other currencies, the value of non-U.S. revenue will decline when reported in U.S. dollars. The impact to net income as a result of a strengthening U.S. dollar will be partially mitigated by the value of non-U.S. expense which will also decline when reported in U.S. dollars. As the U.S. dollar weakens versus other currencies, the value of non-U.S. revenue and expenses will increase when reported in U.S. dollars.
We have established revenue and operating expense hedging and balance sheet risk management programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.
In June 2016 the U.K. voted in a referendum to voluntarily depart from the E.U., known as Brexit. The macroeconomic impact on our results of operations from this vote remains unknown. To date, the foreign exchange impact has been negligible since we hedged the balance sheet foreign currency exchange risk.
Revenue and Operating Expense Hedging Program
Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues and operating expenses. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 18 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 9, Derivative Instruments to our consolidated financial statements included in this report.
Our ability to mitigate the impact of exchange rate changes on revenues and net income diminishes as significant exchange rate fluctuations are sustained over extended periods of time. In particular, devaluation or significant deterioration of foreign currency exchange rates are difficult to mitigate and likely to negatively impact earnings. The cash flows from these contracts are reported as operating activities in our consolidated statements of cash flows.

Balance Sheet Risk Management Hedging Program
We also use forward contracts to mitigate the foreign currency exposure related to certain balance sheet items. The primary objective of our balance sheet risk management program is to mitigate the exposure of foreign currency denominated net monetary assets of foreign affiliates. In these instances, we principally utilize currency forward contracts. We have not elected hedge accounting for the balance sheet related items. The cash flows from these contracts are reported as operating activities in our consolidated statement of cash flows.
The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of December 31, 2016 and 2015, a hypothetical adverse 10% movement in foreign currency rates compared to the U.S. dollar across all maturities would result in a hypothetical decrease in the fair value of forward contracts of approximately $172.0 million and $185.0 million, respectively. The estimated fair value change was determined by measuring the impact of the hypothetical exchange rate movement on outstanding forward contracts. Our use of this methodology to quantify the market risk of such instruments is subject to assumptions and the actual impact could be significantly different. The quantitative information about market risk is limited because it does not take into account all foreign currency operating transactions.
Interest Rate Risk
Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2016 and 2015, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $50.0 million and $43.0 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

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To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts during 2015 for certain of our fixed-rate debt. These derivative contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. As of December 31, 2016 and 2015, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately $6.8 million in each case.

Pricing Pressure

Governments in some international markets in which we operate have implemented measures aimed at reducing healthcare costs to constrain the overall level of government expenditures. These implemented measures vary by country and include, among other things, mandatory rebates and discounts, prospective and possible retroactive price reductions and suspensions on price increases of pharmaceuticals.

In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure favorable prices in a particular country may impair our ability to obtain acceptable prices in existing and potential new markets, which may limit market growth. The continued implementation of pricing actions throughout Europe may also lead to higher levels of parallel trade.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products are prescribed and purchased. It is possible that additional federal health care reform measures will be adopted in the future, which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our financial position or results of operations.

There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. Managed care organizations are also continuing to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs.

Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale distributors, public hospitals, specialty pharmacies and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We operate in certain countries where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

Credit and economic conditions in the E.U. continue to remain uncertain, which has, from time to time, led to long collection periods for our accounts receivable and greater collection risk in certain countries.

We believe that our allowance for doubtful accounts was adequate as of December 31, 2016 and 2015. However, if significant changes occur in the availability of government funding or the reimbursement practices of these or other governments, we may not be able to collect on amounts due to us from customers in such countries and our results of operations could be adversely affected.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-75 of this report and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

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Item 9A. Controls and Procedures

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of December 31, 2016. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with

U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information concerning our executive officers is set forth under the heading “Our Executive Officers” in Part I of this report. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.biogen.com, under the “Corporate Governance” subsection of the “About Us” section of the site. We intend to make all required disclosures regarding any amendments to, or waivers from, provisions of our code of business conduct at the same location of our website.

The response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Proposal 1 - Election of Directors,” “Corporate Governance at Biogen,” “Stock Ownership - Section 16(a) Beneficial Ownership Reporting Compliance” and “Miscellaneous - Stockholder Proposals” contained in the proxy statement for our 2017 annual meeting of stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Executive Compensation Matters” and “Corporate Governance at Biogen” contained in the proxy statement for our 2017 annual meeting of stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Stock Ownership” and “Equity Compensation Plan Information” contained in the proxy statement for our 2017 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Certain Relationships and Related Person Transactions” and “Corporate Governance at Biogen” contained in the proxy statement for our 2017 annual meeting of stockholders.

Item 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto in the section entitled “Proposal 2 — Ratification of the Selection of our Independent Registered Public Accounting Firm” contained in the proxy statement for our 2017 annual meeting of stockholders.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

a. (1) Consolidated Financial Statements:

The following financial statements are filed as part of this report:



Certain totals may not sum due to rounding.

(2) Financial Statement Schedules

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the consolidated financial statements and notes thereto.

(3) Exhibits

The exhibits listed on the Exhibit Index beginning on page A-1, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

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SIGNATURES

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

BIOGEN INC.

By: /S/ MICHEL VOUNATSOS
Michel Vounatsos
Chief Executive Officer
Date: February 2, 2017

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Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Name | Capacity | Date |
|---|---|---|
| /S/ MICHEL VOUNATSOS<br>Michel Vounatsos | Director and Chief Executive Officer<br>(principal executive officer) | February 2, 2017 |
| /S/ PAUL J. CLANCY<br>Paul J. Clancy | Executive Vice President, Finance and Chief Financial Officer<br>(principal financial officer) | February 2, 2017 |
| /S/ GREGORY F. COVINO<br>Gregory F. Covino | Vice President, Finance, Chief Accounting Officer (principal accounting officer) | February 2, 2017 |
| /S/ STELIOS PAPADOPOULOS<br>Stelios Papadopoulos | Director and Chairman of the Board of Directors | February 2, 2017 |
| /S/ ALEXANDER J. DENNER<br>Alexander J. Denner | Director | February 2, 2017 |
| /S/ CAROLINE D. DORSA<br>Caroline D. Dorsa | Director | February 2, 2017 |
| /S/ NANCY L. LEAMING<br>Nancy L. Leaming | Director | February 2, 2017 |
| /S/ RICHARD C. MULLIGAN<br>Richard C. Mulligan | Director | February 2, 2017 |
| /S/ ROBERT W. PANGIA<br>Robert W. Pangia | Director | February 2, 2017 |
| /S/ BRIAN S. POSNER<br>Brian S. Posner | Director | February 2, 2017 |
| /S/ ERIC K. ROWINSKY<br>Eric K. Rowinsky | Director | February 2, 2017 |
| /S/ LYNN SCHENK<br>Lynn Schenk | Director | February 2, 2017 |
| /S/ STEPHEN A. SHERWIN<br>Stephen A. Sherwin | Director | February 2, 2017 |

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(In millions, except per share amounts)

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| Revenues: | | | |
| Product, net | $9,817.9 | $9,188.5 | $8,203.4 |
| Revenues from anti-CD20 therapeutic programs | 1,314.5 | 1,339.2 | 1,195.4 |
| Other | 316.4 | 236.1 | 304.5 |
| Total revenues | 11,448.8 | 10,763.8 | 9,703.3 |
| Cost and expenses: | | | |
| Cost of sales, excluding amortization of acquired intangible assets | 1,478.7 | 1,240.4 | 1,171.0 |
| Research and development | 1,973.3 | 2,012.8 | 1,893.4 |
| Selling, general and administrative | 1,947.9 | 2,113.1 | 2,232.3 |
| Amortization of acquired intangible assets | 385.6 | 382.6 | 489.8 |
| Restructuring charges | 33.1 | 93.4 | — |
| Loss (gain) on fair value remeasurement of contingent consideration | 14.8 | 30.5 | (38.9) |
| Collaboration profit (loss) sharing | 10.2 | — | — |
| TECFIDERA litigation settlement and license charges | 454.8 | — | — |
| Total cost and expenses | 6,298.4 | 5,872.8 | 5,747.7 |
| Gain on sale of rights | — | — | 16.8 |
| Income from operations | 5,150.4 | 4,891.0 | 3,972.4 |
| Other income (expense), net | (217.4) | (123.7) | (25.8) |
| Income before income tax expense and equity in loss of investee, net of tax | 4,933.0 | 4,767.3 | 3,946.6 |
| Income tax expense | 1,237.3 | 1,161.6 | 989.9 |
| Equity in loss of investee, net of tax | — | 12.5 | 15.1 |
| Net income | 3,695.7 | 3,593.2 | 2,941.6 |
| Net (loss) income attributable to noncontrolling interests, net of tax | (7.1) | 46.2 | 6.8 |
| Net income attributable to Biogen Inc. | $3,702.8 | $3,547.0 | $2,934.8 |
| Net income per share: | | | |
| Basic earnings per share attributable to Biogen Inc. | $16.96 | $15.38 | $12.42 |
| Diluted earnings per share attributable to Biogen Inc. | $16.93 | $15.34 | $12.37 |
| Weighted-average shares used in calculating: | | | |
| Basic earnings per share attributable to Biogen Inc. | 218.4 | 230.7 | 236.4 |
| Diluted earnings per share attributable to Biogen Inc. | 218.8 | 231.2 | 237.2 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In millions)

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| Net income attributable to Biogen Inc. | $3,702.8 | $3,547.0 | $2,934.8 |
| Other comprehensive income: | | | |
| Unrealized gains (losses) on securities available for sale: | | | |
| Unrealized gains (losses) recognized during the period, net of tax | (10.6) | (1.7) | 0.4 |
| Less: reclassification adjustment for (gains) losses included in net income, net of tax | 0.6 | 1.3 | (6.4) |
| Unrealized gains (losses) on securities available for sale, net of tax | (10.0) | (0.4) | (6.0) |
| Unrealized gains (losses) on cash flow hedges: | | | |
| Unrealized gains (losses) recognized during the period, net of tax | 51.6 | 110.8 | 101.7 |
| Less: reclassification adjustment for (gains) losses included in net income, net of tax | (4.0) | (172.3) | (6.3) |
| Unrealized gains (losses) on cash flow hedges, net of tax | 47.6 | (61.5) | 95.4 |
| Unrealized gains (losses) on pension benefit obligation | 5.1 | (6.2) | (12.0) |
| Currency translation adjustment | (138.6) | (96.4) | (109.2) |
| Total other comprehensive income (loss), net of tax | (95.9) | (164.5) | (31.8) |
| Comprehensive income attributable to Biogen Inc. | 3,606.9 | 3,382.5 | 2,903.0 |
| Comprehensive income (loss) attributable to noncontrolling interests, net of tax | (7.1) | 46.2 | 6.8 |
| Comprehensive income | $3,599.8 | $3,428.7 | $2,909.8 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In millions, except per share amounts)

| | As of December 31, | |
|---|---|---|
| | 2016 | 2015 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $2,326.5 | $1,308.0 |
| Marketable securities | 2,568.6 | 2,120.5 |
| Accounts receivable, net | 1,441.6 | 1,227.0 |
| Due from anti-CD20 therapeutic programs, net | 300.6 | 314.5 |
| Inventory | 1,001.6 | 893.4 |
| Other current assets | 1,093.3 | 836.9 |
| Total current assets | 8,732.2 | 6,700.3 |
| Marketable securities | 2,829.4 | 2,760.4 |
| Property, plant and equipment, net | 2,501.8 | 2,187.6 |
| Intangible assets, net | 3,808.3 | 4,085.1 |
| Goodwill | 3,669.3 | 2,663.8 |
| Investments and other assets | 1,335.8 | 1,107.6 |
| Total assets | $22,876.8 | $19,504.8 |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Current portion of notes payable and other financing arrangements | $4.7 | $4.8 |
| Taxes payable | 231.9 | 208.7 |
| Accounts payable | 279.8 | 267.4 |
| Accrued expenses and other | 2,903.5 | 2,096.8 |
| Total current liabilities | 3,419.9 | 2,577.7 |
| Notes payable and other financing arrangements | 6,512.7 | 6,521.5 |
| Deferred tax liability | 93.1 | 124.9 |
| Other long-term liabilities | 722.5 | 905.8 |
| Total liabilities | 10,748.2 | 10,129.9 |
| Commitments and contingencies | | |
| Equity: | | |
| Biogen Inc. shareholders’ equity | | |
| Preferred stock, par value $0.001 per share | — | — |
| Common stock, par value $0.0005 per share | 0.1 | 0.1 |
| Additional paid-in capital | — | — |
| Accumulated other comprehensive loss | (319.9) | (224.0) |
| Retained earnings | 15,071.6 | 12,208.4 |
| Treasury stock, at cost; 22.6 million shares, respectively | (2,611.7) | (2,611.7) |
| Total Biogen Inc. shareholders’ equity | 12,140.1 | 9,372.8 |
| Noncontrolling interests | (11.5) | 2.1 |
| Total equity | 12,128.6 | 9,374.9 |
| Total liabilities and equity | $22,876.8 | $19,504.8 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| Cash flows from operating activities: | | | |
| Net income | $3,695.7 | $3,593.2 | $2,941.6 |
| Adjustments to reconcile net income to net cash flows from operating activities: | | | |
| Depreciation and amortization | 682.7 | 600.4 | 688.1 |
| Share-based compensation | 154.8 | 161.4 | 155.3 |
| Deferred income taxes | (175.0) | (145.6) | (308.2) |
| Other | 91.2 | 82.2 | (50.3) |
| Changes in operating assets and liabilities, net: | | | |
| Accounts receivable | (241.4) | 29.0 | (512.4) |
| Due from anti-CD20 therapeutic programs | 13.9 | (31.1) | (30.7) |
| Inventory | (165.6) | (174.4) | (185.9) |
| Other assets | 59.1 | (127.0) | (108.7) |
| Accrued expenses and other current liabilities | 570.1 | 74.2 | 244.3 |
| Income tax assets and liabilities | (232.6) | (429.4) | 40.3 |
| Other liabilities | 69.5 | 83.2 | 68.7 |
| Net cash flows provided by operating activities | 4,522.4 | 3,716.1 | 2,942.1 |
| Cash flows from investing activities: | | | |
| Proceeds from sales and maturities of marketable securities | 7,378.9 | 4,063.0 | 2,718.9 |
| Purchases of marketable securities | (7,913.2) | (6,864.9) | (3,583.1) |
| Contingent consideration related to Fumapharm AG acquisition | (1,200.0) | (850.0) | (375.0) |
| Acquisitions of businesses, net of cash acquired | — | (198.8) | — |
| Purchases of property, plant and equipment | (616.1) | (643.0) | (287.8) |
| Acquisitions of intangible assets | (111.6) | (15.4) | (28.2) |
| Other | (22.8) | (44.5) | 12.2 |
| Net cash flows used in investing activities | (2,484.8) | (4,553.6) | (1,543.0) |
| Cash flows from financing activities: | | | |
| Purchases of treasury stock | (1,000.0) | (5,000.0) | (886.8) |
| Proceeds from issuance of stock for share-based compensation arrangements | 43.7 | 54.2 | 54.9 |
| Proceeds from borrowings | — | 5,930.5 | — |
| Repayments of borrowings | (2.7) | (2.1) | (2.7) |
| Excess tax benefit from share-based compensation | 12.6 | 78.2 | 96.4 |
| Contingent consideration payments | (38.6) | (13.1) | (20.5) |
| Other | (2.8) | (61.3) | 2.8 |
| Net cash flows provided by (used in) financing activities | (987.8) | 986.4 | (755.9) |
| Net increase in cash and cash equivalents | 1,049.8 | 148.9 | 643.2 |
| Effect of exchange rate changes on cash and cash equivalents | (31.3) | (45.8) | (40.9) |
| Cash and cash equivalents, beginning of the year | 1,308.0 | 1,204.9 | 602.6 |
| Cash and cash equivalents, end of the year | $2,326.5 | $1,308.0 | $1,204.9 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(In millions)

| | Preferred stock | | Common stock | | Additional paid-in capital | Accumulated other comprehensive loss | Retained earnings | Treasury stock | | Total Biogen Inc. shareholders' equity | Noncontrolling interests | Total equity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | Shares | Amount | | | |
| Balance, December 31, 2015 | — | $ — | 241.2 | $ 0.1 | $ — | $ (224.0) | $ 12,208.4 | (22.6) | $ (2,611.7) | $ 9,372.8 | $ 2.1 | $ 9,374.9 |
| Net income | | | | | | | 3,702.8 | | | 3,702.8 | (7.1) | 3,695.7 |
| Other comprehensive income (loss), net of tax | | | | | | (95.9) | | | | (95.9) | 0.1 | (95.8) |
| Acquisition of noncontrolling interests | | | | | | | | | | — | (0.6) | (0.6) |
| Capital contribution to noncontrolling interests | | | | | | | | | | — | 1.5 | 1.5 |
| Deconsolidation of noncontrolling interests | | | | | | | | | | — | (7.5) | (7.5) |
| Repurchase of common stock pursuant to the 2016 Share Repurchase Program, at cost | | | | | | | | (3.3) | (1,000.0) | (1,000.0) | | (1,000.0) |
| Retirement of common stock pursuant to the 2016 Share Repurchase Program, at cost | | | (3.3) | — | (164.9) | | (835.1) | 3.3 | 1,000.0 | — | | — |
| Issuance of common stock under stock option and stock purchase plans | | | 0.2 | — | 43.7 | | — | | | 43.7 | | 43.7 |
| Issuance of common stock under stock award plan | | | 0.4 | — | (47.6) | | (4.5) | | | (52.1) | | (52.1) |
| Compensation expense related to share-based | | | | | 169.4 | | | | | 169.4 | | 169.4 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| payments | | | | | | | | | | |
| Tax benefit from share-based payments | | | | (0.6) | | | | (0.6) | | (0.6) |
| Balance, December 31, 2016 | $— | $(238.5) | $0.1 | $— | $(319.9) | $15,071.6 | (22.6) | $(2,611.7) | $12,140.1 | $(11.5) | $12,128.6 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(In millions)

| | Preferred stock | Common stock | | Additional paid-in capital | Accumulated other comprehensive loss | Retained earnings | Treasury stock | | Total Biogen Inc. shareholders' equity | Noncontrolling interests | Total equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Shares | Amount | | | | Shares | Amount | | | |
| Balance, December 31, 2014 | — | 257.1 | $0.1 | $4,196.2 | $(59.5) | $9,283.9 | (22.6) | $(2,611.7) | $10,809.0 | $5.0 | $10,814.0 |
| Net income | | | | | | 3,547.0 | | | 3,547.0 | 46.2 | 3,593.2 |
| Other comprehensive income (loss), net of tax | | | | | (164.5) | | | | (164.5) | — | (164.5) |
| Distribution to noncontrolling interests | | | | | | | | | — | (60.0) | (60.0) |
| Acquisition of noncontrolling interests | | | | | | | | | — | 10.9 | 10.9 |
| Repurchase of common stock pursuant to the 2015 Share Repurchase Program, at cost | | | | | | | (16.8) | (5,000.0) | (5,000.0) | | (5,000.0) |
| Retirement of common stock pursuant to the 2015 Share Repurchase Program, at cost | | (16.8) | — | (4,377.5) | | (622.5) | 16.8 | 5,000.0 | — | | — |
| Issuance of common stock under stock option and stock purchase plans | | 0.3 | — | 54.2 | | | | | 54.2 | | 54.2 |
| Issuance of common stock under stock award plan | | 0.6 | — | (125.1) | | | | | (125.1) | | (125.1) |
| Compensation expense related to share-based | | | | 183.2 | | | | | 183.2 | | 183.2 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| payments | | | | | | | | | |
| Tax benefit from share-based payments | | | 69.0 | | | | 69.0 | | 69.0 |
| Balance, December 31, 2015 | $ –241.2 | $0.1 | $— | $(224.0) | $12,208.4 | (22.6) | $(2,611.7) | $9,372.8 | $2.1 | $9,374.9 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(In millions)

| | Preferred stock | | Common stock | | Additional paid-in capital | Accumulated other comprehensive loss | Retained earnings | Treasury stock | | Total Biogen Inc. shareholders' equity | Noncontrolling interests | Total equity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | Shares | Amount | | | |
| Balance, December 31, 2013 | — | $ — | 256.0 | $ 0.1 | $ 4,023.6 | $ (27.7) | $ 6,349.1 | (19.7) | $ (1,724.9) | $ 8,620.2 | $ 0.6 | $ 8,620.8 |
| Net income | | | | | | | 2,934.8 | | | 2,934.8 | 6.8 | 2,941.6 |
| Other comprehensive income (loss), net of tax | | | | | | (31.8) | | | | (31.8) | — | (31.8) |
| Distribution to noncontrolling interests | | | | | | | | | | — | (9.1) | (9.1) |
| Other transactions with noncontrolling interests | | | | | | | | | | — | 6.7 | 6.7 |
| Repurchase of common stock for Treasury pursuant to the 2011 Share Repurchase Program, at cost | | | | | | | | (2.9) | (886.8) | (886.8) | | (886.8) |
| Issuance of common stock under stock option and stock purchase plans | | | 0.3 | — | 54.9 | | | | | 54.9 | | 54.9 |
| Issuance of common stock under stock award plan | | | 0.8 | — | (140.3) | | | | | (140.3) | | (140.3) |
| Compensation expense related to share-based payments | | | | | 165.0 | | | | | 165.0 | | 165.0 |
| Tax benefit from share-based payments | | | | | 93.0 | | | | | 93.0 | | 93.0 |
| Balance, December 31, 2014 | — | $ — | 257.1 | $ 0.1 | $ 4,196.2 | $ (59.5) | $ 9,283.9 | (22.6) | $ (2,611.7) | $ 10,809.0 | $ 5.0 | $ 10,814.0 |

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to people living with serious neurological, rare and autoimmune diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), FUMADERM for the treatment of severe plaque psoriasis and SPINRAZA for the treatment of spinal muscular atrophy (SMA). We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma, and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group (Roche Group).

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within areas of our scientific, manufacturing and technical capabilities. Our research is currently focused on additional improvements in the treatment of MS, solving some of the most challenging and complex diseases, including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (ALS), and employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy.

Our innovative drug development and commercialization activities are complemented by our biosimilar therapies that expand access to medicines and reduce the cost burden for healthcare systems. We are leveraging our manufacturing capabilities and know-how to develop, manufacture and market biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics). Under this agreement, we are currently manufacturing and commercializing BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the European Union (E.U.).

Hemophilia Spin-Off

In May 2016 we announced our intention to spin off our hemophilia business, Bioverativ Inc. (Bioverativ), as an independent, publicly traded company. Bioverativ, will focus on the discovery, development and commercialization of therapies for treatment of hemophilia and other blood disorders, including ELOCTATE for the treatment of hemophilia A and ALPROLIX for the treatment of hemophilia B. Bioverativ will also assume all of our rights and obligations under our collaboration agreement with Swedish Orphan Biovitrum AB (Sobi) and our collaboration and license agreement with Sangamo Biosciences Inc. (Sangamo).

On February 1, 2017, we completed the distribution of all the then outstanding shares of common stock of Bioverativ to Biogen stockholders, who received one share of Bioverativ common stock for every two shares of Biogen common stock. As a result of the distribution, Bioverativ is now an independent public company whose shares of common stock are trading under the symbol "BIVV" on the Nasdaq Global Select Market.

The financial results of Bioverativ are reflected in our consolidated results of operations and financial position included in these audited consolidated financial statements for the periods presented in this Form 10-K. The financial results of Bioverativ will be excluded from our consolidated results of operations and financial position commencing February 1, 2017. For additional information regarding the separation of Bioverativ, please read Note 26, Subsequent Events to these consolidated financial statements.

Consolidation

Our consolidated financial statements reflect our financial statements, those of our wholly-owned subsidiaries and those of certain variable interest entities where we are the primary beneficiary. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income (loss) attributable to noncontrolling interests in our consolidated statements of income equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. Intercompany balances and transactions are

eliminated in consolidation.

In determining whether we are the primary beneficiary of an entity, we apply a qualitative approach that determines whether we have both (1) the power to direct the economically significant activities of the entity and (2)

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BIOGEN INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. These considerations impact the way we account for our existing collaborative relationships and other arrangements. We continuously assess whether we are the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in us consolidating or deconsolidating one or more of our collaborators or partners.

Use of Estimates

The preparation of our consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; our price to the customer is fixed or determinable; and collectability is reasonably assured.

Product Revenues

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Product revenue reserves are categorized as follows: discounts, contractual adjustments and returns.

