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. Relapsing-remitting MS (RRMS) in the E.U.	None	U.S. France Germany Italy Spain United Kingdom
	Relapsing forms of MS	None	U.S. France Germany Italy Spain United Kingdom
	Relapsing forms of MS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Spain United Kingdom
	Relapsing forms of MS Crohn's disease in the U.S.	None	U.S. France Germany Italy Spain United Kingdom
	Relapsing forms of MS	AbbVie Inc. (AbbVie)	U.S. Germany
	Walking ability for patients with MS	Acorda Therapeutics, Inc. (Acorda)	France Germany 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 Progressive psoriatic arthritis Axial spondyloarthritis Moderate to severe plaque psoriasis	Denmark Germany Netherlands Norway United Kingdom
	Rheumatoid arthritis Moderate to severe Crohn's disease Severe ulcerative colitis Severe ankylosing spondylitis Psoriatic arthritis Moderate to severe plaque psoriasis	Germany Netherlands 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 CLL Rheumatoid arthritis Two forms of ANCA-associated vasculitis	U.S. Canada
	In combination with chlorambucil for previously untreated CLL 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 AVONEX ELOCTATE PLEGRIDY TYSABRI ZINBRYTA Other*
Hillerød, Denmark	TYSABRI 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 Michel Vounatsos	Director and Chief Executive Officer (principal executive officer)	February 2, 2017
/S/ PAUL J. CLANCY Paul J. Clancy	Executive Vice President, Finance and Chief Financial Officer (principal financial officer)	February 2, 2017
/S/ GREGORY F. COVINO Gregory F. Covino	Vice President, Finance, Chief Accounting Officer (principal accounting officer)	February 2, 2017
/S/ STELIOS PAPADOPOULOS Stelios Papadopoulos	Director and Chairman of the Board of Directors	February 2, 2017
/S/ ALEXANDER J. DENNER Alexander J. Denner	Director	February 2, 2017
/S/ CAROLINE D. DORSA Caroline D. Dorsa	Director	February 2, 2017
/S/ NANCY L. LEAMING Nancy L. Leaming	Director	February 2, 2017
/S/ RICHARD C. MULLIGAN Richard C. Mulligan	Director	February 2, 2017
/S/ ROBERT W. PANGIA Robert W. Pangia	Director	February 2, 2017
/S/ BRIAN S. POSNER Brian S. Posner	Director	February 2, 2017
/S/ ERIC K. ROWINSKY Eric K. Rowinsky	Director	February 2, 2017
/S/ LYNN SCHENK Lynn Schenk	Director	February 2, 2017
/S/ STEPHEN A. SHERWIN 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:		