

BIOGEN INC.  
Form 10-K  
February 03, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2015

or

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  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the 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 \$94,898,425,323.

As of January 29, 2016, the registrant had 218,672,717 shares of common stock, \$0.0005 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for our 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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BIOGEN INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2015

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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;

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;

the anticipated benefits, cost savings, and charges related to our corporate restructuring 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 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.

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.

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NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Throughout this report, “Biogen,” the “Company,” “we,” “us” and “our” refer to Biogen Inc. (formerly Biogen Idec Inc.) and its consolidated subsidiaries. References to “RITUXAN” refer 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), 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

ALPROLIX<sup>®</sup>, AVONEX<sup>®</sup>, BENEPALI<sup>®</sup>, ELOCTATE<sup>®</sup>, FLIXABI<sup>®</sup>, PLEGRIDY<sup>®</sup>, RITUXAN<sup>®</sup>, TECFIDERA<sup>®</sup> and TYSABRI<sup>®</sup> are registered trademarks of Biogen. FUMADERM<sup>™</sup> and ZINBRYTA<sup>™</sup> are trademarks of Biogen. Other trademarks referenced in this report are the property of their respective owners.

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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 patients for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for multiple sclerosis (MS), ELOCTATE for hemophilia A and ALPROLIX for hemophilia B, and FUMADERM for the treatment of severe plaque psoriasis. We also have a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group (Roche Group), which entitles us to 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 other potential anti-CD20 therapies.

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 expertise and scientific adjacencies. In addition to our innovative drug development efforts, we aim to leverage our manufacturing capabilities and scientific expertise to extend our mission to improve the lives of patients living with serious diseases through the development, manufacture and marketing of biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics).

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Key Developments

During 2015 and early 2016, we had a number of key developments affecting our business.

Corporate Matters

Company Name Change

In March 2015, we changed our name from Biogen Idec Inc. to Biogen Inc.

Corporate Restructuring

In October 2015, we announced a corporate restructuring, which includes a reduction in workforce and discontinuation of certain programs. We are reinvesting the resulting savings to support key commercial activities and the advancement of our pipeline candidates.

Capital Allocation

In 2015, our capital allocation strategy included the following elements:

Share Repurchase Program	1	Returned approximately \$5.0 billion to our shareholders through our share repurchase program
	1	Utilized a portion of the proceeds from our \$6.0 billion senior unsecured debt offering completed in September 2015 to fund our share repurchase program

Acquisitions and Collaborations	1	Acquired Convergence Pharmaceuticals (Convergence), a clinical-stage biopharmaceutical company with a focus on developing product candidates for neuropathic pain
	1	Obtained exclusive worldwide license, excluding Asia, from Mitsubishi Tanabe Pharma Corporation (MTPC) to amiselimod (MT-1303), a late stage experimental medicine with potential in multiple autoimmune indications
	1	Entered into a collaboration agreement with Applied Genetic Technologies Corporation (AGTC) to develop gene-based therapies for multiple ophthalmic diseases

Investment in Manufacturing	1	Acquired land in Solothurn, Switzerland, where we plan to build a biologics manufacturing facility in the Commune of Luterbach over the next several years
	1	Acquired the drug product manufacturing facility and supporting infrastructure of Eisai, Inc. (Eisai) in Research Triangle Park (RTP), North Carolina

Corporate Responsibility

Environmental Sustainability

In 2015, we were named the biotechnology industry leader on the Dow Jones Sustainability World Index, an index that tracks the economic, environmental and social strategy and performance of the 2,500 largest companies in the S&P Global Broad Market Index.

In 2015, we announced that we achieved carbon neutrality, meaning we believe we have effectively neutralized all of the carbon emissions associated with our business.

Humanitarian Aid

In 2014, we and Swedish Orphan Biovitrum AB (publ) (Sobi) began working with the World Federation of Hemophilia (WFH) to help people with hemophilia in the developing world through our pledge to donate up to one billion international units (IUs) of clotting factor therapy for humanitarian use, of which up to 500 million IUs will be donated to WFH USA over a period of five years. In 2015, we made the first shipments of hemophilia therapy to WFH USA.

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Product/Pipeline Developments

Multiple Sclerosis

ZINBRYTA (daclizumab high yield process)

1 In March 2015, the European Medicines Agency (EMA) validated our marketing authorization application (MAA) for ZINBRYTA for the treatment of relapsing forms of MS in the European Union (E.U.).