Discounts include trade term discounts and wholesaler incentives. Trade term discounts and wholesaler incentives primarily relate to estimated obligations for credits to be granted to wholesalers for remitting payment on their purchases within established incentive periods and credits to be granted to wholesalers for compliance with various contractually-defined inventory management practices, respectively. We determine these reserves based on our historical experience, including the timing of customer payments.

Contractual adjustments primarily relate to Medicaid and managed care rebates, co-payment (copay) assistance, Veterans Administration (VA) and Public Health Service (PHS) discounts, specialty pharmacy program fees and other governmental rebates or applicable allowances.

- Medicaid rebates relate to our estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in other current liabilities. Our liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid, and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end.
- Governmental rebates or chargebacks, including VA and PHS discounts, represent our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices we

charge to wholesalers which provide those products. The wholesaler charges us for the

difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Rebate and chargeback reserves are established in the same period as the related revenue is recognized, resulting in a reduction in product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and we generally issue credits for such amounts within a few weeks of the wholesaler notifying us about the resale. Our reserves for VA, PHS and chargebacks consist of amounts that we expect to issue for inventory that exists at the wholesalers that we expect will be sold to qualified healthcare providers and chargebacks that wholesalers have claimed for which we have not issued a credit.

- Managed care rebates represent our estimated obligations to third parties, primarily pharmacy benefit managers. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses and other current liabilities. These rebates result from performance-based goals, formulary position and price increase limit allowances (price protection). The calculation of the accrual for these rebates is based on an estimate of the customer's buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period.
- Copay assistance represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The calculation of the accrual for copay is based on an estimate of claims and the cost per claim that we expect to receive associated with inventory that exists in the distribution channel at period end.
- Other governmental rebates or applicable allowances primarily relate to mandatory rebates and discounts in international markets where government-sponsored healthcare systems are the primary payors for healthcare.

Product returns are established for returns expected to be made by wholesalers and are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to product expiration. Expired product return reserves are estimated through a comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product.

In addition to the discounts, rebates and product returns described above and classified as a reduction of revenue, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services, which are generally reflected as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services, we classify these payments in selling, general and administrative expenses.

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs consist of:

(i) our share of pre-tax profits and losses in the U.S. for RITUXAN and GAZYVA;
(ii) reimbursement of our selling and development expenses in the U.S. for RITUXAN; and
(iii) revenues on sales in the rest of world for RITUXAN, which consist of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenue on RITUXAN sales outside the U.S. and Canada by the Roche Group and its sublicensees.

Pre-tax co-promotion profits on RITUXAN and GAZYVA are calculated and paid to us by Genentech in the U.S. Pre-tax co-promotion profits on RITUXAN are calculated and paid to us by the Roche Group in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian net sales to third-party customers less applicable costs to manufacture, third-party royalty expenses, distribution, selling and marketing expenses, and joint development expenses incurred by Genentech, the Roche Group and us. We record our share of the pre-tax co-promotion profits on RITUXAN in Canada and royalty revenues on RITUXAN sales outside the U.S. on a cash basis as we do not have the ability to estimate these profits or royalty revenue in the period incurred. Our share of the pre-tax profits on RITUXAN and GAZYVA in the U.S. includes estimates made by Genentech and those estimates are subject to change. Actual results may differ from our estimates. For additional information related to our collaboration with Genentech, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

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Royalty Revenues

We receive royalty revenues on sales by our licensees of other products covered under patents that we own. We do not have future performance obligations under these license arrangements. We record these revenues based on estimates of the sales that occurred during the relevant period as a component of other revenues. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees. If we are unable to reasonably estimate royalty revenue or do not have access to the information, then we record royalty revenues on a cash basis.

Multiple-Element Revenue Arrangements

We may enter into transactions that involve the sale of products and related services under multiple element arrangements. In accounting for these transactions, we assess the elements of the contract and whether each element has standalone value and allocate revenue to the various elements based on their estimated selling price as a component of total revenues. The selling price of a revenue generating element can be based on current selling prices offered by us or another party for current products or management's best estimate of a selling price. Revenue allocated to an individual element is recognized when all other revenue recognition criteria are met for that element.

Collaborative and Other Relationships

Our development and commercialization arrangements with Sobi and AbbVie Inc. (AbbVie) represent collaborative arrangements as each party is an active participant and exposed to significant risks and rewards of the arrangements. Where we are the principal on sales transactions with third parties, we recognize revenue, cost of sales and operating expenses on a gross basis in their respective lines in our consolidated statements of income. Where we are not the principal on sales transactions with third parties, we record our share of the revenues, cost of sales and operating expenses on a net basis in collaborative and other relationships included in other revenue in our consolidated statements of income.

For additional information related to our collaborations with Sobi and AbbVie, please read Note 19, Collaborative and Other Relationships, to these consolidated financial statements.

Fair Value Measurements

We have certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1 — Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access;
- Level 2 — Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and
- Level 3 — Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The majority of our financial assets have been classified as Level 2. Our financial assets (which include our cash equivalents, derivative contracts, marketable debt securities and plan assets for deferred compensation) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events.

We validate the prices provided by our third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources and analyzing pricing data in certain instances. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2016 and 2015, respectively.

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Other Assets and Liabilities

The carrying amounts reflected in the consolidated balance sheets for current accounts receivable, due from anti-CD20 therapeutic programs, other current assets, accounts payable and accrued expenses and other, approximate fair value due to their short-term maturities.

Cash and Cash Equivalents

We consider only those investments which are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. As of December 31, 2016 and 2015, cash equivalents were comprised of money market funds and commercial paper, overnight reverse repurchase agreements and other debt securities with maturities less than 90 days from the date of purchase.

Accounts Receivable

The majority of our accounts receivable arise from product sales and primarily represent amounts due from our wholesale distributors, public hospitals and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. To date, our historical reserves and write-offs of accounts receivable have not been significant.

In countries where we have experienced a pattern of payments extending beyond our contractual payment term and we expect to collect receivables greater than one year from the time of sale, we have discounted our receivables and reduced related revenues over the period of time that we estimate those amounts will be paid using the country's market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets. We accrete interest income on these receivables, which is recognized as a component of other income (expense), net in our consolidated statements of income.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash and cash equivalents, investments, derivatives and accounts receivable. We attempt to minimize the risks related to cash and cash equivalents and investments by investing in a broad and diverse range of financial instruments as previously defined by us. We have established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. We minimize credit risk resulting from derivative instruments by choosing only highly rated financial institutions as counterparties.

Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. The majority of our accounts receivable arise from product sales in the U.S. and Europe and have standard payment terms which generally require payment within 30 to 90 days. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions and assess their possible impact on our business.

As of December 31, 2016 and 2015, two wholesale distributors individually accounted for approximately 37.2% and 19.2%, and 35.4% and 23.1%, of accounts receivable, net, respectively.

Marketable Securities and Other Investments

Marketable Debt Securities

Available-for-sale debt securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive income (loss) in equity, net of related tax effects, unless the security has experienced a credit loss, we have determined that we have the intent to sell the security or we have determined that it is more likely than not that we will have to sell the security before its expected recovery. Realized gains and losses are reported in other income (expense), net, on a specific identification basis.

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Marketable Equity Securities

Our marketable equity securities represent investments in publicly traded equity securities and are included in investments and other assets in our consolidated balance sheet. When assessing whether a decline in the fair value of a marketable equity security is other-than-temporary, we consider the fair market value of the security, the duration of the security's decline and prospects for the underlying business, including favorable or adverse clinical trial results, new product initiatives and new collaborative agreements with the companies in which we have invested.

Non-Marketable Equity Securities

We also invest in equity securities of companies whose securities are not publicly traded and where fair value is not readily available. These investments are recorded using either the cost method or the equity method of accounting, depending on our ownership percentage and other factors that suggest we have significant influence. We monitor these investments to evaluate whether any decline in their value has occurred that would be other-than-temporary, based on the implied value of recent company financings, public market prices of comparable companies and general market conditions and are included in investments and other assets in our consolidated balance sheet.

Evaluating Investments for Other-than-Temporary Impairments

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in value is other-than-temporary, we consider the fair market value of the security, the duration of the security's decline, and the financial condition of the issuer. We then consider our intent and ability to hold the equity security for a period of time sufficient to recover our carrying value. Where we have determined that we lack the intent and ability to hold an equity security to its expected recovery, the security's decline in fair value is deemed to be other-than-temporary and is reflected in earnings as an impairment loss.

Equity Method of Accounting

In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, we utilize the equity method of accounting for recording investment activity. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, the voting and protective rights we hold, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or other business relationship. Under the equity method of accounting, we record in our results of operations our share of income or loss of the other company. If our share of losses exceeds the carrying value of our investment, we will suspend recognizing additional losses and will continue to do so unless we commit to providing additional funding.

Inventory

Inventories are stated at the lower of cost or market with cost based on the first-in, first-out (FIFO) method. We classify our inventory costs as long-term when we expect to utilize the inventory beyond our normal operating cycle and include these costs in investments and other assets in our consolidated balance sheets. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in a clinical manufacturing campaign.

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Capitalization of Inventory Costs

We capitalize inventory costs associated with our products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We consider numerous attributes in evaluating whether the costs to manufacture a particular product should be capitalized as an asset. We assess the regulatory approval process and where the particular product stands in relation to that approval process, including any known safety or efficacy concerns, potential labeling restrictions and other impediments to approval. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or delay commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize. We expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or significant delay of approval by necessary regulatory bodies.

Obsolescence and Unmarketable Inventory

We periodically review our inventories for excess or obsolescence and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated by us, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Additionally, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. In the event that certain batches or units of product no longer meet quality specifications, we will record a charge to cost of sales to write-down any unmarketable inventory to its estimated net realizable value. In all cases, product inventory is carried at the lower of cost or its estimated net realizable value. Amounts written-down due to unmarketable inventory are charged to cost of sales.

Property, Plant and Equipment

Property, plant and equipment are carried at cost, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The cost of normal, recurring, or periodic repairs and maintenance activities related to property, plant and equipment are expensed as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if the repair will result in future economic benefits.

Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset. We also capitalize certain direct and incremental costs associated with the validation effort required for licensing by regulatory agencies of new manufacturing equipment for the production of a commercially approved drug. These costs primarily include direct labor and material and are incurred in preparing the equipment for its intended use. The validation costs are either amortized over the life of the related equipment or expensed as cost of sales when the product produced in the validation process is sold.

In addition, we capitalize certain internal use computer software development costs. If the software is an integral part of production assets, these costs are included in machinery and equipment and are amortized on a straight-line basis over the estimated useful lives of the related software, which generally range from three to five years.

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We generally depreciate or amortize the cost of our property, plant and equipment using the straight-line method over the estimated useful lives of the respective assets, which are summarized as follows:

| Asset Category | Useful Lives |
|---|---|
| Land | Not depreciated |
| Buildings | 15 to 40 years |
| Leasehold Improvements | Lesser of the useful life or the term of the respective lease |
| Furniture and Fixtures | 5 to 7 years |
| Machinery and Equipment | 5 to 20 years |
| Computer Software and Hardware | 3 to 5 years |

When we dispose of property, plant and equipment, we remove the associated cost and accumulated depreciation from the related accounts on our consolidated balance sheet and include any resulting gain or loss in our consolidated statement of income.

Intangible Assets

Our intangible assets consist of acquired and in-licensed rights and patents, developed technology, out-licensed patents, in-process research and development acquired after January 1, 2009, trademarks and trade names. Our intangible assets are recorded at fair value at the time of their acquisition and are stated in our consolidated balance sheets net of accumulated amortization and impairments, if applicable.

Intangible assets related to acquired and in-licensed rights and patents, developed technology and out-licensed patents are amortized over their estimated useful lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. Amortization is recorded as amortization of acquired intangible assets in our consolidated statements of income. Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Pharma International, Ltd (Elan), an affiliate of Elan Corporation, plc. Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. We amortize the intangible assets related to TYSABRI and AVONEX using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of TYSABRI and AVONEX is performed annually during our long range planning cycle, which is generally updated in the third quarter of each year, and whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of TYSABRI or AVONEX.

Intangible assets related to trademarks, trade names and in-process research and development prior to commercialization are not amortized because they have indefinite lives; however, they are subject to review for impairment. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Acquired In-process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects and discounting the net cash flows to present value. The revenue and costs projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing a new drug. Additionally, the projections consider the relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of new product introductions by us and our competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections. Upon the acquisition of IPR&D, we complete an assessment of whether our acquisition constitutes the purchase of a single asset or a group of assets. We consider multiple factors in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance and our rationale for entering into the transaction.

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If we acquire a business as defined under applicable accounting standards, then the acquired IPR&D is capitalized as an intangible asset. If we acquire an asset or group of assets that do not meet the definition of a business, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

When performing our impairment assessment, we calculate the fair value using the same methodology as described above. If the carrying value of our acquired IPR&D exceeds its fair value, then the intangible asset is written-down to its fair value. Certain IPR&D programs have a fair value that is not significantly in excess of carrying value, including our program for the treatment of trigeminal neuralgia (TGN). Such programs could become impaired if assumptions used in determining the fair value change.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but reviewed for impairment. Goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the goodwill might not be recoverable.

We compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of our reporting unit, then we would need to determine the implied fair value of our reporting unit’s goodwill. If the carrying value of our reporting unit’s goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference. As described in Note 24, Segment Information to these consolidated financial statements, we operate in one operating segment which we consider our only reporting unit.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment and definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

Contingent Consideration

The consideration for our acquisitions often includes future payments that are contingent upon the occurrence of a particular event. For acquisitions completed before January 1, 2009, we record contingent consideration resulting from a business combination when the contingency is resolved. For acquisitions that qualify as business combinations completed after January 1, 2009, we record an obligation for such contingent payments at fair value on the acquisition date. We estimate the fair value of contingent consideration obligations through valuation models that incorporate probability-adjusted assumptions related to the achievement of the milestones and thus likelihood of making related payments. We revalue these contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations are recognized in our consolidated statements of income. Changes in the fair value of the contingent consideration obligations can result from changes to one or multiple inputs, including adjustments to the discount rates, changes in the amount or timing of expected expenditures associated with product development, changes in the amount or timing of cash flows and reserves associated with products upon commercialization, changes in the assumed achievement or timing of any cumulative sales-based and development milestones, changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval.

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Discount rates in our valuation models represent a measure of the credit risk associated with settling the liability. The period over which we discount our contingent obligations is based on the current development stage of the product candidates, our specific development plan for that product candidate adjusted for the probability of completing the development step, and when the contingent payments would be triggered. In estimating the probability of success, we utilize data regarding similar milestone events from several sources, including industry studies and our own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions could have a material impact on the amount of contingent consideration expense we record in any given period.

Derivative Instruments and Hedging Activities

We recognize all derivative instruments as either assets or liabilities at fair value in our consolidated balance sheets. Changes in the fair value of derivatives are recorded each period in current earnings or accumulated other comprehensive income (loss), depending on whether a derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. We classify the cash flows from these instruments in the same category as the cash flows from the hedged items. We do not hold or issue derivative instruments for trading or speculative purposes.

We assess, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows or fair values of the hedged items. We also assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

Translation of Foreign Currencies

The functional currency for most of our foreign subsidiaries is their local currency. For our non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign exchange rates for the period. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of equity. For subsidiaries where the functional currency of the assets and liabilities differ from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other income (expense), net, in our consolidated statements of income.

Royalty Cost of Sales

We make royalty payments to a number of third parties under license or purchase agreements associated with our acquisition of intellectual property. These royalty payments are typically calculated as a percentage (royalty rate) of the sales of our products in a particular year. That royalty rate may remain constant, increase or decrease within each year based on the total amount of sales during the annual period. Each quarterly period, we estimate our total royalty obligation for the full year and recognize the proportional amount as cost of sales based on actual quarterly sales as a percentage of full year estimated sales. For example, if the level of net sales in any calendar year increases the royalty rate within the year, we will record our cost of sales at an even rate over the year, based on the estimated blended royalty rate.

Accounting for Share-Based Compensation

Our share-based compensation programs grant awards that have included stock options, restricted stock units which vest based on stock performance known as market stock units (MSUs), performance-vested restricted stock units which settle in cash (CSPUs), time-vested restricted stock units (RSUs), performance-vested restricted stock units which can be settled in cash or shares of our common stock (PUs) at the sole discretion of the Compensation and

Management Development Committee of the Board of Directors and shares issued under our employee stock purchase plan (ESPP). We charge the estimated fair value of awards against income over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance,

where a portion of the award vests upon retirement eligibility), we estimate and recognize expense based on the period from the grant date to the date on which the employee is retirement eligible.

The fair values of our stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the stock options are then expensed over the options' vesting periods.

The fair values of our MSUs are estimated using a lattice model with a Monte Carlo simulation. We apply an accelerated attribution method to recognize share-based compensation expense over the applicable service period, net of estimated forfeitures, when accounting for our MSUs. The probability of actual shares expected to be earned is considered in the grant date valuation, therefore the expense is not adjusted to reflect the actual units earned.

The fair values of our RSUs are based on the market value of our stock on the date of grant. Compensation expense for RSUs is recognized straight-line over the applicable service period.

We apply an accelerated attribution method to recognize share-based compensation expense when accounting for our CSPUs and PUs and the fair value of the liability is remeasured at the end of each reporting period through expected settlement. Compensation expense associated with CSPUs and PUs are based upon the stock price and the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the associated targeted payout level that is forecasted will be achieved, net of estimated forfeitures. Cumulative adjustments are recorded each quarter to reflect changes in the stock price and estimated outcome of the performance-related conditions until the date results are determined and settled.

The purchase price of common stock under our ESPP is equal to 85% of the lesser of (i) the fair market value per share of the common stock on the first business day of an offering period and (ii) the fair market value per share of the common stock on the purchase date. The fair value of the discounted purchases made under our ESPP is calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 90 day purchase period.

Research and Development Expenses

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities, which include compensation and benefits, facilities and overhead expenses, clinical trial expenses and fees paid to contract research organizations (CROs), clinical supply and manufacturing expenses, write-offs of inventory that was previously capitalized in anticipation of product launch and determined to no longer be realizable, and other outside expenses. Research and development expenses are expensed as incurred. Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets on our consolidated balance sheets and are expensed as the services are provided. We also accrue the costs of ongoing clinical trials associated with programs that have been terminated or discontinued for which there is no future economic benefit at the time the decision is made to terminate or discontinue the program.

From time to time, we enter into development agreements in which we share expenses with a collaborative partner. We record payments received from our collaborative partners for their share of the development costs as a reduction of research and development expense, except as discussed in Note 19, Collaborative and Other Relationships to these consolidated financial statements. Because an initial indication has been approved for both RITUXAN and GAZYVA, expenses incurred by Genentech in the ongoing development of RITUXAN and GAZYVA are not recorded as research and development expense, but rather reduce our share of profits recorded as a component of revenues from anti-CD20 therapeutic programs.

For collaborations with commercialized products, if we are the principal, we record revenue and the corresponding operating costs in their respective line items in our consolidated statements of income. If we are not the principal, we record operating costs as a reduction of revenue.

Selling, General and Administrative Expenses

Selling, general and administrative expenses are primarily comprised of compensation and benefits associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expenses and other general and administrative costs.

Advertising costs are expensed as incurred. For the years ended December 31, 2016, 2015 and 2014, advertising costs totaled $106.3 million, $108.6 million and $92.9 million, respectively.

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Income Taxes

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. We evaluate the realizability of our deferred tax assets and establish a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized.

All tax effects associated with intercompany transfers of assets in our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through the consolidated statement of income when the asset transferred is sold to a third party or otherwise recovered through amortization of the asset's remaining economic life. If the asset transferred becomes impaired, for example through the discontinuation of a research program, we will expense any remaining deferred charge or prepaid tax.

We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Contingencies

We are currently involved in various claims and legal proceedings. Loss contingency provisions are recorded if the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated or a range of loss can be determined. These accruals represent management’s best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may change our estimates. These changes in the estimates of the potential liabilities could have a material impact on our consolidated results of operations and financial position.

Earnings per Share

Basic earnings per share is computed by dividing undistributed net income attributable to Biogen Inc. by the weighted-average number of common shares outstanding during the period.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, we do not believe that the impact of recently issued standards that are not yet effective will have a material impact on our financial position or results of operations upon adoption.

In May 2014 the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB has subsequently issued the following amendments to ASU 2014-09 which have the same effective date and transition date of January 1, 2018:

- In August 2015 the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018.

The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date.

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- In March 2016 the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations.
- In April 2016 the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance.
- In May 2016 the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers.
- In December 2016 the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amends certain narrow aspects of the guidance issued in ASU 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples.

We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

In April 2015 the FASB issued ASU No. 2015-05, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement. Under this standard, if a cloud computing arrangement includes a software license, the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. We adopted this standard as of January 1, 2016, which did not have an impact on our financial position or results of operations.

In July 2015 the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. We adopted this standard as of January 1, 2016, which did not have an impact on our financial position or results of operations.

In September 2015 the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and sets forth new disclosure requirements related to the adjustments. We adopted this standard as of January 1, 2016, which did not have an impact on our financial position or results of operations.

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. This new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in our results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. This new standard will be effective for us on January 1, 2018. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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In February 2016 the FASB issued ASU No. 2016-02, Leases (Topic 842). This new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. This new standard will be effective for us on January 1, 2019. The adoption of this standard is not expected to have a material impact on our net financial position, but will impact the amount of our assets and liabilities. We are currently evaluating the potential impact that this standard may have on our results of operations.

In March 2016 the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments. This new standard simplifies the embedded derivative analysis for debt instruments containing contingent call or put options by removing the requirement to assess whether a contingent event is related to interest rates or credit risks. This new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In March 2016 the FASB issued ASU No. 2016-07, Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting. This new standard eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an adjustment must be made to the investment, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect during all previous periods that the investment has been held. This new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In March 2016 the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This new standard requires recognition of the income tax effects of vested or settled awards in the income statement and involves several other aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have a material impact on our financial position, results of operations or statements of cash flows upon adoption.

In June 2016 the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This new standard changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. This new standard will be effective for us on January 1, 2020. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In August 2016 the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. This new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. This new standard will be effective for us on January 1, 2018. The adoption of this standard is not expected to have a material impact on our statements of cash flows upon adoption.

In October 2016 the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory. This new standard eliminates the exception for an intra-entity transfer of an asset other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. This new standard will be effective for us on January 1, 2018 and will be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the potential impact this standard may have on our financial position and results of operations.

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In January 2017 the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. This new standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This new standard will be effective for us on January 1, 2018. However, we have adopted this standard as of January 1, 2017, with prospective application to any business development transaction.

2. Acquisitions

Convergence Pharmaceuticals

On February 12, 2015, we completed our acquisition of all of the outstanding stock of Convergence Pharmaceuticals (Convergence), a clinical-stage biopharmaceutical company with a focus on developing product candidates for neuropathic pain. Convergence's lead candidate was a Phase 2 clinical candidate BIIB074 (CNV1014802), which had demonstrated clinical activity in proof-of-concept studies for TGN. Additionally, BIIB074 had potential applicability in several other neuropathic pain states, including lumbosacral radiculopathy and erythromelalgia.

The purchase price consisted of a $200.1 million cash payment at closing, plus contingent consideration in the form of development and approval milestones up to a maximum of $450.0 million, of which $350.0 million was associated with the development and approval of BIIB074 for the treatment of TGN. The acquisition was funded from our existing cash on hand and was accounted for as the acquisition of a business. In addition to obtaining the rights to BIIB074 and additional product candidates in preclinical development, we retained the services of key employees of Convergence.

In connection with our acquisition of Convergence, we recorded a liability of $274.5 million representing the fair value of the contingent consideration. This amount was estimated through a valuation model that incorporated industry-based probability adjusted assumptions relating to the achievement of these milestones and thus the likelihood of making the contingent payments. This fair value measurement was based upon significant inputs not observable in the market and therefore represented a Level 3 measurement.

The purchase price, as adjusted, consisted of the following:

| (In millions) | |
|---|---|
| Cash portion of consideration | $200.1 |
| Contingent consideration | 274.5 |
| Total purchase price | $474.6 |

During the second quarter of 2015 we adjusted our preliminary estimate of the fair value of the assets acquired and contingent consideration as of the date of acquisition as a result of finalizing the purchase price accounting. This resulted in an increase in the value of our estimated contingent consideration and goodwill by $36.0 million, respectively. Our revised purchase price allocation is reflected in the chart below. Our purchase price allocation is complete.

Subsequent changes in the fair value of the contingent consideration obligation will be recognized as adjustments to contingent consideration and reflected in our consolidated statements of income. In the fourth quarter of 2016 a $50.0 million milestone related to BIIB074 in an additional neuropathic pain indication was earned and paid, resulting in a reduction to the contingent consideration. For additional information related to the fair value of this obligation, please read Note 7, Fair Value Measurements to these consolidated financial statements.

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The following table summarizes the estimated fair values of the separately identifiable assets acquired and liabilities assumed as of February 12, 2015, as adjusted:

| (In millions) | |
|---|---|
| In-process research and development | $424.6 |
| Other intangible assets | 7.6 |
| Goodwill | 128.3 |
| Deferred tax liability | (84.9) |
| Other, net | (1.0) |
| Total purchase price | $474.6 |

Our estimate of the fair value of the IPR&D programs acquired was determined through a probability adjusted discounted cash flow analysis utilizing a discount rate of 11%. This valuation was primarily driven by the value associated with the lead candidate, BIIB074, which is in development for the treatment of TGN and was expected to be completed no earlier than 2020, at a remaining cost of approximately $145.0 million. The fair value associated with BIIB074 for the treatment of TGN was $200.0 million. We recorded additional IPR&D assets related to the use of BIIB074 in two additional neuropathic pain indications, with a total estimated value of $220.0 million. The remaining cost of development for these two indications was approximately $415.0 million, with an expected completion date of no earlier than 2021. These fair value measurements were based on significant inputs not observable in the market and thus represented Level 3 fair value measurements.

We attributed the goodwill recognized to the Convergence workforce's expertise in chronic pain research and clinical development and to establishing a deferred tax liability for the acquired IPR&D intangible assets which had no tax basis. The goodwill was not tax deductible.

Pro forma results of operations would not be materially different as a result of the acquisition of Convergence and therefore are not presented. Subsequent to the acquisition date, our results of operations include the results of operations of Convergence.

3. Restructuring, Business Transformation and Other Cost Saving Initiatives

2015 Cost Saving Initiatives

2015 Restructuring Charges

On October 21, 2015, we announced a corporate restructuring, which included the termination of certain pipeline programs and an 11% reduction in workforce. Under this restructuring, cash payments were estimated to total approximately $120.0 million, of which $15.9 million were related to previously accrued 2015 incentive compensation, resulting in net restructuring charges totaling approximately $102.0 million. These amounts were substantially paid by the end of 2016.

For the year ended December 31, 2016, we recognized total net restructuring charges of $8.0 million. We previously recognized $93.4 million of restructuring charges in our consolidated statements of income during the fourth quarter of 2015. Our restructuring reserve is included in accrued expenses and other in our consolidated balance sheets.

The following table summarizes the charges and spending related to our 2015 restructuring program during 2016:

| (In millions) | Workforce Reduction | Pipeline Programs | Total |
|---|---|---|---|
| Restructuring reserve as of December 31, 2015 | $ 33.7 | $ 3.6 | $37.3 |
| Expense | 4.9 | 5.4 | 10.3 |
| Payments | (31.2) | (9.0) | (40.2) |
| Adjustments to previous estimates, net | (5.2) | 2.9 | (2.3) |
| Restructuring reserve as of December 31, 2016 | $ 2.2 | $ 2.9 | $5.1 |

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2016 Organizational Changes and Cost Saving Initiatives

2016 Restructuring Charges

During the third quarter of 2016 we initiated cost saving measures primarily intended to realign our organizational structure due to the changes in roles and workforce resulting from our decision to spin off our hemophilia business, and to achieve further targeted cost reductions. For the year ended December 31, 2016, we recognized charges totaling $17.7 million related to this effort, which are in addition to, and separate from, the 2015 corporate restructuring described above. These amounts, which were substantially incurred and paid by the end of 2016, are primarily related to severance and are reflected in restructuring charges in our consolidated statements of income.

Cambridge, MA Manufacturing Facility

In June 2016 following an evaluation of our current and future manufacturing capabilities and capacity needs, we determined that we intend to vacate and cease manufacturing in our 67,000 square foot small-scale biologics manufacturing facility in Cambridge, MA and also vacate our 46,000 square foot warehouse space in Somerville, MA. In December 2016 we subleased our rights to the manufacturing facility in Cambridge, MA to Brammer Bio MA, LLC (Brammer). Brammer also purchased from us certain manufacturing equipment, leasehold improvements and other assets in exchange for shares of Brammer common LLC interests and assumed manufacturing operations effective January 1, 2017. In December 2016 we also closed and vacated our warehouse space in Somerville, MA. Our departure from these facilities shortened the expected useful lives of certain leasehold improvements and other assets at these facilities. As a result, we recorded additional depreciation expense to reflect the assets' new shorter useful lives. For the year ended December 31, 2016, we recognized approximately $45.5 million of this additional depreciation, which was recorded as cost of sales in our consolidated statements of income.

Under the terms of the agreement, Brammer will also provide manufacturing and other transition and support services to us.

In the fourth quarter of 2016 we recognized charges totaling $7.4 million for severance costs related to certain employees separated from Biogen in connection with this transaction. These amounts will be substantially incurred and paid by the end of first quarter of 2017 and are reflected in restructuring charges in our consolidated statements of income.

4. Reserves for Discounts and Allowances

An analysis of the change in reserves for discounts and allowances is summarized as follows:

| (In millions) | Discounts | Contractual Adjustments | Returns | Total |
|---|---|---|---|---|
| 2016 | | | | |
| Beginning balance | $ 56.1 | $ 548.7 | $ 57.9 | $ 662.7 |
| Current provisions relating to sales in current year | 592.6 | 2,044.5 | 30.9 | 2,668.0 |
| Adjustments relating to prior years | (1.4) | 1.5 | (16.8) | (16.7) |
| Payments/returns relating to sales in current year | (522.5) | (1,576.0) | (1.0) | (2,099.5) |
| Payments/returns relating to sales in prior years | (53.2) | (536.0) | (19.8) | (609.0) |
| Ending balance | $ 71.6 | $ 482.7 | $ 51.2 | $ 605.5 |

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| (In millions) | Discounts | Contractual Adjustments | Returns | Total |
|---|---|---|---|---|
| 2015 | | | | |
| Beginning balance | $ 47.6 | $ 387.1 | $ 49.1 | $ 483.8 |
| Current provisions relating to sales in current year | 459.7 | 1,732.1 | 37.6 | 2,229.4 |
| Adjustments relating to prior years | (1.3) | (16.3) | (14.7) | (32.3) |
| Payments/returns relating to sales in current year | (405.9) | (1,258.1) | (2.6) | (1,666.6) |
| Payments/returns relating to sales in prior years | (44.0) | (296.1) | (11.5) | (351.6) |
| Ending balance | $ 56.1 | $ 548.7 | $ 57.9 | $ 662.7 |

| (In millions) | Discounts | Contractual Adjustments | Returns | Total |
|---|---|---|---|---|
| 2014 | | | | |
| Beginning balance | $ 47.0 | $ 345.5 | $ 33.7 | $ 426.2 |
| Current provisions relating to sales in current year | 347.3 | 1,265.4 | 39.1 | 1,651.8 |
| Adjustments relating to prior years | (1.0) | (28.5) | 13.5 | (16.0) |
| Payments/returns relating to sales in current year | (299.7) | (933.4) | (4.1) | (1,237.2) |
| Payments/returns relating to sales in prior years | (46.0) | (261.9) | (33.1) | (341.0) |
| Ending balance | $ 47.6 | $ 387.1 | $ 49.1 | $ 483.8 |

The total revenue-related reserves above, included in our consolidated balance sheets, are summarized as follows:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Reduction of accounts receivable | $166.9 | $144.6 |
| Component of accrued expenses and other | 438.6 | 518.1 |
| Total revenue-related reserves | $605.5 | $662.7 |

5. Inventory

The components of inventory are summarized as follows:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Raw materials | $170.4 | $213.0 |
| Work in process | 698.7 | 577.6 |
| Finished goods | 170.3 | 143.0 |
| Total inventory | $1,039.4 | $933.6 |
| | | |
| Balance Sheet Classification: | | |
| Inventory | $1,001.6 | $893.4 |
| Investments and other assets | 37.8 | 40.2 |
| Total inventory | $1,039.4 | $933.6 |

Long-term inventory, which primarily consists of work in process, is included in investments and other assets in our consolidated balance sheets.

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As of December 31, 2015, our inventory included $24.7 million associated with our ZINBRYTA program, $24.2 million associated with our FLIXABI program and $18.4 million associated with our BENEPALI program, which had been capitalized in advance of regulatory approval. The European Commission (EC) approved the marketing authorization applications for BENEPALI and FLIXABI, two anti-tumor necrosis factor (TNF) biosimilars, for marketing in the E.U. in January 2016 and May 2016, respectively. In addition, ZINBRYTA was approved for the treatment of relapsing forms of MS in the U.S. in May 2016 and in the E.U. in July 2016. For information on our pre-approval inventory policy, please read Note 1, Summary of Significant Accounting Policies to these consolidated financial statements

Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons are charged to cost of sales, and totaled $48.2 million, $41.9 million and $50.6 million for the years ended December 31, 2016, 2015 and 2014, respectively.

6. Intangible Assets and Goodwill

Intangible Assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments, are summarized as follows:

| | | As of December 31, 2016 | | | As of December 31, 2015 | | |
|---|---|---|---|---|---|---|---|
| (In millions) | Estimated Life | Cost | Accumulated Amortization | Net | Cost | Accumulated Amortization | Net |
| Out-licensed patents | 13-23 years | $543.3 | $ (523.6) | $19.7 | $543.3 | $ (506.0) | $37.3 |
| Developed technology | 15-23 years | 3,005.3 | (2,634.3) | 371.0 | 3,005.3 | (2,552.9) | 452.4 |
| In-process research and development | Indefinite until commercialization | 648.0 | — | 648.0 | 730.5 | — | 730.5 |
| Trademarks and trade names | Indefinite | 64.0 | — | 64.0 | 64.0 | — | 64.0 |
| Acquired and in-licensed rights and patents | 6-18 years | 3,481.7 | (776.1) | 2,705.6 | 3,303.2 | (502.3) | 2,800.9 |
| Total intangible assets | | $7,742.3 | $ (3,934.0) | $3,808.3 | $7,646.3 | $ (3,561.2) | $4,085.1 |

Amortization of acquired intangible assets totaled $385.6 million, $382.6 million and $489.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. Amortization of acquired intangible assets during 2016 included impairment charges of $12.2 million related to two of our IPR&D intangible assets. Amortization of acquired intangible assets during 2014 included impairment charges of $34.7 million related to one of our out-licensed patents and $16.2 million related to one of our IPR&D intangible assets.

Out-licensed Patents

Out-licensed patents to third-parties primarily relate to patents acquired in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. During 2014 we recorded a charge of $34.7 million related to the impairment of one of our out-licensed patents to reflect a change in its estimated fair value due to a change in the underlying competitive market for that product. The charge was included in amortization of acquired intangible assets in our consolidated statements of income. The fair value of the intangible asset was based on a discounted cash flow calculated using Level 3 fair value measurements and inputs including estimated revenues. There were no impairment charges related to our out-licensed patents during 2016 or 2015.

Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of December 31, 2016, was $363.3 million.

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IPR&D

IPR&D represents the fair value assigned to research and development assets that we acquire and have not reached technological feasibility at the date of acquisition. Upon commercialization, we will determine the estimated useful life. In connection with our acquisition of Convergence in February 2015, we acquired IPR&D programs with an estimated fair value of $424.6 million. This amount has and will be adjusted for foreign exchange rate fluctuations. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

An analysis of anticipated lifetime revenues and anticipated development costs is performed annually during our long-range planning cycle, which was updated in the third quarter of 2016. This analysis is based upon certain assumptions that we evaluate on a periodic basis, including anticipated future product sales, the expected impact of changes in the amount of development costs and the probabilities of our programs succeeding, the introduction of new products by our competitors and changes in our commercial and pipeline product candidates.

During the fourth quarter of 2016 we terminated our collaboration agreements with Rodin Therapeutics, Inc. and Ataxion Inc., resulting in impairment losses of $8.7 million and $3.5 million, respectively, reflecting the full value of the assets recorded upon entering into the collaboration agreements. These impairment losses are included in amortization of acquired intangible assets in our consolidated statements of income.

During the third quarter of 2014 we updated the probabilities of success related to the early stage programs acquired through our recent acquisitions. The change in probability of success, combined with a delay in one of the projects, resulted in an impairment loss of $16.2 million in one of our IPR&D assets during 2014. This impairment is included in amortization of acquired intangible assets in our consolidated statements of income.

Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Corporation plc (Elan). The net book value of this asset as of December 31, 2016, was $2,493.2 million.

The net change in acquired and in-licensed rights and patents during the year ended December 31, 2016, reflects:

- $60.0 million milestone payment due to Ionis Pharmaceuticals, Inc. (Ionis) for the approval of SPINRAZA in the U.S. in December 2016;
- $50.0 million in total milestone payments due to Samsung Bioepis, which became payable upon the approval of BENEPALI and FLIXABI in the E.U. in January 2016 and May 2016, respectively;
- $32.0 million in total milestone payments due to AbbVie, Inc. (AbbVie), which became payable upon the approval of ZINBRYTA in the U.S. in May 2016 and the E.U. in July 2016; and
- $26.5 million upon the approval of ALPROLIX in the E.U. in May 2016 which is comprised of a $20.0 million contingent payment due to the former owners of Syntonix Pharmaceuticals, Inc. (Syntonix) and $6.5 million related to the establishment of a corresponding deferred tax liability.

For additional information on our relationships with Samsung Bioepis, AbbVie and Ionis, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

Estimated Future Amortization of Intangible Assets

Our amortization expense is based on the economic consumption of intangible assets. Our most significant intangible assets are related to our AVONEX and TYSABRI products. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of AVONEX and TYSABRI. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of either product.

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Our most recent long range planning cycle was completed in the third quarter of 2016. Based upon this analysis, the estimated future amortization of acquired intangible assets is expected to be as follows:

| (In millions) | As of December 31, 2016 |
|---|---|
| 2017 | $ 334.8 |
| 2018 | 312.7 |
| 2019 | 295.2 |
| 2020 | 259.7 |
| 2021 | 242.8 |

Goodwill

The following table provides a roll forward of the changes in our goodwill balance:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Goodwill, beginning of year | $2,663.8 | $1,760.2 |
| Increase to goodwill | 1,026.9 | 908.1 |
| Other | (21.4) | (4.5) |
| Goodwill, end of year | $3,669.3 | $2,663.8 |

The increase in goodwill during 2016 was related to $1.2 billion in contingent milestones achieved (exclusive of $173.1 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights. Other includes changes related to foreign exchange rate fluctuations. The increase in goodwill during 2015 was related to $900.0 million in contingent milestones achieved (exclusive of $120.2 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights and $128.3 million related to our acquisition of Convergence.

For additional information related to future contingent payments to the former shareholders of Fumapharm AG or holders of their rights, please read Note 21, Commitments and Contingencies to these consolidated financial statements. For additional information related to our acquisition of Convergence, please read Note 2, Acquisitions to these consolidated financial statements.

As of December 31, 2016, we had no accumulated impairment losses related to goodwill.

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7. Fair Value Measurements

The tables below present information about our assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques we utilized to determine such fair value:

| (In millions) | As of December 31, 2016 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 2,039.6 | $ — | $ 2,039.6 | $ — |
| Marketable debt securities: | | | | |
| Corporate debt securities | 2,663.8 | — | 2,663.8 | — |
| Government securities | 2,172.5 | — | 2,172.5 | — |
| Mortgage and other asset backed securities | 561.7 | — | 561.7 | — |
| Marketable equity securities | 24.9 | 24.9 | — | — |
| Derivative contracts | 61.0 | — | 61.0 | — |
| Plan assets for deferred compensation | 34.5 | — | 34.5 | — |
| Total | $ 7,558.0 | $ 24.9 | $ 7,533.1 | $ — |
| Liabilities: | | | | |
| Derivative contracts | $ 13.6 | $ — | $ 13.6 | $ — |
| Contingent consideration obligations | 467.6 | — | — | 467.6 |
| Total | $ 481.2 | $ — | $ 13.6 | $ 467.6 |

| (In millions) | As of December 31, 2015 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 909.5 | $ — | $ 909.5 | $ — |
| Marketable debt securities: | | | | |
| Corporate debt securities | 1,510.9 | — | 1,510.9 | — |
| Government securities | 2,875.9 | — | 2,875.9 | — |
| Mortgage and other asset backed securities | 494.1 | — | 494.1 | — |
| Marketable equity securities | 37.5 | 37.5 | — | — |
| Derivative contracts | 27.2 | — | 27.2 | — |
| Plan assets for deferred compensation | 40.1 | — | 40.1 | — |
| Total | $ 5,895.2 | $ 37.5 | $ 5,857.7 | $ — |
| Liabilities: | | | | |
| Derivative contracts | $ 14.7 | $ — | $ 14.7 | $ — |
| Contingent consideration obligations | 506.0 | — | — | 506.0 |
| Total | $ 520.7 | $ — | $ 14.7 | $ 506.0 |

The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities were determined through third-party pricing services. For a description of our validation procedures related to prices provided by third-party pricing services, refer to Note 1, Summary of Significant Accounting Policies: Fair Value Measurements, to these consolidated financial statements.

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Debt Instruments

The fair values of our debt instruments, which are Level 2 liabilities, are summarized as follows:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Notes payable to Fumedica | $6.1 | $9.4 |
| 6.875% Senior Notes due March 1, 2018 | 583.7 | 602.6 |
| 2.900% Senior Notes due September 15, 2020 | 1,521.5 | 1,497.5 |
| 3.625% Senior Notes due September 15, 2022 | 1,026.6 | 1,014.2 |
| 4.050% Senior Notes due September 15, 2025 | 1,796.0 | 1,764.6 |
| 5.200% Senior Notes due September 15, 2045 | 1,874.5 | 1,757.6 |
| Total | $6,808.4 | $6,645.9 |

The fair value of our notes payable to Fumedica was estimated using market observable inputs, including current interest and foreign currency exchange rates. The fair values of each of our series of Senior Notes were determined through market, observable, and corroborated sources. For additional information related to our debt instruments, please read Note 11, Indebtedness to these consolidated financial statements.

Contingent Consideration Obligations

The following table provides a roll forward of the fair values of our contingent consideration obligations which includes Level 3 measurements:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Fair value, beginning of year | $ 506.0 | $ 215.5 |
| Additions | — | 274.5 |
| Changes in fair value | 14.8 | 30.5 |
| Payments and other | (53.2) | (14.5) |
| Fair value, end of year | $ 467.6 | $ 506.0 |

As of December 31, 2016 and 2015, approximately $246.8 million and $301.3 million, respectively, of the fair value of our total contingent consideration obligations was reflected as a component of other long-term liabilities in our consolidated balance sheets with the remaining balance reflected as a component of accrued expenses and other. Payments and other for 2016 includes $7.9 million of a Convergence milestone converted to a short-term obligation under the terms of the acquisition agreement.

There were no changes in valuation techniques or transfers between fair value measurement levels during the years ended December 31, 2016 and 2015. The fair values of the intangible assets and contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenues and probabilities of success. For additional information related to the valuation techniques and inputs utilized in valuation of our financial assets and liabilities, please read Note 1, Summary of Significant Accounting Policies to these consolidated financial statements.

Convergence

In connection with our acquisition of Convergence in February 2015 we recorded a contingent consideration obligation of $274.5 million. This valuation was based on probability weighted net cash outflow projections of $450.0 million, discounted using a rate of 2.0%, which was the estimated cost of debt financing for market participants. This liability reflected the revised estimate from the date of acquisition for our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

As of December 31, 2016 and 2015, the fair value of this contingent consideration obligation was $258.9 million and $297.5 million, respectively. Our most recent valuation was determined based upon probability weighted net cash flow projections of $400.0 million, discounted using a rate of 2.7%, which is a measure of the credit risk associated

with settling the liability.

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For 2016 compared to 2015, the net decrease in the fair value of this obligation was primarily due to achievement of a $50.0 million milestone related to a second indication, partially offset by changes in the discount rate and an increase in the probability of success related to the achievement of certain developmental milestones. Approximately $148.4 million is reflected as a component of accrued expenses and other in our consolidated balance sheets as we expect to make the payment within one year.

Stromedix Inc.

In connection with our acquisition of Stromedix Inc. (Stromedix) in March 2012 we recorded a contingent consideration obligation of $122.2 million. As of December 31, 2016 and 2015, the fair value of this contingent consideration obligation was $133.2 million and $131.5 million, respectively. Our most recent valuation was determined based upon probability weighted net cash outflow projections of $419.0 million, discounted using a rate of 2.2%, which is a measure of the credit risk associated with settling the liability.

For 2016 compared to 2015, the net increase in the fair value of this obligation was primarily due to changes in the discount rate, partially offset by changes in the expected timing related to the achievement of certain remaining developmental milestones. Approximately $56.9 million is reflected as a component of accrued expenses and other in our consolidated balance sheets as we expect to make the payment within one year.

Biogen Idec International Neuroscience GmbH

In connection with our acquisition of Biogen Idec International Neuroscience GmbH (BIN), formerly Panima Pharmaceuticals AG (Panima), in December 2010 we recorded a contingent consideration obligation of $81.2 million. As of December 31, 2016 and 2015, the fair value of this contingent consideration obligation was $75.5 million and $77.0 million, respectively. Our most recent valuation was determined based upon probability weighted net cash outflow projections of $361.7 million, discounted using a rate of 2.7%, which is a measure of the credit risk associated with settling the liability.

For 2016 compared to 2015, the net decrease in the fair value of this obligation was primarily due to payment of $3.3 million in developmental milestones, partially offset by changes in the discount rate. Approximately $15.5 million is reflected as a component of accrued expenses and other in our consolidated balance sheets as we expect to make the payment within one year.

Acquired IPR&D

In connection with our acquisition of Convergence, we also allocated $424.6 million of the total purchase price to acquired IPR&D, which was capitalized as an intangible asset. The amount allocated to acquired IPR&D was based on significant inputs not observable in the market and thus represented a Level 3 fair value measurement. This estimate was also adjusted from our preliminary estimate as of the date of acquisition to reflect revised estimates to our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. These assets will be tested for impairment annually until commercialization, after which time the IPR&D will be amortized over its estimated useful life. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

8. Financial Instruments

The following table summarizes our financial assets with maturities of less than 90 days from the date of purchase included in cash and cash equivalents on the accompanying consolidated balance sheet:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Commercial paper | $31.0 | $21.9 |
| Overnight reverse repurchase agreements | — | 134.7 |
| Money market funds | 741.7 | 673.8 |
| Short-term debt securities | 1,266.9 | 79.1 |
| Total | $2,039.6 | $909.5 |

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The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and our short-term debt securities approximate fair value due to their short term maturities. Our overnight reverse repurchase agreements were collateralized with agency-guaranteed mortgage-backed securities and represented approximately 0.7% of total assets as of December 31, 2015.

The following tables summarize our marketable debt and equity securities, classified as available for sale:

| As of December 31, 2016 (In millions) | Fair Value | Gross Unrealized Gains | Gross Unrealized Losses | Amortized Cost |
|---|---|---|---|---|
| Corporate debt securities | | | | |
| Current | $1,408.6 | $ 0.2 | $ (0.6) | $ 1,409.0 |
| Non-current | 1,255.2 | 1.2 | (4.7) | 1,258.7 |
| Government securities | | | | |
| Current | 1,156.0 | 0.2 | (0.3) | 1,156.1 |
| Non-current | 1,016.5 | 0.5 | (3.4) | 1,019.4 |
| Mortgage and other asset backed securities | | | | |
| Current | 4.0 | — | — | 4.0 |
| Non-current | 557.7 | 0.8 | (2.2) | 559.1 |
| Total marketable debt securities | $5,398.0 | $ 2.9 | $ (11.2) | $ 5,406.3 |
| Marketable equity securities, non-current | $24.9 | $ 0.7 | $ (9.3) | $ 33.5 |

| As of December 31, 2015 (In millions) | Fair Value | Gross Unrealized Gains | Gross Unrealized Losses | Amortized Cost |
|---|---|---|---|---|
| Corporate debt securities | | | | |
| Current | $394.3 | $ — | $ (0.5) | $ 394.8 |
| Non-current | 1,116.6 | 0.1 | (4.1) | 1,120.6 |
| Government securities | | | | |
| Current | 1,723.4 | 0.1 | (1.1) | 1,724.4 |
| Non-current | 1,152.5 | — | (3.1) | 1,155.6 |
| Mortgage and other asset backed securities | | | | |
| Current | 2.8 | — | — | 2.8 |
| Non-current | 491.3 | 0.1 | (1.8) | 493.0 |
| Total marketable debt securities | $4,880.9 | $ 0.3 | $ (10.6) | $ 4,891.2 |
| Marketable equity securities, non-current | $37.5 | $ 9.2 | $ — | $ 28.3 |

Summary of Contractual Maturities: Available-for-Sale Securities

The estimated fair value and amortized cost of our marketable debt securities available-for-sale by contractual maturity are summarized as follows:

| | As of December 31, 2016 | | As of December 31, 2015 | |
|---|---|---|---|---|
| (In millions) | Estimated Fair Value | Amortized Cost | Estimated Fair Value | Amortized Cost |
| Due in one year or less | $2,568.6 | $ 2,569.1 | $2,120.5 | $ 2,122.0 |
| Due after one year through five years | 2,552.6 | 2,559.7 | 2,575.9 | 2,583.9 |
| Due after five years | 276.8 | 277.5 | 184.5 | 185.3 |
| Total available-for-sale securities | $5,398.0 | $ 5,406.3 | $4,880.9 | $ 4,891.2 |

The average maturity of our marketable debt securities available-for-sale as of December 31, 2016 and 2015 was 12 months and 16 months, respectively.