1 In April 2015, the U.S. Food and Drug Administration (FDA) accepted our Biologics License Application (BLA) for ZINBRYTA for the treatment of relapsing forms of MS in the United States (U.S.).

TYSABRI (natalizumab)

1 In July 2015, the results of ACTION, our Phase 2 trial investigating TYSABRI in acute ischemic stroke, did not demonstrate an impact on change in infarct volume, the primary endpoint. Exploratory endpoints suggested that TYSABRI had a beneficial impact on patient functional deficits.

1 In October 2015, the results of ASCEND, our Phase 3 study evaluating TYSABRI in secondary progressive MS (SPMS), did not achieve its primary and secondary endpoints, and the development of TYSABRI in SPMS was discontinued.

Anti-LINGO

1 In January 2015, we announced top-line results from RENEW, our Phase 2 acute optic neuritis trial.

Hemophilia

ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein]

1 In November 2015, the European Commission (EC) approved ELOCTA, the approved trade name for ELOCTATE in the E.U., for the treatment of hemophilia A.

1 Sobi has assumed final development and commercialization of ELOCTA in their territory, which essentially includes Europe, North Africa, Russia, and certain markets in the Middle East (Sobi Territory).

ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein]

1 In June 2015, the EMA validated our MAA for ALPROLIX for the treatment of hemophilia B.

1 In July 2015, Sobi exercised its option to assume final development and commercialization of ALPROLIX in the Sobi Territory.

Neurodegeneration

Aducanumab (BIIB037)

1 In March 2015 and July 2015, we announced data from pre-specified interim analyses of PRIME, our Phase 1b study of aducanumab.

1 In September 2015, we enrolled our first patient in our two global Phase 3 studies, ENGAGE and EMERGE, to assess the efficacy and safety of aducanumab in people with early Alzheimer's disease. In October 2015, we announced that we received FDA agreement on a special protocol assessment on the Phase 3 study protocols. Such agreement constitutes FDA's concurrence on the design and size of the clinical trials which will form the basis for approval of aducanumab.

Other Programs

Nusinersen (ISIS-SMN<sub>Rx</sub>)

1 In June 2015, our collaborator, Ionis Pharmaceuticals, Inc. (Ionis), formerly known as Isis Pharmaceuticals, Inc., announced additional data from two Phase 2 studies of nusinersen for the treatment of SMA in infants and children. There are two ongoing Phase 3 studies of nusinersen.



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Genentech Relationships

GAZYVA (obinutuzumab)

1 In February 2015, the Roche Group announced positive results from its Phase 3 GADOLIN study of GAZYVA in non-Hodgkin's lymphoma.

Ocrelizumab

1 In June 2015, the Roche Group announced positive results from two Phase 3 studies evaluating ocrelizumab compared with interferon beta-1a in people with relapsing forms of MS.

1 In September 2015, the Roche Group announced positive results from a Phase 3 study evaluating ocrelizumab in people with primary progressive MS (PPMS).

1 Under our agreement with Genentech, if ocrelizumab is approved, we will receive tiered royalty payments on sales of ocrelizumab.

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

BENEPALI

1 In November 2015, Samsung Bioepis received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for the MAA for BENEPALI, an etanercept biosimilar referencing ENBREL. In January 2016, the EC approved the MAA for BENEPALI for marketing in the E.U. Under our agreement with Samsung Bioepis, we will manufacture and commercialize BENEPALI in specified E.U. countries.

FLIXABI

1 In March 2015, the EMA validated and accepted Samsung Bioepis' MAA for FLIXABI, an infliximab biosimilar candidate referencing REMICADE.

Discontinued Programs

1 During 2015, we discontinued several programs, including our study of Neublabin in neuropathic pain, our Phase 3 program for TECFIDERA in SPMS, our Phase 3 program evaluating TYSABRI in SPMS, the development of anti-TWEAK in lupus nephritis, and certain activities in immunology and fibrosis research.

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Marketed Products

The following graphs show our product sales and unconsolidated joint business revenues by principal product and geography as a percentage of revenue for the years ended December 31, 2015, 2014 and 2013.