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Proceeds from Marketable Debt Securities

The proceeds from maturities and sales of marketable debt securities and resulting realized gains and losses are summarized as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Proceeds from maturities and sales | $7,378.9 | $4,063.0 | $2,718.9 |
| Realized gains | $3.3 | $1.5 | $0.7 |
| Realized losses | $4.3 | $3.5 | $0.5 |

Realized losses for the year ended December 31, 2016, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities. Realized losses for the year ended December 31, 2015, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities. Realized losses for the year ended December 31, 2014, primarily relate to sales of agency mortgage-backed securities and government securities.

Strategic Investments

As of December 31, 2016 and 2015, our strategic investment portfolio was comprised of investments totaling $99.9 million and $96.0 million, respectively, which are included in investments and other assets in our consolidated balance sheets. Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and investments in venture capital funds where the underlying investments are in equity securities of biotechnology companies.

9. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

Due to the global nature of our operations, portions of our revenues and operating expenses are recorded in currencies other than the U.S. dollar. The value of revenues and operating expenses measured in U.S. dollars is therefore subject to changes in foreign currency exchange rates. In order to mitigate these changes we use foreign currency forward contracts to lock in exchange rates associated with a portion of our forecasted international revenues and operating expenses.

Foreign currency forward contracts in effect as of December 31, 2016 and 2015, had durations of 1 to 18 months, respectively. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses for the effective portion of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized and, beginning in the fourth quarter of 2015, in operating expenses when the expense in the currency being hedged is recorded. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net.

The notional value of foreign currency forward contracts that were entered into to hedge forecasted revenues and operating expenses is summarized as follows:

| | Notional Amount As of December 31, | |
|---|---|---|
| Foreign Currency: (In millions) | 2016 | 2015 |
| Euro | $ 871.7 | $ 945.5 |
| Swiss francs | — | 80.8 |
| Canadian dollar | — | 76.7 |
| Total foreign currency forward contracts | $ 871.7 | $ 1,103.0 |

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The portion of the fair value of these foreign currency forward contracts that was included in accumulated other comprehensive income (loss) in total equity reflected net gains of $49.8 million, $1.8 million and $72.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. We expect all contracts to be settled over the next 18 months and any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of December 31, 2016 and 2015, credit risk did not change the fair value of our foreign currency forward contracts.

The following table summarizes the effect of foreign currency forward contracts designated as hedging instruments on our consolidated statements of income:

| For the Years Ended December 31, | | | | | | | |
|---|---|---|---|---|---|---|---|
| Net Gains/(Losses) Reclassified from AOCI into Net Income (Effective Portion) | | | | Net Gains/(Losses) Recognized into Net Income (Ineffective Portion) | | | |
| Location | 2016 | 2015 | 2014 | Location | 2016 | 2015 | 2014 |
| Revenue | $5.3 | $173.2 | $6.8 | Other income (expense) | $2.9 | $4.9 | $(1.5) |
| Operating expenses | $(1.5) | $— | $— | Other income (expense) | $0.1 | $— | $— |

Interest Rate Contracts - Hedging Instruments

We have entered into interest rate lock contracts or interest rate swap contracts on certain borrowing transactions to manage our exposure to interest rate changes and to reduce our overall cost of borrowing.

Interest Rate Lock Contracts

During 2015 we entered into treasury rate locks, with an aggregated notional amount of $1.1 billion, which were designated as cash flow hedges to hedge against changes in the 10-year and 30-year U.S. treasury interest rates that could have impacted our anticipated debt offering. In connection with the issuance of our 4.05% and 5.20% Senior Notes, as described in Note 11, Indebtedness, we settled the treasury rate locks and realized an $8.5 million gain. As the hedging relationship was effective, the gain was recorded in AOCI and will be recognized in other income (expense), net over the life of the 4.05% and 5.20% Senior Notes.

Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes, as described in Note 11, Indebtedness, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in the 2.90% Senior Notes attributable to changes in interest rates. Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recorded as a component of the 2.90% Senior Notes with no net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recognized as a component of interest expense in our consolidated statements of income.

Foreign Currency Forward Contracts - Other Derivatives

We also enter into other foreign currency forward contracts, usually with durations of one month or less, to mitigate the foreign currency risk related to certain balance sheet positions. We have not elected hedge accounting for these transactions.

The aggregate notional amount of these outstanding foreign currency contracts was $902.1 million and $721.0 million as of December 31, 2016 and 2015, respectively. Net losses of $29.2 million, $23.8 million and $15.5 million related to these contracts were recognized as a component of other income (expense), net, for the years ended December 31, 2016, 2015 and 2014, respectively.

Summary of Derivatives

While certain of our derivatives are subject to netting arrangements with our counterparties, we do not offset derivative assets and liabilities in our consolidated balance sheets.

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The following table summarizes the fair value and presentation in our consolidated balance sheets of our outstanding derivatives including those designated as hedging instruments:

| (In millions) | Balance Sheet Location | Fair Value As of December 31, 2016 |
|---|---|---|
| Hedging Instruments: | | |
| Asset derivatives | Other current assets | $ 50.4 |
| | Investments and other assets | $ 6.6 |
| Liability derivatives | Other long-term liabilities | $ 4.6 |
| Other Derivatives: | | |
| Asset derivatives | Other current assets | $ 4.0 |
| Liability derivatives | Accrued expenses and other | $ 9.0 |

| (In millions) | Balance Sheet Location | Fair Value As of December 31, 2015 |
|---|---|---|
| Hedging Instruments: | | |
| Asset derivatives | Other current assets | $ 16.6 |
| | Investments and other assets | $ 0.3 |
| Liability derivatives | Accrued expenses and other | $ 10.2 |
| | Other long-term liabilities | $ 2.5 |
| Other Derivatives: | | |
| Asset derivatives | Other current assets | $ 10.3 |
| Liability derivatives | Accrued expenses and other | $ 2.0 |

10. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Components of property, plant and equipment, net are summarized as follows:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Land | $137.8 | $74.7 |
| Buildings | 1,107.8 | 1,035.6 |
| Leasehold improvements | 123.7 | 166.6 |
| Machinery and equipment | 1,105.8 | 1,079.6 |
| Computer software and hardware | 746.8 | 647.1 |
| Furniture and fixtures | 60.6 | 72.9 |
| Construction in progress | 658.6 | 441.2 |
| Total cost | 3,941.1 | 3,517.7 |
| Less: accumulated depreciation | (1,439.3 ) | (1,330.1 ) |
| Total property, plant and equipment, net | $2,501.8 | $2,187.6 |

Depreciation expense totaled $309.3 million, $217.9 million and $198.4 million for 2016, 2015 and 2014, respectively.

For 2016, 2015 and 2014, we capitalized interest costs related to construction in progress totaling approximately $12.9 million, $10.4 million and $6.4 million, respectively.

Solothurn, Switzerland Facility

During the first quarter of 2016 we closed on the purchase of land in Solothurn, Switzerland for 64.4 million Swiss Francs (approximately $62.5 million). We are building a biologics manufacturing facility on this land in the

Commune of Luterbach over the next several years. As of December 31, 2016 and 2015, we had approximately $481.5 million and $99.0 million, respectively, capitalized as construction in progress related to the construction of this facility.

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Research Triangle Park Facility Purchase

On August 24, 2015, we purchased from Eisai, Inc. (Eisai) its drug product manufacturing facility and supporting infrastructure in Research Triangle Park (RTP), North Carolina for $104.8 million. The purchase price consisted of $58.6 million for buildings, $25.9 million for machinery and equipment and $20.3 million for land.

On August 24, 2015, we also amended our existing 10-year lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. As amended, the lease provides for a three-year term and our agreement to purchase the facility upon expiration of the lease term and Eisai's completion of certain activities. Accordingly, we recorded the assets along with a corresponding financing obligation on our consolidated balance sheet for $20.3 million, the net present value of the future minimum lease payments. The assets were recorded as a component of buildings and machinery and equipment. We expect to complete the purchase of the oral solid products manufacturing facility at the end of the lease term in the third quarter of 2018.

11. Indebtedness

Our indebtedness is summarized as follows:

| (In millions) | As of December 31, 2016 | 2015 |
|---|---|---|
| Current portion: | | |
| Notes payable to Fumedica | $ 3.0 | $ 3.1 |
| Financing arrangement for the purchase of the RTP facility | 1.7 | 1.7 |
| Current portion of notes payable and other financing arrangements | $ 4.7 | $ 4.8 |
| Non-current portion: | | |
| 6.875% Senior Notes due March 1, 2018 | $ 558.5 | $ 565.3 |
| 2.900% Senior Notes due September 15, 2020 | 1,485.3 | 1,485.5 |
| 3.625% Senior Notes due September 15, 2022 | 993.2 | 992.2 |
| 4.050% Senior Notes due September 15, 2025 | 1,734.8 | 1,733.4 |
| 5.200% Senior Notes due September 15, 2045 | 1,721.5 | 1,721.1 |
| Notes payable to Fumedica | 3.0 | 5.9 |
| Financing arrangement for the purchase of the RTP | 16.4 | 18.1 |

| | | |
|---|---|---|
| facility | | |
| Non-current portion of notes payable and other financing arrangements | $ 6,512.7 | $ 6,521.5 |

The following is a summary of our principal indebtedness as of December 31, 2016:

- $550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018, valued at 99.184% of par;
- $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;
- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;
- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and
- $1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

The costs associated with these offerings of approximately $52.0 million have been recorded as a reduction to the carrying amount of the debt on our consolidated balance sheet. These costs along with the discounts will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. These notes are senior unsecured obligations. The notes may be redeemed at our option at any time at 100% of the principal amount plus accrued interest and a specified make-whole amount. The 6.875% Senior Notes due in

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2018 contain a change of control provision that may require us to purchase the notes under certain circumstances. There is also an interest rate adjustment feature that requires us to pay interest at an increased rate on the notes if the credit rating on the notes declines below investment grade. The remaining Senior Notes contain a change of control provision that may require us to purchase the notes at a price equal to 101% of the principal amount plus accrued and unpaid interest to the date of purchase under certain circumstances.

In connection with the 2.90% Senior Notes offering due in 2020, we entered into interest rate swap contracts. The carrying value of the 2.90% Senior Notes includes approximately $4.6 million related to changes in the fair value of these contracts. For additional information, please read Note 9, Derivative Instruments, to these consolidated financial statements.

In connection with the 6.875% Senior Notes due in 2018, we entered into interest rate swap contracts where we received a fixed rate and paid a variable rate. These contracts were terminated in December 2008. Upon termination of these swaps, the carrying amount of the 6.875% Senior Notes due in 2018 was increased by $62.8 million and is being amortized using the effective interest rate method over the remaining life of the Senior Notes and is being recognized as a reduction of interest expense. As of December 31, 2016, $9.9 million remains to be amortized.

Notes Payable to Fumedica

In connection with our 2006 distribution agreement with Fumedica, we issued notes totaling 61.4 million Swiss Francs which were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a carrying value of 6.2 million Swiss Francs ($6.0 million) and 8.9 million Swiss Francs ($9.0 million) as of December 31, 2016 and 2015, respectively.

Credit Facility

In August 2015 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of December 31, 2016, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Financing Arrangement

During 2015 we recorded a financing obligation in relation to the amendment of our lease agreement of Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. As of December 31, 2016 and 2015, the financing obligation totaled approximately $18.1 million and $19.8 million, respectively. For additional information, please read Note 10, Property, Plant and Equipment to these consolidated financial statements.

Debt Maturity

The total gross payments, excluding our financing arrangement, due under our debt arrangements are as follows:

| (In millions) | As of December 31, 2016 |
|---|---|
| 2017 | $ 3.1 |
| 2018 | 553.1 |
| 2019 | — |
| 2020 | 1,500.0 |
| 2021 | — |
| 2022 and thereafter | 4,500.0 |
| Total | $ 6,556.2 |

The fair value of our debt is disclosed in Note 7, Fair Value Measurements to these consolidated financial statements.

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12. Equity

Preferred Stock

We have 8.0 million shares of Preferred Stock authorized, of which 1.75 million shares are authorized as Series A, 1.0 million shares are authorized as Series X junior participating and 5.25 million shares are undesignated. Shares may be issued without a vote or action of stockholders from time to time in classes or series with the designations, powers, preferences, and the relative, participating, optional or other special rights of the shares of each such class or series and any qualifications, limitations or restrictions thereon as set forth in the instruments governing such shares. Any such Preferred Stock may rank prior to common stock as to dividend rights, liquidation preference or both, and may have full or limited voting rights and may be convertible into shares of common stock. No shares of Preferred Stock were issued and outstanding during 2016, 2015 and 2014.

Common Stock

The following table describes the number of shares authorized, issued and outstanding of our common stock as of December 31, 2016 and 2015:

| | As of December 31, 2016 | | | As of December 31, 2015 | | |
|---|---|---|---|---|---|---|
| (In millions) | Authorized | Issued | Outstanding | Authorized | Issued | Outstanding |
| Common stock | 1,000.0 | 238.5 | 215.9 | 1,000.0 | 241.2 | 218.6 |

Share Repurchases

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. As of December 31, 2016, we repurchased and retired 3.3 million shares of common stock at a cost of $1.0 billion under our 2016 Share Repurchase Program.

In May 2015 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2015 Share Repurchase Program), which was completed as of December 31, 2015. As of December 31, 2015, we repurchased and retired approximately 16.8 million shares of common stock at a cost of $5.0 billion under our 2015 Share Repurchase Program.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of our common stock (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under our share-based compensation plans. The 2011 Share Repurchase Program does not have an expiration date. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program during the years ended December 31, 2016 and 2015. During 2014 we purchased approximately 2.9 million shares of common stock at a cost of $886.8 million under our 2011 Share Repurchase Program. We have approximately 1.3 million shares remaining available for repurchase under this authorization.

13. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss), net of tax by component:

| (In millions) | Unrealized Gains (Losses) on Securities Available for Sale | Unrealized Gains (Losses) on Cash Flow Hedges | Unfunded Status of Postretirement Benefit Plans | Translation Adjustments | Total |
|---|---|---|---|---|---|
| Balance, December 31, 2015 | $ (0.8) | $ 10.2 | $ (37.8) | $ (195.6) | $(224.0) |
| Other comprehensive income (loss) before reclassifications | (10.6) | 51.6 | 5.1 | (138.6) | (92.5) |
| Amounts reclassified from accumulated other comprehensive income (loss) | 0.6 | (4.0) | — | — | (3.4) |
| Net current period other comprehensive income (loss) | (10.0) | 47.6 | 5.1 | (138.6) | (95.9) |

| | | | | |
|---|---|---|---|---|
| Balance, December 31, 2016 | $ (10.8 ) | $ 57.8 | $ (32.7 ) | $ (334.2 ) | $(319.9) |

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| (In millions) | Unrealized Gains (Losses) on Securities Available for Sale | Unrealized Gains (Losses) on Cash Flow Hedges | Unfunded Status of Postretirement Benefit Plans | Translation Adjustments | Total |
|---|---|---|---|---|---|
| Balance, December 31, 2014 | $ (0.4) | $ 71.7 | $ (31.6) | $ (99.2) | $(59.5) |
| Other comprehensive income (loss) before reclassifications | (1.7) | 110.8 | (6.2) | (96.4) | 6.5 |
| Amounts reclassified from accumulated other comprehensive income (loss) | 1.3 | (172.3) | — | — | (171.0) |
| Net current period other comprehensive income (loss) | (0.4) | (61.5) | (6.2) | (96.4) | (164.5) |
| Balance, December 31, 2015 | $ (0.8) | $ 10.2 | $ (37.8) | $ (195.6) | $(224.0) |

| (In millions) | Unrealized Gains (Losses) on Securities Available for Sale | Unrealized Gains (Losses) on Cash Flow Hedges | Unfunded Status of Postretirement Benefit Plans | Translation Adjustments | Total |
|---|---|---|---|---|---|
| Balance, December 31, 2013 | $ 5.6 | $ (23.7) | $ (19.6) | $ 10.0 | $(27.7) |
| Other comprehensive income (loss) before reclassifications | 0.4 | 101.7 | (12.0) | (109.2) | (19.1) |
| Amounts reclassified from accumulated other comprehensive income (loss) | (6.4) | (6.3) | — | — | (12.7) |
| Net current period other comprehensive income (loss) | (6.0) | 95.4 | (12.0) | (109.2) | (31.8) |
| Balance, December 31, 2014 | $ (0.4) | $ 71.7 | $ (31.6) | $ (99.2) | $(59.5) |

The following table summarizes the amounts reclassified from accumulated other comprehensive income:

| (In millions) | Income Statement Location | Amounts Reclassified from Accumulated Other Comprehensive Income For the Years Ended December 31, 2016 | 2015 | 2014 |
|---|---|---|---|---|
| Gains (losses) on securities available for sale | Other income (expense) | $(0.9) | $(2.0) | $9.9 |
| | Income tax benefit (expense) | 0.3 | 0.7 | (3.5) |
| Gains (losses) on cash flow hedges | Revenues | 5.3 | 173.2 | 6.8 |
| | Operating expenses | (1.5) | — | — |
| | Other income (expense) | 0.2 | (0.1) | — |
| | Income tax benefit (expense) | — | (0.8) | (0.5) |
| Total reclassifications, net of tax | | $3.4 | $171.0 | $12.7 |

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14. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Numerator: | | | |
| Net income attributable to Biogen Inc. | $3,702.8 | $3,547.0 | $2,934.8 |
| Denominator: | | | |
| Weighted average number of common shares outstanding | 218.4 | 230.7 | 236.4 |
| Effect of dilutive securities: | | | |
| Stock options and employee stock purchase plan | 0.1 | 0.1 | 0.1 |
| Time-vested restricted stock units | 0.2 | 0.3 | 0.5 |
| Market stock units | 0.1 | 0.1 | 0.2 |
| Dilutive potential common shares | 0.4 | 0.5 | 0.8 |
| Shares used in calculating diluted earnings per share | 218.8 | 231.2 | 237.2 |

Amounts excluded from the calculation of net income per diluted share because their effects were anti-dilutive were insignificant.

Earnings per share for the years ended December 31, 2016, 2015 and 2014, reflects, on a weighted average basis, the repurchase of 0.7 million shares, 4.6 million shares and 1.0 million shares, respectively, of our common stock under our share repurchase authorizations.

15. Share-based Payments

Share-based Compensation Expense

The following table summarizes share-based compensation expense included in our consolidated statements of income:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Research and development | $ 84.5 | $ 88.6 | $ 102.1 |
| Selling, general and administrative | 121.7 | 127.3 | 150.3 |
| Restructuring charges | (1.8) | (8.6) | — |
| Subtotal | 204.4 | 207.3 | 252.4 |
| Capitalized share-based compensation costs | (14.6) | (11.0) | (10.0) |
| Share-based compensation expense included in total cost and expenses | 189.8 | 196.3 | 242.4 |
| Income tax effect | (54.0) | (55.8) | (72.2) |
| Share-based compensation expense included in net income attributable to Biogen Inc. | $ 135.8 | $ 140.5 | $ 170.2 |

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The following table summarizes share-based compensation expense associated with each of our share-based compensation programs:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Market stock units | $ 38.4 | $ 38.1 | $ 37.4 |
| Time-vested restricted stock units | 120.0 | 119.0 | 115.4 |
| Cash settled performance units | 16.3 | 22.4 | 65.5 |
| Performance units | 18.6 | 13.9 | 21.9 |
| Employee stock purchase plan | 11.1 | 13.9 | 12.2 |
| Subtotal | 204.4 | 207.3 | 252.4 |
| Capitalized share-based compensation costs | (14.6) | (11.0) | (10.0) |
| Share-based compensation expense included in total cost and expenses | $ 189.8 | $ 196.3 | $ 242.4 |

Windfall tax benefits from vesting of stock awards, exercises of stock options and ESPP participation were $12.6 million, $78.2 million and $96.4 million in 2016, 2015 and 2014, respectively. These amounts have been calculated under the alternative transition method.

As of December 31, 2016, unrecognized compensation cost related to unvested share-based compensation was approximately $189.8 million, net of estimated forfeitures. We expect to recognize the cost of these unvested awards over a weighted-average period of 1.9 years.

Share-Based Compensation Plans

We have three share-based compensation plans pursuant to which awards are currently being made: (i) the Biogen Inc. 2006 Non-Employee Directors Equity Plan (2006 Directors Plan); (ii) the Biogen Inc. 2008 Amended and Restated Omnibus Equity Plan (2008 Omnibus Plan); and (iii) the Biogen Inc. 2015 Employee Stock Purchase Plan (ESPP).

Directors Plan

In May 2006 our stockholders approved the 2006 Directors Plan for share-based awards to our directors. Awards granted from the 2006 Directors Plan may include stock options, shares of restricted stock, restricted stock units, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the plan. We have reserved a total of 1.6 million shares of common stock for issuance under the 2006 Directors Plan. The 2006 Directors Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares reserved under the plan in a 1.5-to-1 ratio. In June 2015 our stockholders approved an amendment to extend the term of the 2006 Directors Plan until June 2025.

Omnibus Plans

In June 2008 our stockholders approved the 2008 Omnibus Plan for share-based awards to our employees. Awards granted from the 2008 Omnibus Plan may include stock options, shares of restricted stock, restricted stock units, performance shares, shares of phantom stock, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the plan. Shares of common stock available for issuance under the 2008 Omnibus Plan consist of 15.0 million shares reserved for this purpose, plus shares of common stock that remained available for issuance under our 2005 Omnibus Equity Plan on the date that our stockholders approved the 2008 Omnibus Plan, plus shares that were subject to awards under the 2005 Omnibus Equity Plan that remain unissued upon the cancellation, surrender, exchange or termination of such awards. The 2008 Omnibus Equity Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares available under the plan in a 1.5-to-1 ratio.

We have not made any awards pursuant to the 2005 Omnibus Equity Plan since our stockholders approved the 2008 Omnibus Plan, and do not intend to make any awards pursuant to the 2005 Omnibus Equity Plan in the future, except that unused shares under the 2005 Omnibus Equity Plan have been carried over for use under the 2008 Omnibus Plan.

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Stock Options

We currently do not grant stock options to our employees or directors. Outstanding stock options previously granted to our employees and directors generally have a ten-year term and vest over a period of between one and four years, provided the individual continues to serve at Biogen through the vesting dates. Options granted under all plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the options' vesting periods. The fair value of the stock options granted in 2010 was estimated as of the date of grant using a Black-Scholes option valuation model. There were no grants of stock options made in 2016, 2015 and 2014. As of December 31, 2016, all outstanding options were exercisable.

The expected life of options granted is derived using assumed exercise rates based on historical exercise patterns and represents the period of time that options granted are expected to be outstanding. Expected stock price volatility is based upon implied volatility for our exchange-traded options and other factors, including historical volatility. After assessing all available information on either historical volatility, implied volatility, or both, we have concluded that a combination of both historical and implied volatility provides the best estimate of expected volatility. The risk-free interest rate used is determined by the market yield curve based upon risk-free interest rates established by the Federal Reserve, or non-coupon bonds that have maturities equal to the expected term. The dividend yield of zero is based upon the fact that we have not historically granted cash dividends, and do not expect to issue dividends in the foreseeable future. Stock options granted prior to January 1, 2006 were valued based on the grant date fair value of those awards, using the Black-Scholes option pricing model, as previously calculated for pro-forma disclosures.