(1) Other includes FAMPYRA, ELOCTATE, ALPROLIX and FUMADERM

Product sales for TECFIDERA, AVONEX and TYSABRI and unconsolidated joint business revenues for RITUXAN each accounted for more than 10% of our total revenue for the years ended December 31, 2015, 2014 and 2013. 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.	None	U.S. United Kingdom France
	Relapsing-remitting MS (RRMS) in the E.U.		Germany Italy Spain
	Relapsing forms of MS	None	U.S. United Kingdom France Germany Italy Spain
	Relapsing forms of MS in the U.S. RRMS in the E.U.	None	U.S. United Kingdom France Germany Italy Spain
	Relapsing forms of MS Crohn's disease in the U.S.	None	U.S. United Kingdom France Germany Italy Spain
	Walking ability for patients with MS	Acorda Therapeutics, Inc. (Acorda)	France Germany Spain Canada

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## Hemophilia

We develop, manufacture and market products designed to treat patients with hemophilia A and B. Hemophilia A is caused by having substantially reduced or no Factor VIII activity and hemophilia B is caused by having substantially reduced or no Factor IX activity, each of which is needed for normal blood clotting. People with hemophilia A and B experience bleeding episodes that may cause pain, irreversible joint damage and life-threatening hemorrhages.

Prophylactic infusions of Factor VIII or Factor IX, as applicable, temporarily replace clotting factor necessary to control bleeding and help protect against new bleeding episodes.

Our products for hemophilia and major markets include:

Product	Indication	Collaborator	Major Markets
	Adults and children with hemophilia A for control of bleeding episodes	Sobi	U.S. Japan
	Adults and children with hemophilia B for control of bleeding episodes	Sobi	U.S. Japan

In November 2015, the EC approved ELOCTA for the treatment of hemophilia A in the E.U. Under our collaboration agreement with Sobi, Sobi has assumed responsibility for final development and commercialization of ELOCTA in the Sobi Territory.

## 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	U.S.

For information about our unconsolidated joint business and agreement 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.

## Other

Product	Indication	Collaborator	Major Market
	Moderate to severe plaque psoriasis	None	Germany

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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 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.

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, 2015, 2014 and 2013, 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.

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 and order, delivery and fulfillment services.

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 and their caregivers and healthcare professionals understand, compare and select insurance options and programs that are available to them. In the U.S., we have established programs that provide qualified uninsured or underinsured patients with marketed products at no or reduced charge, based on specific eligibility criteria. We also provide charitable contributions that may assist eligible commercially-insured patients with out-of-pocket expenses associated with their costs for our products.

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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 <sup>(1)</sup>
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 <sup>(2)</sup>
	Europe	2137537	Methods of use	2028 <sup>(3)</sup>
	AVONEX and PLEGRIDY	U.S.	7,588,755	Use of recombinant beta interferon for immunomodulation
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
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
	Europe	0804237	Humanized immunoglobulins; nucleic acids; pharmaceutical compositions; medical uses	2020
	Europe	1485127	Methods of use	2023
FAMPYRA	Europe	0484186	Formulations containing aminopyridines, including fampridine	2016 <sup>(4)</sup>
	Europe	1732548	Sustained-release aminopyridine compositions for increasing walking speed in patients with MS	2025 <sup>(5)</sup>
	Europe	23775536	Sustained-release aminopyridine compositions for treating MS	2025 <sup>(6)</sup>
ELOCTATE and ALPROLIX	U.S.	7,348,004	Methods of treatment	2024
	U.S.	7,862,820	Methods of treatment	2024
	U.S.	8,329,182	Composition of matter covering rFIXFc and rFVIII Fc	2024
	U.S.	7,404,956	Composition of matter covering rFIXFc and rFVIII Fc	2025
	Europe	1624891	Composition of matter covering rFIXFc and rFVIII Fc	2024
	Europe	1625209	Composition of matter covering rFIXFc and rFVIII Fc	2024
	Europe	2298347		2024



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		Composition of matter covering rFIXFc and rFVIII Fc		
ELOCTATE	U.S.	9,050,318	Methods of treatment	2031
	U.S.	9,241,978	Methods of treatment	2031
ALPROLIX	U.S.	9,233,145	Methods of treatment	2031

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
ELOCTATE	U.S.	2026
ELOCTA*	E.U.	2025
ALPROLIX	U.S.	2026

\*ELOCTA is commercialized by Sobi per our collaboration agreement.

- (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 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, except for Germany where the application for SPC is pending.
- (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 are 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 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 an important 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 may result in increased competition for our marketed products or could result in pricing pressure on our 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.