The following table summarizes our stock option activity:

| | Shares | Weighted Average Exercise Price |
|---|---|---|
| Outstanding at December 31, 2015 | 107,000 | $ 53.94 |
| Granted | — | $ — |
| Exercised | (41,000 ) | $ 53.75 |
| Cancelled | — | $ — |
| Outstanding at December 31, 2016 | 66,000 | $ 54.06 |

The total intrinsic values of options exercised in 2016, 2015 and 2014 totaled $10.4 million, $38.0 million and $42.7 million, respectively. The aggregate intrinsic values of options outstanding as of December 31, 2016 totaled $15.0 million. The weighted average remaining contractual term for options outstanding as of December 31, 2016 was 2.0 years.

The following table summarizes the amount of tax benefit realized for stock options and cash received from the exercise of stock options:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Tax benefit realized for stock options | $ 4.0 | $ 11.9 | $ 13.0 |
| Cash received from the exercise of stock options | $ 2.2 | $ 6.3 | $ 8.5 |

Market Stock Units (MSUs)

MSUs awarded to employees prior to 2014 vested in four equal annual increments beginning on the first anniversary of the grant date. Participants may ultimately earn between 0% and 150% of the target number of units granted based on actual stock performance.

MSUs awarded to employees in 2014, 2015 and 2016 vest in three equal annual increments beginning on the first anniversary of the grant date, and participants may ultimately earn between 0% and 200% of the target number of units granted based on actual stock performance.

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The vesting of these awards is subject to the respective employee's continued employment. The number of MSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain market-based criteria involving our stock price. The number of MSUs earned is calculated at each annual anniversary from the date of grant over the respective vesting periods, resulting in multiple performance periods. Accordingly, additional MSUs may be issued or currently outstanding MSUs may be cancelled upon final determination of the number of awards earned. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our MSU activity:

| | Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2015 | 269,000 | $ 339.89 |
| Granted (a) | 168,000 | $ 328.03 |
| Vested | (155,000) | $ 244.68 |
| Forfeited | (52,000 ) | $ 371.62 |
| Unvested at December 31, 2016 | 230,000 | $ 355.60 |

(a) MSUs granted in 2016 include approximately 15,000 and 20,000 MSUs issued in 2016 based upon the attainment of performance criteria set for 2013 and 2012, respectively, in relation to awards granted in those years. The remainder of MSUs granted during 2016 include awards granted in conjunction with our annual awards made in February 2016 and MSUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

We value grants of MSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, including the 60 calendar day average closing stock price on grant date for MSUs awarded prior to 2014, the 30 calendar day average closing stock price on the date of grant for MSUs awarded in 2014, 2015 and 2016, expected volatility of our stock price, risk-free rates of return and expected dividend yield.

The assumptions used in our valuation are summarized as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| Expected dividend yield | —% | —% | —% |
| Range of expected stock price volatility | 38.2% - 40.7% | 31.0% - 33.2% | 31.7% - 35.1% |
| Range of risk-free interest rates | 0.6% - 0.9% | 0.2% - 1.0% | 0.1% - 0.7% |
| 30 calendar day average stock price on grant date | $260.67 - $304.86 | $277.35 - $426.27 | $280.88 - $335.65 |
| Weighted-average per share grant date fair value | $328.03 | $493.43 | $395.22 |

The total fair values of MSUs vested in 2016, 2015 and 2014 totaled $39.3 million, $109.0 million and $117.4 million, respectively.

Cash Settled Performance Units (CSPUs)

CSPUs awarded to employees vest in three equal annual increments beginning on the first anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment with such awards settled in cash. The number of CSPUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional CSPUs may be issued or currently outstanding CSPUs may be cancelled upon final determination of the number of units earned. CSPUs awarded prior to 2014 are settled in cash based on the 60 calendar day average closing stock price through each vesting date once the actual vested and earned number of units is known. CSPUs awarded in 2014, 2015 and 2016 will be settled in cash based on the 30 calendar day average closing stock price through each vesting date, once the actual

vested and earned number of units is known. Since no shares are issued, these awards do not dilute equity. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

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The following table summarizes our CSPU activity:

| | Shares |
|---|---|
| Unvested at December 31, 2015 | 192,000 |
| Granted (a) | 86,000 |
| Vested | (117,000) |
| Forfeited | (39,000 ) |
| Unvested at December 31, 2016 | 122,000 |

(a) CSPUs granted in 2016 include awards granted in conjunction with our annual awards made in February 2016 and CSPUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

The total cash paid in settlement of CSPUs vested in 2016, 2015 and 2014 totaled $31.9 million, $79.8 million and $92.8 million, respectively.

Performance-vested Restricted Stock Units (PUs)

In 2014 we revised our long term incentive program to include a new type of award granted to certain employees in the form of restricted stock units that may be settled in cash or shares of our common stock at the sole discretion of the Compensation and Management Development Committee of our Board of Directors. These awards are structured and accounted for the same way as the cash settled performance units, and vest in three equal annual increments beginning on the first anniversary of the grant date. The number of PUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional PUs may be issued or currently outstanding PUs may be cancelled upon final determination of the number of units earned. PUs settling in cash are based on the 30 calendar day average closing stock price through each vesting date once the actual vested and earned number of units is known. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our PU activity:

| | Shares |
|---|---|
| Unvested at December 31, 2015 | 103,000 |
| Granted (a) | 55,000 |
| Vested | (31,000 ) |
| Forfeited | (17,000 ) |
| Unvested at December 31, 2016 | 110,000 |

(a) PUs granted in 2016 include awards granted in conjunction with our annual awards made in February 2016 and PUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

During 2015 32,000 PU were converted to share settlements, of which approximately 11,000 shares were vested and issued. All other PUs that vested in 2015 were settled in cash totaling $12.4 million.

All PUs that vested in 2016 were settled in cash totaling $8.1 million.

Time-Vested Restricted Stock Units (RSUs)

RSUs awarded to employees generally vest no sooner than one-third per year over three years on the anniversary of the date of grant, or upon the third anniversary of the date of the grant, provided the employee remains continuously employed with us, except as otherwise provided in the plan. Shares of our common stock will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. RSUs awarded to directors for service on our Board of Directors vest on the first anniversary of the date of grant, provided in each case that the director continues to serve on our Board of Directors through the vesting date. Shares of our common stock will be delivered to the director upon vesting and are not subject to any withholding taxes. The fair value of all RSUs is based on the market value of our stock on the date of grant. Compensation expense, including the effect of forfeitures, is

recognized over the applicable service period.

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The following table summarizes our RSU activity:

| | Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2015 | 810,000 | $ 323.87 |
| Granted (a) | 649,000 | $ 268.52 |
| Vested | (406,000) | $ 285.13 |
| Forfeited | (165,000) | $ 310.30 |
| Unvested at December 31, 2016 | 888,000 | $ 303.49 |

(a) RSUs granted in 2016 primarily represent RSUs granted in conjunction with our annual awards made in February 2016 and awards made in conjunction with the hiring of new employees. RSUs granted in 2016 also include approximately 11,000 RSUs granted to our Board of Directors.

RSUs granted in 2015 and 2014 had weighted average grant date fair values of $388.88 and $321.72, respectively. The total fair values of RSUs vested in 2016, 2015 and 2014 totaled $104.6 million, $239.7 million and $281.1 million, respectively.

Employee Stock Purchase Plan (ESPP)

In June 2015 our stockholders approved the Biogen Inc. 2015 ESPP (2015 ESPP). The 2015 ESPP, which became effective on July 1, 2015, replaced the Biogen Idec Inc. 1995 ESPP (1995 ESPP), which expired on June 30, 2015. The maximum aggregate number of shares of our common stock that may be purchased under the 2015 ESPP is 6.2 million.

The following table summarizes our ESPP activity:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions, except share amounts) | 2016 | 2015 | 2014 |
| Shares issued under the 2015 ESPP | 190,000 | 78,000 | ** |
| Shares issued under the 1995 ESPP | — | 98,000 | 180,000 |
| Cash received under the 2015 ESPP | $ 41.5 | $ 19.3 | ** |
| Cash received under the 1995 ESPP | $ — | $ 30.0 | $ 46.4 |

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16. Income Taxes

Income Tax Expense

Income before income tax provision and the income tax expense consist of the following:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Income before income taxes (benefit): | | | |
| Domestic | $3,655.4 | $3,386.7 | $2,557.4 |
| Foreign | 1,277.6 | 1,380.6 | 1,389.2 |
| Total | $4,933.0 | $4,767.3 | $3,946.6 |
| Income tax expense (benefit): | | | |
| Current: | | | |
| Federal | $1,304.3 | $1,214.1 | $1,159.5 |
| State | 55.1 | 38.6 | 65.2 |
| Foreign | 52.9 | 54.5 | 73.4 |
| Total | 1,412.3 | 1,307.2 | 1,298.1 |
| Deferred: | | | |
| Federal | $(125.6) | $(129.6) | $(280.9) |
| State | (3.8) | (1.9) | (21.0) |
| Foreign | (45.6) | (14.1) | (6.3) |
| Total | (175.0) | (145.6) | (308.2) |
| Total income tax expense | $1,237.3 | $1,161.6 | $989.9 |

Deferred Tax Assets and Liabilities

Significant components of our deferred tax assets and liabilities are summarized as follows:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Deferred tax assets: | | |
| Tax credits | $201.1 | $189.3 |
| Inventory, other reserves and accruals | 250.6 | 243.9 |
| Intangibles, net | 459.8 | 328.3 |
| Net operating loss | 65.9 | 24.7 |
| Share-based compensation | 61.5 | 63.8 |
| Other | 49.0 | 35.8 |
| Valuation allowance | (16.1) | (14.1) |
| Total deferred tax assets | $1,071.8 | $871.7 |
| Deferred tax liabilities: | | |
| Purchased intangible assets | $(376.6) | $(440.1) |
| Depreciation, amortization and other | (113.5) | (102.7) |
| Total deferred tax liabilities | $(490.1) | $(542.8) |

In addition to deferred tax assets and liabilities, we have recorded prepaid tax and deferred charges related to intercompany transactions. As of December 31, 2016 and 2015, the total deferred charges and prepaid taxes were $989.8 million and $697.9 million, respectively.

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Tax Rate

A reconciliation between the U.S. federal statutory tax rate and our effective tax rate is summarized as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2015 | 2014 |
| Statutory rate | 35.0 % | 35.0 % | 35.0 % |
| State taxes | 0.9 | 0.5 | 1.2 |
| Taxes on foreign earnings | (9.6) | (10.0) | (9.5) |
| Credits and net operating loss utilization | (1.4) | (1.3) | (1.1) |
| Purchased intangible assets | 1.2 | 1.0 | 1.2 |
| Manufacturing deduction | (1.9) | (1.8) | (1.8) |
| Other permanent items | 0.5 | 0.7 | 0.5 |
| Other | 0.4 | 0.3 | (0.4) |
| Effective tax rate | 25.1 % | 24.4 % | 25.1 % |

Our effective tax rate for 2016 compared to 2015 increased primarily due to a net state tax benefit in 2015 resulting from the remeasurement of one of our uncertain tax positions, described below, and a higher relative percentage of our earnings being attributed to the U.S., a higher tax jurisdiction.

Our effective tax rate for 2015 compared to 2014 benefited from lower taxes on foreign earnings and reflects a $27.0 million benefit from the 2015 remeasurement of one of our uncertain tax positions.

As of December 31, 2016, we had net operating losses and general business credit carry forwards for federal income tax purposes of approximately $22.5 million and $140.0 million, respectively, which begin to expire in 2020. Additionally, for state income tax purposes, we had net operating loss carry forwards of approximately $86.4 million, which begin to expire in 2017. For state income tax purposes, we also had research and investment credit carry forwards of approximately $126.6 million, which begin to expire in 2017. For foreign income tax purposes, we had $489.4 million of net operating loss carryforwards, which begin to expire in 2021.

In assessing the realizability of our deferred tax assets, we have considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial reporting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies. Our estimates of future taxable income take into consideration, among other items, our estimates of future income tax deductions related to the exercise of stock options. Based upon the level of historical taxable income and income tax liability and projections for future taxable income over the periods in which the deferred tax assets are utilizable, we believe it is more likely than not that we will realize the net benefits of the deferred tax assets of our wholly owned subsidiaries. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

As of December 31, 2016, undistributed foreign earnings of non-U.S. subsidiaries included in consolidated retained earnings and other basis differences aggregated approximately $7.6 billion. We intend to reinvest these earnings indefinitely in operations outside the U.S. The residual U.S. tax liability, if cumulative amounts were repatriated, would be between $1.8 billion to $2.3 billion as of December 31, 2016.

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Accounting for Uncertainty in Income Taxes

A reconciliation of the beginning and ending amount of our unrecognized tax benefits is summarized as follows:

| (In millions) | 2016 | 2015 | 2014 |
|---|---|---|---|
| Balance at January 1, | $67.9 | $131.5 | $110.1 |
| Additions based on tax positions related to the current period | 7.2 | 10.5 | 20.8 |
| Additions for tax positions of prior periods | 36.3 | 19.5 | 86.1 |
| Reductions for tax positions of prior periods | (13.3) | (49.9) | (23.4) |
| Statute expirations | (1.4) | (1.2) | (1.6) |
| Settlements | (64.3) | (42.5) | (60.5) |
| Balance at December 31, | $32.4 | $67.9 | $131.5 |

We and our subsidiaries are routinely examined by various taxing authorities. We file income tax returns in the U.S. federal jurisdiction, various U.S. states, and foreign jurisdictions. With few exceptions, including the proposed disallowance we discuss below, we are no longer subject to U.S. federal tax examination for years before 2013 or state, local, or non-U.S. income tax examinations for years before 2005.

Included in the balance of unrecognized tax benefits as of December 31, 2016, 2015 and 2014 are $26.9 million, $15.7 million and $53.6 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in future periods.

We recognize potential interest and penalties accrued related to unrecognized tax benefits in income tax expense. In 2016 we recognized a net interest expense of $9.1 million. In 2015 we recognized net interest expense of $3.1 million. In 2014 we recognized a net interest expense of approximately $4.1 million. We have accrued approximately $25.2 million and $12.5 million for the payment of interest as of December 31, 2016 and 2015, respectively.

In March 2015 we received a final assessment from the Danish Tax Authority (SKAT) for fiscal 2009 regarding withholding taxes and the treatment of certain intercompany transactions involving a Danish affiliate and another of our affiliates. In April 2016 we received final assessments from the SKAT for 2011 and 2013 regarding withholding taxes for similar intercompany transactions. The total amount assessed for 2009, 2011 and 2013 is estimated to be $58.3 million, including interest. For the assessments related to 2011 and 2013 we have made payments to SKAT totaling $12.2 million. We continue to dispute the assessments for all of these periods and believe that the positions taken in our historical filings are valid.

Federal Uncertain Tax Positions

During the year ended December 31, 2015, the net effect of adjustments to one of our uncertain tax positions was a net benefit of approximately $27.0 million, primarily related to the state impact of a federal uncertain tax item.

It is reasonably possible that we will adjust the value of our uncertain tax positions related to our revenues from anti-CD20 therapeutic programs and certain transfer pricing issues as we receive additional information from various taxing authorities, including reaching settlements with the authorities. In addition, the IRS and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

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17. Other Consolidated Financial Statement Detail

Supplemental Cash Flow Information

Supplemental disclosure of cash flow information for the years ended December 31, 2016, 2015 and 2014, is as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Cash paid during the year for: | | | |
| Interest | $ 281.2 | $ 39.1 | $ 41.2 |
| Income taxes | $ 1,642.2 | $ 1,674.8 | $ 1,163.2 |

Non-cash Operating, Investing and Financing Activity

In December 2016 we accrued $454.8 million related to the recent settlement and license agreement with Forward Pharma A/S (Forward Pharma). For additional information related to this transaction, please read Note 21, Commitment and Contingencies to these consolidated financial statements.

In the fourth quarter of 2016 we accrued $300.0 million upon reaching $11.0 billion in total cumulative sales of Fumapharm Products. The amount, net of tax benefit, was accounted for as an increase to goodwill in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm and is expected to be paid in the first quarter of 2017. For additional information related to this transaction, please read Note 21, Commitments and Contingencies to these consolidated financial statements.

In connection with the construction of our manufacturing facility in Solothurn, Switzerland, we accrued charges related to processing equipment and engineering services of approximately $100.0 million in our consolidated balance sheet. For additional information related to this transaction, please read Note 10, Property, Plant and Equipment to these consolidated financial statements.

In February 2015 upon completion of our acquisition of Convergence, we recorded a contingent consideration obligation of $274.5 million as part of the purchase price. For additional information related to this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

Other Income (Expense), Net

Components of other income (expense), net, are summarized as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Interest income | $ 63.4 | $ 22.1 | $ 12.2 |
| Interest expense | (260.0) | (95.5) | (29.5) |
| Gain (loss) on investments, net | 6.0 | (3.8) | 11.8 |
| Foreign exchange gains (losses), net | (9.8) | (32.7) | (11.6) |
| Other, net | (17.0) | (13.8) | (8.7) |
| Total other income (expense), net | $ (217.4) | $ (123.7) | $ (25.8) |

Other Current Assets

Other current assets include prepaid taxes totaling approximately $817.0 million and $550.6 million as of December 31, 2016 and 2015, respectively.

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Accrued Expenses and Other
Accrued expenses and other consists of the following:

| | As of December 31, | |
|---|---|---|
| (In millions) | 2016 | 2015 |
| Current portion of contingent consideration obligations | $580.8 | $504.7 |
| Accrued TECFIDERA litigation settlement and license charges | 454.8 | — |
| Revenue-related reserves for discounts and allowances | 438.6 | 518.1 |
| Employee compensation and benefits | 282.9 | 270.8 |
| Royalties and licensing fees | 195.8 | 167.9 |
| Construction in progress | 134.0 | 87.9 |
| Collaboration expenses | 130.9 | 31.2 |
| Other | 685.7 | 516.2 |
| Total accrued expenses and other | $2,903.5 | $2,096.8 |

Pricing of TYSABRI in Italy - AIFA
In the fourth quarter of 2011 Biogen Italia SRL, our Italian subsidiary, received a notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 through mid-February 2011 exceeded by EUR30.7 million a reimbursement limit established pursuant to a Price Determination Resolution granted by AIFA in December 2006. In January 2012 we filed an appeal against AIFA in administrative court in Rome, Italy seeking a ruling that the reimbursement limit in the Price Determination Resolution should apply as written to only “the first 24 months” of TYSABRI sales, which ended in mid-February 2009. That appeal is still pending. Since being notified in the fourth quarter of 2011 that AIFA believed a reimbursement limit was still in effect, we deferred revenue on sales of TYSABRI as if the reimbursement limit were in effect for each biannual period beginning in mid-February 2009.
In July 2013 we negotiated an agreement in principle with AIFA's Price and Reimbursement Committee that would have resolved all of AIFA's claims relating to sales of TYSABRI in excess of the reimbursement limit for the periods from February 2009 through January 2013 for an aggregate repayment of EUR33.3 million. As a result of this agreement in principle, we recorded a liability and reduction to revenue of EUR15.4 million at June 30, 2013, which approximated 50% of the claim related to the period from mid-February 2009 through mid-February 2011. As of December 31, 2016, we have approximately EUR79 million recorded as accrued expenses and other in our consolidated balance sheets for the periods mid-February 2009 through January 2013, respectively.
In June 2014 AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. As a result, we recognized $53.5 million of TYSABRI revenues related to the periods February 2013 through June 2014 that were previously deferred.
In January 2017 we negotiated an agreement in principle with AIFA's Price and Reimbursement Committee to settle all of AIFA's existing claims relating to sales of TYSABRI in excess of the reimbursement limit for the periods from February 2009 through January 2013 for an aggregate repayment of EUR37.4 million. The agreement is subject to ratification by AIFA. If this most recent settlement agreement is accepted, we will recognize approximately EUR42 million in revenue upon final resolution of this matter.

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18. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

Our consolidated financial statements include the financial results of variable interest entities in which we are the primary beneficiary. The following are our significant variable interest entities.

Neurimmune SubOne AG

In 2007 we entered into a collaboration agreement with Neurimmune SubOne AG (Neurimmune), a subsidiary of Neurimmune AG, for the development and commercialization of antibodies for the treatment of Alzheimer's disease. Neurimmune conducts research to identify potential therapeutic antibodies and we are responsible for the development, manufacturing and commercialization of all products. Our anti-amyloid beta antibody, aducanumab, for the treatment of Alzheimer's disease resulted from this collaboration. In September 2015 we announced that the first patient had been enrolled in a Phase 3 trial for aducanumab, which triggered a $60.0 million milestone payment due to Neurimmune. As we consolidate the financial results of Neurimmune, we recognized this payment as a charge to noncontrolling interest in the third quarter of 2015. Based upon our current development plans for aducanumab, we may pay Neurimmune up to $275.0 million in remaining milestone payments. We may also pay royalties in the low-to-mid-teens on sales of any resulting commercial products.

We determined that we are the primary beneficiary of Neurimmune because we have the power through the collaboration to direct the activities that most significantly impact the entity's economic performance and are required to fund 100% of the research and development costs incurred in support of the collaboration agreement. Accordingly, we consolidate the results of Neurimmune.

We are required to reimburse Neurimmune for amounts that are incurred by Neurimmune for research and development expenses in support of the collaboration. Amounts reimbursed are reflected in research and development expense in our consolidated statements of income. During the years ending December 31, 2016, 2015 and 2014, these amounts were immaterial. Future milestone payments and royalties, if any, will be reflected in our consolidated statements of income as a charge to noncontrolling interest, net of tax, when such milestones are achieved.

The assets and liabilities of Neurimmune are not significant to our financial position or results of operations as it is a research and development organization. We have provided no financing to Neurimmune other than previously contractually required amounts.

Rodin Therapeutics, Inc.

In December 2015 we paid $8.0 million for preferred stock in Rodin Therapeutics, Inc. (Rodin) and entered into an option and collaboration agreement which gave us the right to purchase all remaining outstanding shares of Rodin at any time until 35 days after acceptance of an Investigational New Drug (IND) application by the FDA. As we determined that we were the primary beneficiary of Rodin, we consolidated the results of Rodin and recorded an IPR&D intangible asset of approximately $8.7 million and assigned approximately $10.9 million to noncontrolling interest.

During the fourth quarter of 2016 we terminated our collaboration agreement with Rodin. Upon termination of the collaboration agreement, we deconsolidated the results of Rodin and impaired the IPR&D asset, resulting in an impairment loss of $8.7 million related to the IPR&D asset recorded upon entering into the collaboration agreement.

The assets and liabilities of Rodin were not significant to our financial position or results of operations as Rodin is a research and development organization. We had provided no financing to Rodin other than the contractually required amounts disclosed above.

Ataxion Inc.

In February 2014 we paid $1.6 million for preferred stock in Ataxion, Inc. (Ataxion) and entered into an option and collaboration agreement which gave us the right to purchase all outstanding shares of Ataxion at any time until 30 days after delivery of a Phase 1 clinical trial study report. As we determined that we were the primary beneficiary of Ataxion, we consolidated the results of Ataxion and recorded an IPR&D intangible asset of $3.5 million and assigned that amount to noncontrolling interest.

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During the fourth quarter of 2016 we terminated our option agreement with Ataxion. Upon termination of the collaboration agreement, we deconsolidated the results of Ataxion and impaired the IPR&D asset, resulting in an impairment loss of $3.5 million related to the IPR&D asset recorded upon entering into the collaboration agreement. The assets and liabilities of Ataxion were not significant to our financial position or results of operations as Ataxion is a research and development organization. We had provided no financing to Ataxion other than the contractually required amounts disclosed above.

Unconsolidated Variable Interest Entities

We have relationships with other variable interest entities that we do not consolidate as we lack the power to direct the activities that significantly impact the economic success of these entities. These relationships include investments in certain biotechnology companies and research collaboration agreements.

As of December 31, 2016 and 2015, the total carrying value of our investments in biotechnology companies totaled $47.4 million and $29.2 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

We have also entered into research collaboration agreements with certain variable interest entities where we are required to fund certain development activities. These development activities are included in research and development expense in our consolidated statements of income, as they are incurred. We have provided no financing to these variable interest entities other than previously contractually required amounts.

19. Collaborative and Other Relationships

In connection with our business strategy, we have entered into various collaboration agreements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. Terms of the various collaboration agreements may require us to make milestone payments upon the achievement of certain product research and development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

Depending on the collaborative arrangement, we may record funding receivable or payable balances with our partners, based on the nature of the cost-sharing mechanism and activity within the collaboration. Our significant collaboration arrangements are discussed below.

Genentech (Roche Group)

We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma, and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S.

Our collaboration agreement will continue in effect until we mutually agree to terminate the collaboration, except that if we undergo a change in control, as defined in the collaboration agreement, Genentech has the right to present an offer to buy the rights to RITUXAN and we must either accept Genentech’s offer or purchase Genentech’s rights on the same terms as its offer. Genentech will also be deemed concurrently to have purchased our rights to any other anti-CD20 products in development in exchange for a royalty and our rights to GAZYVA in exchange for the compensation described in the table below. Our collaboration with Genentech was created through a contractual arrangement and not through a joint venture or other legal entity.

RITUXAN

Genentech is responsible for the worldwide manufacturing of RITUXAN. Development and commercialization rights and responsibilities under this collaboration are divided as follows:

U.S.

We share with Genentech co-exclusive rights to develop, commercialize and market RITUXAN in the U.S.

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Canada

We and Genentech have assigned our rights under our collaboration agreement with respect to Canada to the Roche Group.

GAZYVA

We recognize our share of the development and commercialization expenses of GAZYVA as a reduction of our share of pre-tax profits in revenues from anti-CD20 therapeutic programs.

Commercialization of GAZYVA impacts our percentage of the co-promotion profits for RITUXAN, as summarized in the table below.

OCREVUS (Ocrelizumab)

Genentech is solely responsible for development and commercialization of OCREVUS, a humanized anti-CD20 monoclonal antibody currently in development for MS, and funding future costs. Genentech cannot develop OCREVUS in CLL, NHL or Rheumatoid Arthritis (RA). We will receive tiered royalties between 13.5% and 24% on U.S. net sales of OCREVUS if approved for commercial sale by the FDA. The FDA has accepted for review the Biologics License Application for OCREVUS for the treatment of relapsing multiple sclerosis (RMS) and primary-progressive multiple sclerosis (PPMS), and has granted the application Priority Review Designation. There will be a 50% reduction to these royalties if a biosimilar to OCREVUS is approved in the U.S. In addition, we will receive a 3% royalty on net sales of OCREVUS outside the U.S., with the royalty period lasting 11 years from the first commercial sale of OCREVUS on a country-by-country basis. In June 2016 the European Medicines Agency (EMA) validated its marketing authorization application (MAA) of OCREVUS for the treatment of RMS and PPMS in the E.U.

Commercialization of OCREVUS will not impact the percentage of the co-promotion profits we receive for RITUXAN or GAZYVA.

Profit-sharing Formulas

RITUXAN Profit Share

Our current pretax co-promotion profit-sharing formula for RITUXAN provides for a 30% share on the first $50.0 million of co-promotion operating profits earned each calendar year. Our share of annual co-promotion profits in excess of $50.0 million varies, as summarized in the table below, upon the following events:

| | |
|---|---|
| Until GAZYVA First Non-CLL FDA Approval | 40.0% |
| After GAZYVA First Non-CLL FDA Approval until First GAZYVA Threshold Date | 39.0% |
| After First GAZYVA Threshold Date until Second GAZYVA Threshold Date | 37.5% |
| After Second GAZYVA Threshold Date | 35.0% |

First Non-CLL GAZYVA FDA Approval means the FDA’s first approval of GAZYVA in an indication other than CLL.

First GAZYVA Threshold Date means the earlier of (1) the date of the First Non-CLL GAZYVA FDA approval if U.S. gross sales of GAZYVA for the preceding consecutive 12 month period were at least $150.0 million or (2) the first day of the calendar quarter after the date of the First Non-CLL GAZYVA FDA Approval that U.S. gross sales of GAZYVA within any consecutive 12 month period have reached $150.0 million.

Second GAZYVA Threshold Date means the first day of the calendar quarter after U.S. gross sales of GAZYVA within any consecutive 12 month period have reached $500.0 million. The Second GAZYVA Threshold Date can be achieved regardless of whether GAZYVA has been approved in a non-CLL indication.

Our share of RITUXAN pre-tax profits in the U.S. decreased to 39% from 40% as GAZYVA was approved by the FDA in follicular lymphoma in February 2016.

In addition, should the FDA approve an anti-CD20 product other than OCREVUS or GAZYVA that is acquired or developed by Genentech and subject to the collaboration agreement, our share of the co-promotion operating profits would be between 30% and 38% based on certain events.

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GAZYVA Profit Share

Our current pretax profit-sharing formula for GAZYVA provides for a 35% share on the first $50.0 million of operating profits earned each calendar year. Our share of annual profits in excess of $50.0 million varies, as summarized in the table below, upon the following events:

| | |
|---|---|
| Until First GAZYVA Threshold Date | 39.0% |
| After First GAZYVA Threshold Date until Second GAZYVA Threshold Date | 37.5% |
| After Second GAZYVA Threshold Date | 35.0% |

In 2016, 2015 and 2014, our share of operating losses on GAZYVA was 35%.

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs are summarized as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA, including the reimbursement of selling and development expenses | $ 1,249.5 | $ 1,269.8 | $ 1,117.1 |
| Revenue on sales in the rest of world for RITUXAN | 65.0 | 69.4 | 78.3 |
| Total revenues from anti-CD20 therapeutic programs | $ 1,314.5 | $ 1,339.2 | $ 1,195.4 |

In 2016 the 39% profit-sharing threshold was met during the first quarter. In 2015 and 2014, the 40% profit-sharing threshold was met during the first quarter.

Prior to regulatory approval, we record our share of the expenses incurred by the collaboration for the development of anti-CD20 products in research and development expense in our consolidated statements of income. After an anti-CD20 product is approved, we record our share of the development expenses related to that product as a reduction of our share of pre-tax profits in revenues from anti-CD20 therapeutic programs.

Acorda

In 2009 we entered into a collaboration and license agreement with Acorda Therapeutics, Inc. (Acorda) to develop and commercialize products containing fampridine in markets outside the U.S, including FAMPYRA. We also have responsibility for regulatory activities and the future clinical development of related products in those markets. Under the terms of the collaboration and license agreement, we pay Acorda tiered royalties based on the level of ex-U.S. net sales. We may pay up to $375.0 million of additional milestone payments to Acorda based on the successful achievement of certain regulatory and commercial milestones. The next expected milestone would be $15.0 million, due if ex-U.S. net sales reach $100.0 million over a period of four consecutive quarters. We will capitalize these additional milestones as intangible assets upon achievement of the milestone which will then be amortized utilizing an economic consumption model and recognized as amortization of acquired intangible assets. Royalty payments are recognized as a cost of goods sold.

In connection with the collaboration and license agreement, we have also entered into a supply agreement with Acorda for the commercial supply of FAMPYRA. This agreement is a sublicense arrangement of an existing agreement between Acorda and Alkermes, who acquired Elan Drug Technologies, the original party to the license with Acorda. During the years ending December 31, 2016, 2015 and 2014, total cost of sales related to royalties and commercial supply of FAMPRYA reflected in our consolidated statements of income were $31.5 million, $30.6 million and $29.2 million, respectively.

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AbbVie

We have a collaboration agreement with AbbVie aimed at advancing the development and commercialization of ZINBRYTA in MS, which was approved for the treatment of relapsing forms of MS in the U.S. in May 2016 and the E.U. in July 2016. We made milestone payments totaling $32.0 million related to these approvals, which were capitalized as intangible assets, net in our consolidated balance sheets.

Under the agreement, we and AbbVie conduct ZINBRYTA co-promotion activities in the U.S., E.U. and Canadian territories (Collaboration Territory), where development and commercialization costs and profits are shared equally. Outside of the Collaboration Territory, we are solely responsible for development and commercialization of ZINBRYTA and will pay a tiered royalty to AbbVie as a percentage of net sales in the low to high teens.

We are responsible for manufacturing and research and development activities in both the Collaboration Territory and outside the Collaboration Territory and will record these activities within their respective lines in our consolidated statements of income, net of any reimbursement of research and development expenditures received from AbbVie. For the years ended December 31, 2016, 2015 and 2014, the collaboration incurred $48.6 million, $113.8 million and $117.8 million for research and development activities, for which we recognized $24.3 million, $60.8 million and $67.4 million, respectively, in our consolidated statements of income. During 2015 we made milestone payments of $16.0 million for the development of ZINBRYTA as a result of filing for regulatory approval in the U.S. and E.U. during the year. These payments were recorded as research and development expense in our consolidated statements of income.

Prior to regulatory approval, we also recognized $22.0 million of pre-commercialization expenses within our selling, general and administrative expense, which represents 50% of the collaboration's pre-commercialization costs for 2016. After ZINBRYTA was approved by the FDA and EMA in 2016, we began to recognize our share of the collaboration activities within the U.S., E.U. and Canadian territories as described below.

Co-promotion Profits and Losses

In the U.S., AbbVie recognizes revenues on sales to third parties and we recognize our 50% share of the co-promotion profits or losses as a component of total revenues in our consolidated statements of income. The collaboration began selling ZINBRYTA in the U.S. in the third quarter of 2016. For the year ended December 31, 2016, we recognized a net reduction in revenue of $21.9 million to reflect our share of an overall net loss within the collaboration.

The following table provides a summary of the U.S. collaboration and our share of the co-promotion losses on ZINBRYTA in the U.S.:

| (In millions) | For the Year Ended December 31, 2016 |
|---|---|
| Product revenues, net | $ 6.1 |
| Costs and expenses | 50.0 |
| Co-promotion losses in the U.S. | $ 43.9 |
| Biogen's share of co-promotion losses in the U.S. | $ 21.9 |

In the E.U. and Canada, we recognize revenues on sales to third parties in product revenues, net in our consolidated statements of income. We also record the related cost of revenues and sales and marketing expenses to their respective line items in our consolidated statements of income as these costs are incurred. We reimburse AbbVie for their 50% share of the co-promotion profits or losses in the E.U. and Canada. This reimbursement is recognized in collaboration profit (loss) sharing in our consolidated statements of income. We began to recognize product revenues on sales of ZINBRYTA in the E.U. in the third quarter of 2016. For the year ended December 31, 2016, we recognized income of $4.9 million to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada.

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Swedish Orphan Biovitrum AB (publ)

In January 2007 we acquired 100% of the stock of Syntonix. Syntonix, now known as Bioverativ Therapeutics Inc. (formerly Biogen Hemophilia Inc.), had previously entered into a collaboration agreement with Swedish Orphan Biovitrum AB (publ) (Sobi) to jointly develop and commercialize Factor VIII and Factor IX hemophilia products, including ELOCTATE and ALPROLIX. Under an amended and restated collaboration agreement, we have commercial rights for North America (the Biogen North America Territory) and for rest of the world markets outside of the Sobi Territory, as defined below (the Biogen Direct Territory). Subject to the exercise of an option right that Sobi controls, Sobi has commercial rights in substantially all of Europe, Russia and certain countries in Northern Africa and the Middle East (the Sobi Territory). The collaboration agreement was amended and restated in April 2014. (References to the collaboration agreement refer to the amended and restated collaboration agreement).

In November 2014 Sobi exercised its option to assume final development and commercialization activities in the Sobi Territory for ELOCTA (the trade name for ELOCTATE in the E.U.). In July 2015 Sobi exercised its option to assume final development and commercialization of ALPROLIX in the Sobi Territory. Upon each exercise of opt-in right under the terms of the collaboration agreement, Sobi made a $10.0 million payment in escrow.

ELOCTA was approved by the EC in November 2015 and Sobi had its first commercial sale of ELOCTA in January 2016. In March 2016 the EC approved the transfer of the marketing authorization for ELOCTA in the E.U. from Biogen to Sobi, making Sobi the marketing authorization holder of ELOCTA in the E.U. As the marketing authorization holder, Sobi assumes full legal responsibility for ELOCTA, from a regulatory perspective, during its entire life cycle in the E.U. As of December 31, 2016, approximately $144.0 million in expenditures for ELOCTA, net of the $10.0 million escrow payment and other royalty adjustments as described in the table and its footnote (3) below, are reimbursable by Sobi under the collaboration agreement due to its election to assume final development and commercialization of ELOCTA within the Sobi Territory, which is the Opt-In Consideration for ELOCTA. This reimbursement will be recognized by us as royalty revenue in proportion to collaboration revenues, over a ten-year period, consistent with the initial patent term of the product.

ALPROLIX was approved in the E.U. by the EC in May 2016 and Sobi had its first commercial sale in June 2016. In September 2016 the EC approved the transfer of the marketing authorization for ALPROLIX in the E.U. from Biogen to Sobi, making Sobi the marketing authorization holder of ALPROLIX in the E.U. As the marketing authorization holder, Sobi assumes full legal responsibility for ALPROLIX, from a regulatory perspective, during its entire life cycle in the E.U. As of December 31, 2016, approximately $123.0 million in expenditures for ALPROLIX, net of the $10.0 million escrow payment and other royalty adjustments as described in the table and its footnote (3) below, are reimbursable to us by Sobi under the collaboration agreement due to Sobi's election to assume final development and commercialization of ALPROLIX in the Sobi Territory, which is the Opt-In Consideration for ALPROLIX. This reimbursement will be recognized by us as royalty revenue in proportion to collaboration revenues, over a ten-year period, consistent with the initial patent term of the product.

The Opt-In Consideration for each product will be paid by Sobi using a cross-royalty cash payment structure for sales in each company’s respective territories as an adjustment to the Base Rate in the table below. Under the collaboration agreement, cash payments are as follows:

| | | Rates post Sobi Opt-In[3] | |
|---|---|---|---|
| Royalty and Net Revenue Share Rates: | Method | Base Rate following 1st commercial sale in the Sobi Territory: | Rate during the Reimbursement Period: |
| Sobi rate to Biogen on net sales in the Sobi Territory | Royalty | 12% | Base Rate plus 5% |
| Biogen rate to Sobi on net sales in the Biogen North America Territory | Royalty | 12% | Base Rate less 5% |
| Biogen rate to Sobi on net sales in the Biogen Direct Territory | Royalty | 17% | Base Rate less 5% |

| | | |
|---|---|---|
| Biogen rate to Sobi on net revenue[1] from the Biogen Distributor Territory[2] | Net Revenue Share | 50% Base Rate less 15% |

(1) Net revenue represents Biogen's pre-tax receipts from third-party distributors, less expenses incurred by Biogen in the conduct of commercialization activities supporting the distributor activities.

(2) The Biogen Distributor Territory represents Biogen territories where sales are derived utilizing a third-party distributor.

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(3) A credit will be issued to Sobi against its reimbursement of the Opt-in Consideration for each product in an amount equal to the difference in the rate paid by Biogen to Sobi on sales in the Biogen territories for certain periods prior to the first commercial sale in the Sobi Territory versus the rate that otherwise would have been payable on such sales.

We are recording revenue at the effective royalty rate expected over the term of the agreement of approximately 14% and recording cost of sales at the effective royalty rate expected over the term of the agreement of approximately 11%. If the reimbursement of the Opt-in Consideration has not been achieved within six years of the first commercial sale of such product, we maintain the right to require Sobi to pay any remaining balances due to us within 90 days of the six-year anniversary date of the first commercial sale.

Following the spin-off of our hemophilia business, this collaboration agreement with Sobi will continue with Bioverativ, an independent public company. For additional information about the spin-off, please see Note 1, Summary of Significant Accounting Policies and Note 26, Subsequent Events to these consolidated financial statements.

Ionis Pharmaceuticals, Inc.

Long-Term Strategic Research Collaboration

In September 2013 we entered into a six-year research collaboration with Ionis, formerly known as Isis Pharmaceuticals Inc. under which both companies collaborate to perform discovery level research and then develop and commercialize antisense or other therapeutics for the treatment of neurological disorders. Under the collaboration, Ionis will perform research on a set of neurological targets identified within the agreement. Once the research has reached a specific stage of development, we will make the determination whether antisense is the preferred approach to develop a therapeutic candidate or whether another modality is preferred. If antisense is selected, Ionis will continue development and identify a product candidate. If another modality is used, we will assume the responsibility for identifying a product candidate and developing it.

Under the terms of this agreement, we paid Ionis an upfront amount of $100.0 million. Of this payment, we recorded prepaid research and discovery services of approximately $25.0 million, representing the value of the Ionis full time equivalent employee resources which are required by the collaboration to provide research and discovery services to us over the term. The remaining $75.0 million of the upfront payment was recorded as research and development expense as it represented the purchase of intellectual property that had not reached technological feasibility.

Ionis is also eligible to receive milestone payments, license fees and royalty payments for all product candidates developed through this collaboration, with the specific amount dependent upon the modality of the product candidate advanced by us. During the years ending December 31, 2016, 2015 and 2014, we triggered milestones of $5.5 million, $20.0 million and $20.0 million, respectively, related to the advancement of IONIS-SOD1$_{Rx}$ for the treatment of ALS and other neurological targets identified.

For non-ALS antisense product candidates, Ionis will be responsible for global development through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. For ALS antisense product candidates, we are responsible for global development, clinical trial design and regulatory strategy. We have an option to license a product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a $70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive additional milestone payments upon the achievement of certain regulatory milestones of up to $130.0 million, plus additional amounts related to the cost of clinical trials conducted by Ionis under the collaboration, and royalties on future sales if we successfully develop the product candidate after option exercise.

For product candidates using a different modality, we will be responsible for global development through all stages and will pay Ionis up to $90.0 million upon the achievement of certain regulatory milestones and royalties on future sales if we successfully develop the product candidate.

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Product Collaborations

In 2012 we entered into three separate exclusive worldwide option and collaboration agreements with Ionis under which both companies will develop and commercialize SPINRAZA (nusinersen) for the treatment of SMA, antisense therapeutics for up to three gene targets and IONIS-DMPK$_{RX}$ for the treatment of myotonic dystrophy type 1 (DM1), respectively.

SPINRAZA (nusinersen)

In January 2012 we entered into an exclusive worldwide option and collaboration agreement with Ionis under which both companies will develop and commercialize the antisense investigational drug candidate, SPINRAZA, for the treatment of SMA. Under the terms of this agreement, we paid Ionis $29.0 million as an upfront payment. During 2014 we amended the agreement to adjust the amount of potential additional payments and terms of the exercise of our opt-in right to license SPINRAZA, which included providing for additional opt-in scenarios, based on the filing or acceptance of a new drug application (NDA) or marketing authorization application with the FDA or EMA. Consistent with the initial agreement, Ionis remained responsible for conducting the pivotal/Phase 3 trials and we provided input on the clinical trial design and regulatory strategy for the development of SPINRAZA.

During 2016, 2015 and 2014, we triggered clinical trial payments of $35.3 million, $42.8 million and $57.3 million, respectively, related to the advancement of the program.

In August 2016 we and Ionis announced that SPINRAZA met the primary endpoint for the interim analysis of the Phase 3 trial evaluating SPINRAZA in infantile-onset SMA. In November 2016 we and Ionis announced that SPINRAZA met the primary endpoint for the interim analysis of the Phase 3 trial evaluating SPINRAZA in later-onset SMA. During the third quarter of 2016 we exercised our option to develop and commercialize SPINRAZA and paid Ionis a $75.0 million license fee in connection with the option exercise. This amount was recognized as research and development expense in our consolidated statements of income. In December 2016 SPINRAZA was approved by the FDA for the treatment of SMA in pediatric and adult patients in the U.S. During the fourth quarter of 2016 we accrued a $60.0 million milestone payment due to Ionis for the approval of SPINRAZA in the U.S. This amount was capitalized in intangible assets, net in our consolidated balance sheets.

During the years ending December 31, 2016, 2015 and 2014, $257.8 million, $74.9 million and $27.7 million, respectively, were reflected in research and development expense in our consolidated statements of income related to the advancement of the program.

We may pay Ionis up to approximately $90.0 million in additional milestone payments upon the achievement of certain regulatory milestones as well as a royalty rate in the mid-teens on future sales of SPINRAZA.

Antisense Therapeutics

Under the terms of the December 2012 agreement relating to the development and commercialization of up to three gene targets we provided Ionis with an upfront payment of $30.0 million and agreed to make potential additional payments, prior to licensing, of up to $10.0 million based on the development of the selected product candidate as well as a mark-up of the cost estimate of the Phase 1 and Phase 2 trials. During 2015 we triggered a $10.0 million milestone payment. Ionis will be responsible for global development of any product candidate through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. We have an option to license the product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a $70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive up to another $130.0 million in milestone payments upon the achievement of certain regulatory milestones as well as royalties on future sales if we successfully develop the product candidate after option exercise.

IONIS-DMPK$_{Rx}$

Under the terms of the June 2012 agreement for the DM1 candidate, we provided Ionis with an upfront payment of $12.0 million and agreed to make potential additional payments, prior to licensing, of up to $59.0 million based on the development of the selected product candidate. During 2015 we amended the agreement to adjust the amount of potential additional payments by an additional $4.2 million due to changes in the clinical trial design.

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During 2016 we terminated the development of the IONIS-DMPK$_{Rx}$ product candidate to treat DM1 and returned the product to Ionis. During the years ending December 31, 2016, 2015 and 2014, $3.1 million, $9.0 million and $10.9 million, respectively, were reflected in research and development expense in our consolidated statements of income.

Eisai Co., Ltd.

BAN2401 and E2609 Collaboration

In March 2014 we entered into a collaboration agreement with Eisai Co., Ltd. (Eisai) (Eisai Collaboration Agreement) to jointly develop and commercialize two Eisai product candidates for the treatment of Alzheimer's disease, BAN2401, a monoclonal antibody that targets amyloid-beta aggregates, and E2609, a BACE inhibitor. Under the Eisai Collaboration Agreement, Eisai serves as the global operational and regulatory lead for both compounds and all costs, including research, development, sales and marketing expenses, will be shared equally by us and Eisai. Following marketing approval in major markets, such as the U.S., the E.U. and Japan, we will co-promote BAN2401 and E2609 with Eisai and share profits equally. In smaller markets, Eisai will distribute these products and pay us a royalty. The Eisai Collaboration Agreement also provides the parties with certain rights and obligations in the event of a change in control of either party.

The Eisai Collaboration Agreement also provides Eisai an option to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for Alzheimer's disease (Aducanumab Option) and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). Upon exercise of each of the Aducanumab Option and the Anti-Tau Option, we will execute a separate collaboration agreement with Eisai on terms and conditions that mirror the Eisai Collaboration Agreement.

Aducanumab Option

Eisai may exercise the Aducanumab Option after either (i) the Phase 1b clinical trial for aducanumab and the Phase 2 clinical trial for BAN2401 (Post-Phase 2 Aducanumab Option), or (ii) completion of the Phase 3 clinical trial for aducanumab (Post-Phase 3 Aducanumab Option) under certain conditions.

The consideration we will receive if Eisai exercises the Post-Phase 2 Aducanumab Option depends on the development status of BAN2401. If BAN2401 is then determined to advance to Phase 3, we will be entitled to receive a single payment from Eisai upon regulatory approval of aducanumab and we will no longer be required to pay Eisai any milestone payments for products containing BAN2401 under the Eisai Collaboration Agreement. If the development of BAN2401 has instead been terminated, we will receive development and commercial milestone payments from Eisai (Post-Phase 2 Aducanumab Milestone Payments). If Eisai does not exercise its Post-Phase 2 Aducanumab Option, we may elect to terminate the Eisai Collaboration Agreement with respect to BAN2401 but, under certain conditions, will have the option to reinstate the Eisai Collaboration Agreement after completion of a BAN2401 Phase 3 clinical trial.

If Eisai exercises its Post-Phase 3 Aducanumab Option, Eisai will be required to pay us all Phase 3 development and commercialization costs plus a mark-up and an amount equal to any unpaid Post-Phase 2 Aducanumab Milestone Payments that would have been payable if Eisai had exercised its Post-Phase 2 Aducanumab Option.

Anti-Tau Option

Eisai may exercise the Anti-Tau Option after completion of the Phase 1 clinical trial of such anti-tau monoclonal antibody. If Eisai exercises its Anti-Tau Option, we will receive an upfront payment from Eisai and will be entitled to additional development and commercial milestone payments.

Upon the effective date of the Eisai Collaboration Agreement, we paid Eisai $100.0 million and recorded $17.7 million, reflecting the fair value of the options granted under the Eisai Collaboration Agreement, both of which were classified as research and development expense in our consolidated statements of income. During the second quarter of 2014 Eisai exercised its option under the Eisai Collaboration Agreement to expand the joint development and commercialization activities to include Japan. Upon such exercise, we paid Eisai an additional $35.0 million, and recorded $21.6 million as research and development expense in our consolidated statements of income, which represented the difference between the payment made upon exercise of the option and the fair value of that option recorded as research and development expense upon closing of the agreement in the first quarter of 2014. During the

fourth quarter of 2016 we recognized a $50.0 million milestone payment related to the initiation of a phase 3

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trial for E2609, which is included in research and development expense in our consolidated statements of income. We could pay Eisai up to an additional $1.0 billion under the Eisai Collaboration Agreement based on the future achievement of certain development, regulatory and commercial milestones.

In addition to our arrangements with Eisai, Neurimmune is entitled to milestone and royalty payments related to the development and commercialization of aducanumab and certain anti-tau antibodies. For additional information regarding our agreement with Neurimmune, please see Note 18, Investments in Variable Interest Entities to these consolidated financial statements.

A summary of activity related to our collaboration with Eisai is as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| (In millions) | 2016 | 2015 | 2014 |
| Total development expense incurred by the collaboration | $95.1 | $84.1 | $57.5 |
| Biogen's share of development expense, excluding upfront and milestone payments, reflected in our consolidated statements of income | $50.5 | $40.4 | $29.1 |

Applied Genetic Technologies Corporation

In July 2015 we announced a collaboration and license agreement to develop gene-based therapies for multiple ophthalmic diseases with Applied Genetic Technologies Corporation (AGTC). The collaboration will focus on the development of a portfolio of AGTC's therapeutic programs, including both a clinical-stage candidate for X-linked Retinoschisis (XLRS) and a pre-clinical candidate for the treatment of X-Linked Retinitis Pigmentosa (XLRP). The agreement also includes options for early stage discovery programs in two ophthalmic diseases and one non-ophthalmic condition, as well as an equity investment in AGTC.

During the third quarter of 2015 we made an upfront payment of $124.0 million, which included a $30.0 million equity investment in AGTC, prepaid research and development expenditures of $58.4 million and total licensing and other fees of $35.6 million. The $58.4 million of prepaid research and development expenditures were recorded in investments and other assets in our consolidated balance sheets and will be expensed as the services are provided. During 2015 we recorded $54.5 million as research and development expense associated with AGTC in our consolidated statements of income, including the $35.6 million total licensing and other fees, $6.5 million in research and development services, a $7.5 million premium on our equity investment and a $5.0 million clinical development milestone related to XLRS. During 2016 we recorded $26.5 million in research and development services in research and development expense in our consolidated statements of income.

AGTC is eligible to receive development, regulatory and commercial milestone payments aggregating in excess of $1.1 billion, which includes up to $472.5 million collectively for the two lead programs and up to $592.5 million across the discovery programs. AGTC is also eligible to receive royalties in the mid-single digit to mid-teen percentages of annual net sales.

We were granted worldwide commercialization rights for the XLRS and XLRP programs. AGTC has an option to share development costs and profits after the initial clinical trial data are available, and an option to co-promote the second of these products to be approved in the U.S. AGTC will lead the clinical development programs of XLRS through product approval and of XLRP through the completion of first-in-human trials. We will support the clinical development costs, subject to certain conditions, following the first-in-human study for XLRS and IND-enabling studies for XLRP. Under the manufacturing license, we have received an exclusive license to use AGTC's proprietary technology platform to make AAV vectors for up to six genes, three of which are in AGTC's discretion, in exchange for payment of milestones and royalties.

University of Pennsylvania

In May 2016 we entered into a collaboration and alliance with the University of Pennsylvania (UPenn) to advance gene therapy and gene editing technologies. The collaboration will primarily focus on the development of therapeutic approaches that target the eye, skeletal muscle and the central nervous system. The alliance is also expected to focus

on the research and validation of next-generation gene transfer technology using adeno-associated virus gene delivery vectors and exploring the expanded use of genome editing technology as a potential therapeutic platform.

During the second quarter of 2016 we paid Penn an upfront fee of $20.0 million, which was recorded as research and development expense in our consolidated statements of income, and prepaid research and development expenditures of $15.0 million, which was recorded in investments and other assets in our consolidated balance sheets. We also expect to fund an additional $47.5 million in the aggregate in research and development costs extending over the next three to five years in seven preclinical research and development programs, as well as the exploration of genome-editing technology.

If all of the collaborations programs are successful and we exercise all of our options under the Penn collaboration and alliance, we may be required to make future payments of over $2.0 billion in research funding, options and milestone payments, in addition to royalties payable on net sales of products.

Sangamo BioSciences, Inc.

In February 2014 we completed an exclusive worldwide research, development and commercialization collaboration and license agreement with Sangamo under which both companies will develop and commercialize product candidates for the treatment of two inherited blood disorders, sickle cell disease and beta-thalassemia. The collaboration is currently in the research stage of development.

Under the terms of the agreement, we paid Sangamo an upfront payment of $20.0 million in cash, with additional payments of up to approximately $300.0 million based on the achievement of certain development, regulatory and commercial milestones, plus royalties based on sales. We recorded the $20.0 million upfront payment as research and development expense in our consolidated statements of income. Under this arrangement, Sangamo will be responsible for identifying a product candidate for the treatment of beta-thalassemia and advancing that candidate through a completed Phase 1 human clinical trial, at which point we would assume responsibility for development. We will jointly develop a sickle cell disease candidate through the potential filing of an investigative new drug application, after which we would assume clinical responsibilities. We will lead the global development and commercialization efforts and Sangamo will have the option to assume co-promotion responsibilities in the U.S.

During the years ending December 31, 2016, 2015 and 2014, $13.4 million, $13.6 million and $28.9 million, respectively, of expense was reflected in our consolidated statements of income.

Following the spin-off of our hemophilia business, this collaboration and license agreement with Sangamo will continue with Bioverativ, an independent public company. For additional information about the spin-off, please see Note 1, Summary of Significant Accounting Policies and Note 26, Subsequent Events to these consolidated financial statements.

Mitsubishi Tanabe Pharma Corporation

In September 2015 we announced an agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) to exclusively license amiselimod (MT-1303), a late stage experimental medicine with potential in multiple autoimmune indications. Amiselimod is an oral compound that targets the sphingosine 1-phosphate receptor. During the fourth quarter of 2015 the agreement became effective and we made an upfront payment of $60.0 million, which was recorded as research and development expense in our consolidated statements of income.

During the third quarter of 2016 we discontinued our development of amiselimod. We expect to formally terminate the agreement and return the program to MTPC in the first quarter of 2017. We will have no further license to or continuing involvement in the development of this compound. For the year ended December 31, 2016, $22.8 million was reflected in research and development expense in our consolidated statements of income.

Other Research and Discovery Arrangements

During the years ended December 31, 2016, 2015 and 2014, we entered into several research, discovery and other related arrangements that resulted in $10.3 million, $9.7 million and $40.0 million, respectively, recorded as research and development expense in our consolidated statements of income.

These additional arrangements include the potential for future milestone payments based on clinical and commercial development over a period of several years.

Samsung Bioepis

Joint Venture Agreement

In February 2012 we entered into a joint venture agreement with Samsung BioLogics Co. Ltd. (Samsung Biologics), establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. Samsung Biologics contributed 280.5 billion South Korean won (approximately $250.0 million) for an 85% stake in Samsung Bioepis and we contributed approximately 49.5 billion South Korean won (approximately $45.0 million) for the remaining 15% ownership interest. Under the joint venture agreement, we have no obligation to provide any additional funding and our ownership interest may be diluted due to financings in which we do not participate. As of December 31, 2016, our ownership interest is approximately 6.5%, which reflects the effect of additional equity financings in which we did not participate. We maintain an option to purchase additional stock in Samsung Bioepis that would allow us to increase our ownership percentage up to 49.9%. The exercise of this option is within our control and is based on paying for 49.9% of the total investment made by Samsung Biologics into Samsung Bioepis in excess of what we have already contributed under the agreement plus a rate that will represent their return on capital. If we do not exercise this option by a date in 2018 determined pursuant to the joint venture agreement, this option will expire and Samsung Biologics will have the right to purchase all of Samsung Bioepis' shares then held by us. Samsung Biologics has the power to direct the activities of Samsung Bioepis which will most significantly and directly impact its economic performance. We account for this investment under the equity method of accounting as we maintain the ability to exercise significant influence over Samsung Bioepis through a presence on the entity's Board of Directors and our contractual relationship. Under the equity method, we recorded our original investment at cost and subsequently adjust the carrying value of our investment for our share of equity in the entity's income or losses according to our percentage of ownership. We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears when the results of the entity become available, which is reflected as equity in loss of investee, net of tax in our consolidated statements of income. During the years ended December 31, 2015 and 2014, we recognized a loss on our investment of $12.5 million and $15.1 million, respectively. During 2015, as our share of losses exceeded the carrying value of our investment, we suspended recognizing additional losses and will continue to do so unless we commit to providing additional funding.

Commercial Agreement

In December 2013 pursuant to our rights under the joint venture agreement with Samsung Biologics, we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, three anti-tumor necrosis factor (TNF) biosimilar product candidates in Europe and in the case of one anti-TNF biosimilar, Japan. Under the terms of this agreement, we have made total upfront and clinical development milestone payments of $46.0 million, all of which have been recorded as research and development expense in our consolidated statements of income as the programs they relate to had not achieved regulatory approval. We also agreed to make additional milestone payments of $25.0 million upon regulatory approval in the E.U. for each of the three anti-TNF biosimilar product candidates. During the year ended December 31, 2016, we paid $50.0 million in milestone payments, which have been capitalized in intangible assets, net in our consolidated balance sheets as BENEPALI received regulatory approval in the E.U. in January 2016 and FLIXABI received regulatory approval in the E.U. in May 2016. In July 2016 the EMA accepted Samsung Bioepis' MAA for SB5, an adalimumab biosimilar candidate referencing HUMIRA.

We began to recognize revenue on sales of BENEPALI in the E.U. in the first quarter of 2016 and FLIXABI in the E.U. in the third quarter of 2016. We reflect revenues on sales of BENEPALI and FLIXABI to third parties in product revenues, net in our consolidated statements of income and record the related cost of revenues and sales and marketing expenses in our consolidated statements of income to their respective line items when these costs are incurred. We share 50% of the profit or loss related to our commercial agreement with Samsung Bioepis. This profit sharing with Samsung Bioepis is recognized in collaboration profit (loss) sharing in our consolidated statements of income. For the year ended December 31, 2016, we recognized a net expense of $15.1 million related to the collaboration profit share.

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Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a license agreement, a technical development services agreement and a manufacturing agreement with Samsung Bioepis. Under the terms of the license agreement, we granted Samsung Bioepis an exclusive license to use, develop, manufacture and commercialize biosimilar products created by Samsung Bioepis using Biogen product-specific technology. In exchange, we will receive single digit royalties on all biosimilar products developed and commercialized by Samsung Bioepis. Under the terms of the technical development services agreement, we provide Samsung Bioepis technical development and technology transfer services, which include, but are not limited to, cell culture development, purification process development, formulation development and analytical development. Under the terms of our manufacturing agreement, we manufacture clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis pursuant to contractual terms. Under limited circumstances, we may also supply Samsung Bioepis with quantities of drug product of biosimilar products for use in clinical trials through arrangements with third-party contract manufacturers.

For the years ended December 31, 2016, 2015 and 2014, we recognized $20.2 million, $62.9 million and $58.5 million, respectively, in revenues in relation to these services, which is reflected as a component of other revenues in our consolidated statements of income.

20. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read Note 1, Summary of Significant Accounting Policies to these consolidated financial statements.

With respect to some loss contingencies, an estimate of the possible loss or range of loss cannot be made until management has further information, including, for example, (i) which claims, if any, will survive dispositive motion practice; (ii) information to be obtained through discovery; (iii) information as to the parties' damages claims and supporting evidence; (iv) the parties’ legal theories; and (v) the parties' settlement positions.

The claims and legal proceedings in which we are involved also include challenges to the scope, validity or enforceability of the patents relating to our products, pipeline or processes, and challenges to the scope, validity or enforceability of the patents held by others. These include claims by third parties that we infringe their patents. An adverse outcome in any of these proceedings could result in one or more of the following and have a material impact on our business or consolidated results of operations and financial position: (i) loss of patent protection; (ii) inability to continue to engage in certain activities; and (iii) payment of significant damages, royalties, penalties and/or license fees to third parties.

Loss Contingencies

Forward Pharma German Patent Litigation

On November 18, 2014, Forward Pharma A/S (Forward Pharma) filed suit against us in the Regional Court of Düsseldorf, Germany (the German Infringement Litigation) alleging that TECFIDERA infringes German Utility Model DE 20 2005 022 112 U1 (the utility model), which was issued in April 2014 and expired in October 2015. Forward Pharma subsequently extended its allegations to assert that TECFIDERA infringes Forward Pharma's European Patent No. 2,801,355 (the '355 patent), which was issued in May 2015 and expires in October 2025. We have entered a settlement and license agreement with Forward Pharma that will provide us an irrevocable license to all intellectual property owned by Forward Pharma and result in the termination of the German Infringement Litigation. For more information on the settlement and license agreement please read Note 21, Commitments and Contingencies to these consolidated financial statements.

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Italian National Medicines Agency

In the fourth quarter of 2011 Biogen Italia SRL received notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. On January 12, 2012, we filed an appeal in the Regional Administrative Tribunal of Lazio (Il Tribunale Amministrativo Regionale per il Lazio) in Rome, Italy seeking a ruling that the reimbursement limit in the Price Resolution should apply as written to only “the first 24 months” of TYSABRI sales, which ended in mid-February 2009. The appeal is still pending. In June 2014 AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. In January 2017 we negotiated an agreement in principle with AIFA's Price and Reimbursement Committee to settle all of AIFA's existing claims relating to sales of TYSABRI in excess of the reimbursement limit for the periods from February 2009 through January 2013 for an aggregate repayment of EUR37.4 million. The agreement is subject to ratification by AIFA.

For additional information regarding this matter, please read Note 17, Other Consolidated Financial Statement Detail to these consolidated financial statements.

Qui Tam Litigation

On July 6, 2015, a qui tam action filed on behalf of the United States and certain states were unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts, and seeks single and treble damages, civil penalties, interest, attorneys’ fees and costs. Our motion to dismiss is pending. The United States has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

Securities Litigation

We and certain current and former officers are defendants in In re Biogen Inc. Securities Litigation, filed by a shareholder on August 18, 2015 in the U.S. District Court for the District of Massachusetts. The amended complaint alleges violations of federal securities laws under 15 U.S.C. §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5. The lead plaintiff sought a declaration of the action as a class action, certification as a representative of the class and its counsel as class counsel, and an award of damages, interest and attorneys' fees. On July 1, 2016, the U.S. District Court dismissed the case and in September 2016 denied the plaintiff's motion to vacate the order of dismissal. The plaintiff has appealed. An estimate of the possible loss or range of loss cannot be made at this time.

We and certain current and former officers are also defendants in an action filed by another shareholder on October 20, 2016 in the U.S. District Court for the District of Massachusetts, related to the matter described above. The complaint alleges violations of federal securities laws under 15 U.S.C. §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeks a declaration of the action as a class action and an award of damages, interest and attorney's fees. An estimate of the possible loss or range of loss cannot be made at this time.

Other Matters

Interference Proceeding with Forward Pharma

In April 2015 the U.S. Patent and Trademark Office (USPTO) declared an interference between Forward Pharma’s pending U.S. Patent Application No. 11/576,871 and our U.S. Patent No. 8,399,514 (the '514 patent). The '514 patent includes claims covering the treatment of multiple sclerosis with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. We are awaiting a decision in this matter.

Inter Partes Review Proceeding

On March 22, 2016, the USPTO instituted inter partes review of the '514 patent on the petition of the Coalition for Affordable Drugs V LLC, an entity associated with a hedge fund. We are awaiting a decision in this matter.

On April 18, 2016, Swiss Pharma International AG filed petitions in the USPTO for inter partes review of U.S. Patent Nos. 8,349,321 and 8,900,577, relating to specific formulations of natalizumab (TYSABRI), and U.S. Patent No. 8,815,236, relating to methods for treating MS and Crohn's disease using specific formulations of natalizumab (TYSABRI). In October 2016 the USPTO declined to institute proceedings under all three petitions. Swiss Pharma filed requests for rehearing, which are pending.

European Patent Office Oppositions

In June 2016 the European Patent Office issued a written decision confirming its earlier revocation of our European patent number 2 137 537 (the '537 patent), which we have appealed. The '537 patent includes claims covering the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label.

Patent Revocation Matter

In December 2015 Swiss Pharma International AG brought an action in the Patents Court of the United Kingdom to revoke the UK counterpart of our European Patent Number 1 485 127 (“Administration of agents to treat inflammation”) (the '127 patent), which was issued in June 2011 and concerns administration of natalizumab (TYSABRI) to treat MS. The patent expires in February 2023. Subsequently, the same entity brought an actions in the District Court of The Hague (on January 11, 2016) and the German Patents Court (on March 3, 2016) to invalidate the Dutch and German counterparts of the '127 patent. In September 2016 we resolved the UK action by agreeing to revocation of the UK patent. A hearing has been scheduled in the Dutch action for early 2017 and the German action for early 2018.

'755 Patent Litigation

On May 28, 2010, Biogen MA Inc. (formerly Biogen Idec MA Inc.) filed a complaint in the U.S. District Court for the District of New Jersey alleging infringement by Bayer Healthcare Pharmaceuticals Inc. (Bayer) (manufacturer, marketer and seller of BETASERON and manufacturer of EXTAVIA), EMD Serono, Inc. (EMD Serono) (manufacturer, marketer and seller of REBIF), Pfizer Inc. (co-marketer of REBIF) and Novartis Pharmaceuticals Corp. (Novartis) (marketer and seller of EXTAVIA) of our U.S. Patent No. 7,588,755 ('755 Patent), which claims the use of interferon beta for immunomodulation or treating a viral condition, viral disease, cancers or tumors. The complaint seeks monetary damages, including lost profits and royalties. Bayer had previously filed a complaint against us in the same court, on May 27, 2010, seeking a declaratory judgment that it does not infringe the '755 Patent and that the patent is invalid, and seeking monetary relief in the form of attorneys' fees, costs and expenses. The court has consolidated the two lawsuits, and we refer to the two actions as the “Consolidated '755 Patent Actions.”

Bayer, Pfizer, Novartis and EMD Serono have all filed counterclaims in the Consolidated '755 Patent Actions seeking declaratory judgments of patent invalidity and non-infringement, and seeking monetary relief in the form of costs and attorneys' fees, and EMD Serono and Bayer have each filed a counterclaim seeking a declaratory judgment that the '755 Patent is unenforceable based on alleged inequitable conduct. Bayer has also amended its complaint to seek such a declaration. Trial has been set for September 2017.

Government Matters

We have learned that state and federal governmental authorities are investigating our sales and promotional practices and have received related subpoenas. We are cooperating with the government.

On March 4, 2016, we received a subpoena from the federal government for documents relating to our relationship with non-profit organizations that provide assistance to patients taking drugs sold by Biogen. We are cooperating with the government.

On July 1, 2016, we received a civil investigative demand from the federal government for documents and information relating to our treatment of certain service agreements with wholesalers when calculating and reporting Average Manufacturer Prices in connection with the Medicaid Drug Rebate Program. We are cooperating with the government.

On December 5, 2016, we received a subpoena from the federal government for documents relating to government price reporting, rebate payments and Biogen's co-pay assistance programs for AVONEX, TECFIDERA, TYSABRI and PLEGRIDY. We are cooperating with the government.

On December 29, 2016, we received a civil investigative demand from the federal government for documents and information relating to our relationships with entities providing clinical education and reimbursement support services. We are cooperating with the government.

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Product Liability and Other Legal Proceedings

We are also involved in product liability claims and other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

21. Commitments and Contingencies

TECFIDERA Litigation Settlement and License Agreement

In January 2017 we agreed to enter into a settlement and license agreement with Forward Pharma that will provide us an irrevocable license to all intellectual property owned by Forward Pharma and results in the termination of the German Infringement Litigation. Under the terms of the settlement and license agreement with Forward Pharma, we have agreed to pay Forward Pharma $1.25 billion in cash. Under certain circumstances outlined in the agreement, we will pay Forward Pharma royalties on net sales of our products for the treatment of multiple sclerosis that are covered by a Forward Pharma patent and have dimethyl fumarate (“DMF”) as an active pharmaceutical ingredient.

During the fourth quarter of 2016 we recognized a pre-tax charge of $454.8 million related to this matter. This amount represents the fair value of estimated royalties on our sales of TECFIDERA during the period April 2014 through December 31, 2016. When the cash payment is made following approval of the settlement and license agreement, we will recognize assets of $656.3 million and $138.9 million, reflecting the estimated fair value of the license acquired that is attributable to the U.S. and E.U., respectively. If Forward Pharma does not receive a patent in either the Interference Proceeding pending in the U.S. or the pending European Opposition Proceeding (which proceedings are defined in the settlement and license agreement), we would likely recognize an immediate impairment charge equal to the value of the license that is attributable to that jurisdiction as additional litigation expense and we would not be obligated to pay Forward Pharma royalties in such jurisdiction. If Forward Pharma receives a patent in either the U.S. Interference Proceeding or the E.U. Opposition Proceeding, we would amortize the assets related to a license of intellectual property in the related jurisdiction utilizing an economic consumption model and we may be obligated to royalties on a country by country basis in Europe and other ex-U.S. markets.

For additional information with respect to the terms of this agreement, including potential royalties payable, please read the Settlement and License Agreement dated January 17, 2017, between Biogen Swiss Manufacturing GmbH, Biogen International Holding Ltd, Forward Pharma A/S and the other parties thereto which is filed as Exhibit 10.41 to this 2016 Form 10-K. For additional information related to the ongoing Interference Proceeding with Forward Pharma in the U.S. or the European Office Opposition in the E.U., please read Note 20, Litigation to these consolidated financial statements.

TYSABRI Contingent Payments

In 2013 we acquired from Elan full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the terms of the acquisition agreement, we are obligated to make contingent payments to Elan of 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013. Following that acquisition, we began making these royalty payments to Perrigo.

Contingent Consideration related to Business Combinations

In connection with our acquisitions of Convergence, Stromedix and Biogen International Neuroscience GmbH (BIN), we agreed to make additional payments based upon the achievement of certain milestone events.

As the acquisitions of Convergence, Stromedix and BIN, formerly Panima Pharmaceuticals AG, occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately $1.2 billion in remaining milestones related to these acquisitions. For additional information related to our acquisition of Convergence please read Note 2, Acquisitions, to these consolidated financial statements.

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Fumapharm AG

In 2006 we acquired Fumapharm AG. As part of this acquisition we acquired FUMADERM and TECFIDERA (together, Fumapharm Products). We paid $220.0 million upon closing of the transaction and agreed to pay an additional $15.0 million if a Fumapharm Product was approved for MS in the U.S. or E.U. In the second quarter of 2013 we paid this $15.0 million contingent payment as TECFIDERA was approved in the U.S. for MS by the FDA. We are also required to make additional contingent payments to former shareholders of Fumapharm AG or holders of their rights based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior twelve month period, as defined in the acquisition agreement.

During 2016 we paid $1.2 billion in contingent payments as we reached the $7.0 billion, $8.0 billion, $9.0 billion and $10.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2015 and the first, second and third quarters of 2016, respectively, and accrued $300.0 million upon reaching $11.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2016.

We will owe an additional $300.0 million contingent payment for every additional $1.0 billion in cumulative sales level of Fumapharm Products reached if the prior 12 months sales of the Fumapharm Products exceed $3.0 billion, until such time as the cumulative sales level reaches $20.0 billion, at which time no further contingent payments shall be due. If the prior 12 months sales of Fumapharm Products are less than $3.0 billion, contingent payments remain payable on a decreasing tiered basis. These payments will be accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm. Any portion of the payment which is tax deductible will be recorded as a reduction to goodwill. Payments are due within 60 days following the end of the quarter in which the applicable cumulative sales level has been reached.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2016, we could make potential future milestone payments to third parties of up to approximately $3.1 billion, including approximately $0.5 billion in development milestones, approximately $0.8 billion in regulatory milestones and approximately $1.8 billion in commercial milestones as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2016, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones.

Other Funding Commitments

As of December 31, 2016, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $21.0 million on our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2016. We have approximately $500.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2016.

Tax Related Obligations

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2016, we have approximately $47.8 million of net liabilities associated with uncertain tax positions.

Solothurn, Switzerland Facility

On December 1, 2015, we purchased land in Solothurn, Switzerland where we are building a biologics manufacturing facility over the next several years. As of December 31, 2016, we had contractual commitments of $176.3 million for the construction of this facility.

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Leases

We rent laboratory and office space and certain equipment under non-cancelable operating leases. These lease agreements contain various clauses for renewal at our option and, in certain cases, escalation clauses typically linked to rates of inflation. Rental expense under these leases, net of amounts recognized in relation to exiting our manufacturing facility in Cambridge, Massachusetts and our Weston, Massachusetts facility, which terminate at various dates through 2028, amounted to $68.7 million, $68.6 million and $62.4 million in 2016, 2015 and 2014, respectively. In addition to rent, the leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

As of December 31, 2016, minimum rental commitments under non-cancelable leases, net of income from subleases, for each of the next five years and total thereafter were as follows:

| (In millions) | 2017 | 2018 | 2019 | 2020 | 2021 | Thereafter | Total |
|---|---|---|---|---|---|---|---|
| Minimum lease payments | $75.3 | $69.8 | $69.1 | $65.7 | $64.6 | $ 331.9 | $676.4 |
| Less: income from subleases (1) | (8.9) | (15.2) | (15.5) | (15.7) | (16.2) | (55.4) | (126.9) |
| Net minimum lease payments | $66.4 | $54.6 | $53.6 | $50.0 | $48.4 | $ 276.5 | $549.5 |

(1) Represents sublease income expected to be received for the vacated manufacturing facility in Cambridge, MA, the vacated portion of our Weston, Massachusetts facility and other facilities throughout the world. For additional information related to the sublease of the vacated manufacturing facility in Cambridge, MA, please read Note 3, Restructuring, Business Transformation and Other Cost Savings Initiatives to these consolidated financial statements.

Under certain of our lease agreements, we are contractually obligated to return leased space to its original condition upon termination of the lease agreement. At the inception of a lease with such conditions, we record an asset retirement obligation liability and a corresponding capital asset in an amount equal to the estimated fair value of the obligation. In subsequent periods, for each such lease, we record interest expense to accrete the asset retirement obligation liability to full value and depreciate each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. Our asset retirement obligations were not significant as of December 31, 2016 or 2015.

Eisai Financing Arrangement

During 2015 we amended our existing lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. For additional information, please read Note 10, Property, Plant and Equipment to these consolidated financial statements. As of December 31, 2016, the net present values of the future minimum lease payments were as follows:

| (In millions) | As of December 31, 2016 |
|---|---|
| 2017 | $ 2.0 |
| 2018 | 16.7 |
| Total | 18.7 |
| Less: interest | (0.6) |
| Net present value of the future minimum lease payments | $ 18.1 |

22. Guarantees

As of December 31, 2016 and 2015, we did not have significant liabilities recorded for guarantees.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or

settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2016 and 2015.

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23. Employee Benefit Plans

We sponsor various retirement and pension plans. Our estimates of liabilities and expenses for these plans incorporate a number of assumptions, including expected rates of return on plan assets and interest rates used to discount future benefits.

401(k) Savings Plan

We maintain a 401(k) Savings Plan, which is available to substantially all regular employees in the U.S. over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. The 401(k) Savings Plan also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The expense related to our 401(k) Savings Plan primarily consists of our matching contributions.

Expense related to our 401(k) Savings Plan totaled $45.2 million, $51.8 million and $49.3 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Deferred Compensation Plan

We maintain a non-qualified deferred compensation plan, known as the Supplemental Savings Plan (SSP), which allows a select group of management employees in the U.S. to defer a portion of their compensation. The SSP also provides certain credits to highly compensated U.S. employees, which are paid by the company. These credits are known as the Restoration Match. The deferred compensation amounts are accrued when earned. Such deferred compensation is distributable in cash in accordance with the rules of the SSP. Deferred compensation amounts under such plan as of December 31, 2016 and 2015, totaled approximately $128.5 million and $126.9 million, respectively, and are included in other long-term liabilities in our consolidated balance sheets. The SSP also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The Restoration Match and participant contributions vest immediately. Distributions to participants can be either in one lump sum payment or annual installments as elected by the participants.

Pension Plans

Our retiree benefit plans include defined benefit plans for employees in our affiliates in Switzerland and Germany as well as other insignificant defined benefit plans in certain other countries in which we maintain an operating presence. Our Swiss plan is a government-mandated retirement fund that provides employees with a minimum investment return. The minimum investment return is determined annually by the Swiss government and was 1.25% in 2016 and 1.75% in 2015 and 2014, respectively. Under the Swiss plan, both we and certain of our employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. Minimum employee contributions are based on the respective employee's age, salary and gender. As of December 31, 2016 and 2015, the Swiss plan had an unfunded net pension obligation of approximately $39.1 million and $42.4 million, respectively, and plan assets which totaled approximately $68.6 million and $63.9 million, respectively. In 2016, 2015 and 2014, we recognized expense totaling $15.3 million, $12.9 million and $9.8 million, respectively, related to our Swiss plan.

The obligations under the German plans are unfunded and totaled $35.4 million and $27.6 million as of December 31, 2016 and 2015, respectively. Net periodic pension cost related to the German plans totaled $4.2 million, $4.0 million and $3.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

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24. Segment Information

We operate as one operating segment, which is discovering, developing, manufacturing and delivering therapies to people living with serious neurological, rare and autoimmune diseases. Our Chief Executive Officer (CEO), as the chief operating decision-maker, manages and allocates resources to the operations of our company on a total company basis. Our research and development organization is responsible for the research and discovery of new product candidates and supports development and registration efforts for potential future products. Our pharmaceutical, operations and technology organization manages the development of the manufacturing processes, clinical trial supply, commercial product supply, distribution, buildings and facilities. Our commercial organization is responsible for U.S. and international development of our commercial products. The company is also supported by corporate staff functions. Managing and allocating resources on a total company basis enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas, and research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

Enterprise-wide disclosures about product revenues, other revenues and long-lived assets by geographic area and information relating to major customers are presented below. Revenues are primarily attributed to individual countries based on location of the customer or licensee.

Revenue by product is summarized as follows:

| | For the Years Ended December 31, | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2016 | | | 2015 | | | 2014 | | |
| (In millions) | United States | Rest of World | Total | United States | Rest of World | Total | United States | Rest of World | Total |
| Multiple Sclerosis (MS): | | | | | | | | | |
| TECFIDERA | $3,169.4 | $798.7 | $3,968.1 | $2,908.2 | $730.2 | $3,638.4 | $2,426.6 | $482.6 | $2,909.2 |
| AVONEX | 1,675.3 | 638.2 | 2,313.5 | 1,790.2 | 840.0 | 2,630.2 | 1,956.7 | 1,056.4 | 3,013.1 |
| PLEGRIDY | 305.0 | 176.7 | 481.7 | 227.1 | 111.4 | 338.5 | 27.8 | 16.7 | 44.5 |
| TYSABRI | 1,182.9 | 780.9 | 1,963.8 | 1,103.1 | 783.0 | 1,886.1 | 1,025.1 | 934.4 | 1,959.5 |
| FAMPYRA | — | 84.9 | 84.9 | — | 89.7 | 89.7 | — | 80.2 | 80.2 |
| ZINBRYTA | — | 7.8 | 7.8 | — | — | — | — | — | — |
| Hemophilia: | | | | | | | | | |
| ELOCTATE | 445.2 | 68.0 | 513.2 | 308.3 | 11.4 | 319.7 | 58.4 | — | 58.4 |
| ALPROLIX | 268.0 | 65.7 | 333.7 | 208.9 | 25.6 | 234.5 | 72.1 | 3.9 | 76.0 |
| Other product revenues: | | | | | | | | | |
| FUMADERM | — | 45.9 | 45.9 | — | 51.4 | 51.4 | — | 62.5 | 62.5 |
| SPINRAZA | 4.6 | — | 4.6 | — | — | — | — | — | — |
| BENEPALI | — | 100.6 | 100.6 | — | — | — | — | — | — |
| FLIXABI | — | 0.1 | 0.1 | — | — | — | — | — | — |
| Total product revenues | $7,050.4 | $2,767.5 | $9,817.9 | $6,545.8 | $2,642.7 | $9,188.5 | $5,566.7 | $2,636.7 | $8,203.4 |

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Geographic Information

The following tables contain certain financial information by geographic area:

| December 31, 2016 (In millions) | U.S. | Europe[1] | Germany | Asia | Other | Total |
|---|---|---|---|---|---|---|
| Product revenues from external customers | $7,050.4 | $1,533.5 | $ 703.7 | $217.3 | $313.0 | $9,817.9 |
| Revenues from anti-CD20 therapeutic programs | $1,249.5 | $1.9 | $ — | $— | $63.1 | $1,314.5 |
| Other revenues from external customers | $224.7 | $70.0 | $ 1.5 | $20.2 | $— | $316.4 |
| Long-lived assets | $1,272.3 | $1,219.3 | $ 1.8 | $7.0 | $1.4 | $2,501.8 |

| December 31, 2015 (In millions) | U.S. | Europe[1] | Germany | Asia | Other | Total |
|---|---|---|---|---|---|---|
| Product revenues from external customers | $6,545.8 | $1,497.6 | $ 668.1 | $143.7 | $333.3 | $9,188.5 |
| Revenues from anti-CD20 therapeutic programs | $1,269.8 | $3.5 | $ — | $— | $65.9 | $1,339.2 |
| Other revenues from external customers | $142.0 | $29.6 | $ 1.6 | $62.9 | $— | $236.1 |
| Long-lived assets | $1,296.5 | $879.4 | $ 2.3 | $7.7 | $1.7 | $2,187.6 |

| December 31, 2014 (In millions) | U.S. | Europe[1] | Germany | Asia | Other | Total |
|---|---|---|---|---|---|---|
| Product revenues from external customers | $5,566.7 | $1,383.9 | $ 811.8 | $112.8 | $328.2 | $8,203.4 |
| Revenues from anti-CD20 therapeutic programs | $1,117.1 | $7.7 | $ — | $— | $70.6 | $1,195.4 |
| Other revenues from external customers | $212.6 | $31.6 | $ 1.8 | $58.5 | $— | $304.5 |
| Long-lived assets | $1,055.5 | $701.9 | $ 2.5 | $2.6 | $3.2 | $1,765.7 |

(1) Represents amounts related to Europe less those attributable to Germany.

Revenues from Anti-CD20 Therapeutic Programs

Approximately 11%, 12% and 12% of our total revenues in 2016, 2015 and 2014, respectively, are derived from our collaboration agreement with Genentech. For additional information related to our collaboration with Genentech, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

Significant Customers

We recorded revenue from two wholesalers accounting for 35% and 22% of gross product revenues in 2016, 34% and 26% of gross product revenues in 2015, and 33% and 27% of gross product revenues in 2014, respectively.

Other

As of December 31, 2016, 2015 and 2014, approximately $643.6 million, $684.9 million and $676.0 million, respectively, of our long-lived assets were related to our manufacturing facilities in Denmark.

As of December 31, 2016 and 2015, approximately $545.5 million and $161.5 million, respectively, of our long-lived assets were related to the construction of a biologics manufacturing facility in Solothurn, Switzerland.

For additional information related to our manufacturing facility in Solothurn, Switzerland, please read Note 10, Property, plant and equipment to these consolidated financial statements.

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25. Quarterly Financial Data (Unaudited)

| (In millions, except per share amounts) 2016 | First Quarter (a) | Second Quarter (b) | Third Quarter (b) (c) | Fourth Quarter (b) (d) (e) | Total Year |
|---|---|---|---|---|---|
| Product revenues, net | $2,309.4 | $2,466.0 | $2,539.6 | $2,502.9 | $9,817.9 |
| Revenues from anti-CD20 therapeutic programs | $329.5 | $349.2 | $317.6 | $318.2 | $1,314.5 |
| Other revenues | $87.9 | $79.0 | $98.6 | $50.9 | $316.4 |
| Total revenues | $2,726.8 | $2,894.2 | $2,955.8 | $2,872.0 | $11,448.8 |
| Gross profit (1) | $2,413.8 | $2,523.9 | $2,538.9 | $2,493.5 | $9,970.1 |
| Net income | $969.2 | $1,048.4 | $1,030.2 | $647.9 | $3,695.7 |
| Net income attributable to Biogen Inc. | $970.9 | $1,049.8 | $1,032.9 | $649.2 | $3,702.8 |
| Net income per share: | | | | | |
| Basic earnings per share attributable to Biogen Inc. | $4.44 | $4.79 | $4.72 | $3.00 | $16.96 |
| Diluted earnings per share attributable to Biogen Inc. | $4.43 | $4.79 | $4.71 | $2.99 | $16.93 |
| Weighted-average shares used in calculating: | | | | | |
| Basic earnings per share attributable to Biogen Inc. | 218.9 | 219.1 | 218.9 | 216.6 | 218.4 |
| Diluted earnings per share attributable to Biogen Inc. | 219.3 | 219.4 | 219.4 | 217.0 | 218.8 |

| (In millions, except per share amounts) 2015 | First Quarter | Second Quarter | Third Quarter (f) (g) | Fourth Quarter (a) (h) | Total Year |
|---|---|---|---|---|---|
| Product revenues, net | $2,172.3 | $2,198.6 | $2,391.7 | $2,425.9 | $9,188.5 |
| Revenues from anti-CD20 therapeutic programs | $330.6 | $337.5 | $337.2 | $333.9 | $1,339.2 |
| Other revenues | $52.0 | $55.6 | $49.0 | $79.5 | $236.1 |
| Total revenues | $2,555.0 | $2,591.6 | $2,777.9 | $2,839.3 | $10,763.8 |
| Gross profit (1) | $2,242.6 | $2,305.5 | $2,467.9 | $2,507.5 | $9,523.4 |
| Net income | $820.2 | $924.8 | $1,019.5 | $828.7 | $3,593.2 |
| Net income attributable to Biogen Inc. | $822.5 | $927.3 | $965.6 | $831.6 | $3,547.0 |
| Net income per share: | | | | | |
| Basic earnings per share attributable to Biogen Inc. | $3.50 | $3.94 | $4.16 | $3.77 | $15.38 |
| Diluted earnings per share attributable to Biogen Inc. | $3.49 | $3.93 | $4.15 | $3.77 | $15.34 |
| Weighted-average shares used in calculating: | | | | | |
| Basic earnings per share attributable to Biogen Inc. | 235.0 | 235.3 | 232.2 | 220.4 | 230.7 |
| Diluted earnings per share attributable to Biogen Inc. | 235.6 | 235.7 | 232.6 | 220.8 | 231.2 |

(1) Gross profit is calculated as total revenues less cost of sales, excluding amortization of acquired intangible assets.

(a) Net income and net income attributable to Biogen Inc., for the first quarter of 2016 and the fourth quarter of 2015, includes pre-tax restructuring charges totaling $9.7 million and $93.4 million, respectively related to the 2015 corporate restructuring program.

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BIOGEN INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(b) Net income and net income attributable to Biogen Inc. for the second, third and fourth quarters of 2016 includes pre-tax additional depreciation expense totaling $15.8 million, $15.7 million and $14.0 million, respectively, as part of our determination to cease manufacturing in our small-scale biologics manufacturing facility in Cambridge, MA as well as vacate our warehouse space in Somerville, MA. Our departure from these facilities has shortened the expected useful lives of certain leasehold improvements and other assets at these facilities.

(c) Net income and net income attributable to Biogen Inc. for the third quarter of 2016 includes a pre-tax charge to research and development expense of $75.0 million for a license fee paid to Ionis as we exercised our option to develop and commercialize SPINRAZA.

(d) Net income and net income attributable to Biogen Inc. for the fourth quarter of 2016 includes a pre-tax charge to research and development expense of $50.0 million for a milestone payment due to Eisai related to the initiation of a phase 3 trial for E2609.

(e) Net income and net income attributable to Biogen Inc. for the fourth quarter of 2016 includes a pre-tax charge of $454.8 million related to the January 2017 settlement and license agreement with Forward Pharma.

(f) Net income and net income attributable to Biogen Inc. for the third quarter of 2015 includes a pre-tax charge to research and development expense of $48.1 million recorded upon entering into the collaboration agreement with AGTC.

(g) Net income attributable to Biogen Inc. for the third quarter of 2015 reflects the attribution of a $60.0 million charge to noncontrolling interests, net of tax, related to a milestone payment due Neurimmune upon the enrollment of the first patient in a Phase 3 trial for aducanumab.

(h) Net income and net income attributable to Biogen Inc. for the fourth quarter of 2015 includes a pre-tax charge to research and development expense of $60.0 million recorded upon entering into the collaboration agreement with MTPC.

26. Subsequent Events

On February 1, 2017, we completed the distribution of the issued and outstanding common stock of Bioverativ to Biogen stockholders. For additional information related to the distribution of Bioverativ, please read Note 1, Summary of Significant Accounting Policies, to these consolidated financial statements.

In connection with the distribution, we entered into a separation and distribution agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between the two companies going forward. They also provide for the performance of services by each company for the benefit of the other for a period of time (including under the manufacturing and supply agreement pursuant to which we will manufacture and supply certain products and materials to Bioverativ).

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Biogen Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, comprehensive income, equity and cash flows present fairly, in all material respects, the financial position of Biogen Inc. and its subsidiaries at December 31, 2016 and December 31, 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting under item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

February 2, 2017

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EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 2.1† | Asset Purchase Agreement among Biogen Idec International Holding Ltd., Elan Pharma International Limited and Elan Pharmaceuticals, Inc., dated as of February 5, 2013. Filed as Exhibit 2.1 to our Current Report on Form 8-K/A filed on February 12, 2013. |
| 2.2 | Separation Agreement between Biogen Inc. and Bioverativ Inc. Filed as Exhibit 2.1 to our Current Report on Form 8-K filed on February 2, 2017. |
| 3.1 | Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012. |
| 3.2 | Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015. |
| 3.3 | Third Amended and Restated Bylaws. Filed as Exhibit 3.2 to our Current Report on Form 8-K filed on March 27, 2015. |
| 4.1 | Reference is made to Exhibit 3.1 for a description of the rights, preferences and privileges of our Series A Preferred Stock and Series X Junior Participating Preferred Stock. |
| 4.2 | Indenture between Biogen Idec and The Bank of New York Trust Company, N.A. dated as of February 26, 2008. Filed as Exhibit 4.1 to our Registration Statement on Form S-3 (File No. 333-149379). |
| 4.3 | First Supplemental Indenture between Biogen Idec and The Bank of New York Trust Company, N.A. dated as of March 4, 2008. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on March 4, 2008. |
| 4.4 | Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015. |
| 4.5 | First Supplemental Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015. |
| 10.1 | Credit Agreement, dated August 28, 2015, between Biogen Inc., Bank of America, N.A., as administrative agent, swing line lender and an L/C issuer, and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015. |
| 10.2† | Expression Technology Agreement between Biogen Idec and Genentech. Inc. dated March 16, 1995. Filed as an exhibit to Biogen Idec's Quarterly Report on Form 10-Q for the quarter ended March 31, 1995. |
| 10.3 | Letter Agreement between Biogen Idec and Genentech, Inc. dated May 21, 1996. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 6, 1996. |
| 10.4† | Second Amended and Restated Collaboration Agreement between Biogen Idec and Genentech, Inc. dated as of October 18, 2010. Filed as Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2010. |
| 10.5† | Letter agreement regarding GA101 financial terms between Biogen Idec and Genentech, Inc. dated October 18, 2010. Filed as Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 31, 2010. |
| 10.6* | Biogen Idec Inc. 2008 Amended and Restated Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. |
| 10.7* | Form of performance unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. |
| 10.8* | Form of market stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. |
| 10.9* | Form of restricted stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on August 1, 2008. |
| 10.10* | Form of nonqualified stock option award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K filed on August 1, 2008. |

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| Exhibit No. | Description |
|---|---|
| 10.11* | Form of cash-settled performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010. |
| 10.12* | Form of performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.12 to our Annual Report on Form 10-K for the year ended December 31, 2013. |
| 10.13* | Form of market stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010. |
| 10.14* | Biogen Inc. 2006 Non-Employee Directors Equity Plan, as amended. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015. |
| 10.15* | Biogen Idec Inc. 2005 Omnibus Equity Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 15, 2005. |
| 10.16* | Amendment No. 1 to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated April 4, 2006. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007. |
| 10.17* | Amendment No. 2 to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated February 12, 2007. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007. |
| 10.18* | Amendment to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated April 18, 2008. Filed as Exhibit 10.7 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008. |
| 10.19* | Amendment to Biogen Idec Inc. 2005 Omnibus Equity Plan dated October 13, 2008. Filed as Exhibit 10.30 to our Annual Report on Form 10-K for the year ended December 31, 2008. |
| 10.20* | Biogen Inc. 2015 Employee Stock Purchase Plan. Filed as Appendix A to Biogen's Definitive Proxy Statement on Schedule 14A filed on April 30, 2015. |
| 10.21* | Biogen Idec Inc. 2008 Performance-Based Management Incentive Plan. Filed as Appendix B to Biogen Idec’s Definitive Proxy Statement on Schedule 14A filed on May 8, 2008. |
| 10.22* | Voluntary Executive Supplemental Savings Plan, as amended and restated effective January 1, 2004. Filed as Exhibit 10.13 to our Annual Report on Form 10-K for the year ended December 31, 2003. |
| 10.23* | Supplemental Savings Plan, as amended. Filed as Exhibit 10.23 to our Annual Report on Form 10-K for the year ended December 31, 2015. |
| 10.24* | Voluntary Board of Directors Savings Plan, as amended. Filed as Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 31, 2015. |
| 10.25* | Biogen Idec Inc. Executive Severance Policy — U.S. Executive Vice President, as amended effective January 1, 2014. Filed as Exhibit 10.39 to our Annual Report on Form 10-K for the year ended December 31, 2013. |
| 10.26* | Biogen Idec Inc. Executive Severance Policy — International Executive Vice President, as amended effective January 1, 2014. Filed as Exhibit 10.40 Annual Report on Form 10-K for the year ended December 31, 2013. |
| 10.27* | Biogen Idec Inc. Executive Severance Policy — U.S. Senior Vice President, as amended effective October 13, 2008. Filed as Exhibit 10.53 to our Annual Report on Form 10-K for the year ended December 31, 2008. |
| 10.28* | Biogen Idec Inc. Executive Severance Policy — International Senior Vice President, as amended effective October 13, 2008. Filed as Exhibit 10.54 to our Annual Report on Form 10-K for the year ended December 31, 2008. |
| 10.29* | Annual Retainer Summary for Board of Directors. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. |
| 10.30* | Form of indemnification agreement for directors and executive officers. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 7, 2011. |
| 10.31* | Employment Agreement between Biogen Idec and George A. Scangos amended as of August 23, 2013. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on August 26, 2013. |
| 10.32* | |

Letter regarding employment arrangement of Paul J. Clancy dated August 17, 2007. Filed as Exhibit 10.49 to our Annual Report on Form 10-K for the year ended December 31, 2007.

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| Exhibit No. | Description |
|---|---|
| 10.33* | Employment Agreement between Biogen Inc. and Michel Vounatsos dated December 18, 2016. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on December 19, 2016. |
| 10.34* | Letter regarding employment arrangement of Kenneth DiPietro dated December 12, 2011. Filed as Exhibit 10.49 to our Annual Report on Form 10-K for the year ended December 31, 2012. |
| 10.35* | Letter regarding employment arrangement of Alfred Sandrock dated May 7, 2013. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013. |
| 10.36* | Letter regarding employment arrangement of Alfred Sandrock dated October 19, 2015. Filed as Exhibit 10.37 to our Annual Report on Form 10-K for the year ended December 31, 2015. |
| 10.37* | Letter regarding employment arrangement of Susan Alexander dated December 13, 2005. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2009. |
| 10.38* | Letter regarding employment arrangement of Adriana Karaboutis dated August 7, 2014. Filed as Exhibit 10.44 to our Annual Report on Form 10-K for the year ended December 31, 2014. |
| 10.39* | Letter regarding employment arrangement of John Cox dated May 19, 2016. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. |
| 10.40* | Letter regarding separation arrangement of Tony Kingsley dated November 12, 2015. Filed as Exhibit 10.42 to our Annual Report on Form 10-K for the year ended December 31, 2015. |
| 10.41 | Settlement and License Agreement, dated January 17, 2017, between Biogen Swiss Manufacturing GmbH, Biogen International Holding Ltd, Forward Pharma A/S and the other parties thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 1, 2017. |
| 21+ | Subsidiaries. |
| 23+ | Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm. |
| 31.1+ | Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2+ | Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1++ | Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101++ | The following materials from Biogen Inc.'s Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Equity and (vi) Notes to Consolidated Financial Statements. |

^ References to "our" filings mean filings made by Biogen Inc. and filings made by IDEC Pharmaceuticals Corporation prior to the merger with Biogen, Inc. Unless otherwise indicated exhibits were previously filed with the Securities and Exchange Commission under Commission File Number 0-19311 and are incorporated herein by reference.

* Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit.

+ Filed herewith.

++ Furnished herewith.