TECFIDERA, AVONEX, PLEGRIDY and TYSABRI

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

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

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 ocrelizumab, a potential treatment for PPMS being developed by the Roche Group. While we have a financial interest in ocrelizumab, future sales of our MS products may be adversely affected by the commercialization of ocrelizumab, 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.

FAMPYRA

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.

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## ELOCTATE and ALPROLIX

ELOCTATE and ALPROLIX compete with recombinant Factor VIII and IX products, respectively, including:  
 Competing Product Competitor

## ELOCTATE:

## ADVATE

[Antihemophilic Factor (Recombinant)]

Baxalta

## ADYNOVATE

[Antihemophilic Factor (Recombinant), PEGylated]

Baxalta

## KOGENATE FS

[Antihemophilic Factor (Recombinant)]

Bayer

## HELIXATE FS

[Antihemophilic Factor (Recombinant)]

CSL Behring

## RECOMBINATE

[Antihemophilic Factor (Recombinant)]

Baxalta

## XYNTHA

[Antihemophilic Factor (Recombinant)], Plasma/Albumin-Free

Pfizer

## ALPROLIX:

BENEFIX Coagulation Factor IX (Recombinant)

Pfizer

IXINITY Coagulation Factor IX (Recombinant)

Emergent Biosolutions

RIXUBIS [Coagulation Factor IX (Recombinant)]

Baxalta

Our hemophilia products also compete with a number of plasma-derived Factor VIII and IX products. We are also aware of other longer-acting products as well as other technologies, such as gene therapies, that are in development, and if successfully developed and approved would compete with our hemophilia products.

## 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.

## FUMADERM

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

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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
ZINBRYTA	AbbVie Therapeutics	Multiple Sclerosis (MS)			
GAZYVA	Genentech (Roche Group)	RITUXAN-Refractory Indolent Non Hodgkin’s Lymphoma			
GAZYVA	Genentech (Roche Group)	Front-Line Indolent Non Hodgkin’s Lymphoma			
GAZYVA	Genentech (Roche Group)	Front-Line Diffuse Large B-Cell Lymphoma			
Nusinersen	Ionis Pharmaceuticals	Spinal Muscular Atrophy			
Aducanumab	Neurimmune SubOne AG	Alzheimer's Disease			
Ocrelizumab	Genentech (Roche Group)	Primary Progressive & Relapsing Multiple Sclerosis			
Anti-LINGO	None	Optic Neuritis; Multiple Sclerosis			
Amiselimod	Mitsubishi Tanabe	Multiple Autoimmune Indications			
BAN2401	Eisai	Alzheimer's Disease			
E2609	Eisai	Alzheimer's Disease			
Raxatrigine	None	Trigeminal Neuralgia			
TYSABRI	None	Acute Ischemic Stroke			

rAAV-XLRS	AGTC	X-linked Juvenile Retinoschisis
BG00011 (STX-100)	None	Idiopathic Pulmonary Fibrosis
Dapirolizumab pegol	UCB Pharma	SLE*
BIIB061	None	Multiple Sclerosis
IONIS-DMPK <sub>Rx</sub>	Ionis Pharmaceuticals	Myotonic Dystrophy
Anti-BDCA2	None	SLE*
Anti-alpha-synuclein	None	Parkinson's Disease
BIIB063	None	Sjogren's Syndrome
IONIS-SOD1 <sub>Rx</sub> (BIIB067)	Ionis Pharmaceuticals	ALS
FLIXABI (infliximab)	Samsung Bioepis	Multiple Immunology Indications in Europe
Biosimilar adalimumab	Samsung Bioepis	Multiple Immunology Indications in Europe
* Systemic lupus erythematosus		

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

### 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.

#### Multiple Sclerosis

##### ZINBRYTA (daclizumab high yield process)

1 ZINBRYTA is a monoclonal antibody for the treatment of RRMS.

1 In June 2014, we announced positive top-line results from the Phase 3 DECIDE clinical trial, which investigated ZINBRYTA as a potential once-monthly, subcutaneous treatment for RRMS. Results showed that ZINBRYTA was superior on the study's primary endpoint, demonstrating a statistically significant reduction in annualized relapse rates when compared to interferon beta-1a.

1 Our MAA for ZINBRYTA was validated by the EMA in March 2015, and the BLA was accepted by the FDA in April 2015.

##### TYSABRI (natalizumab)

1 In May 2013, we completed patient enrollment in a Phase 3 study of TYSABRI in SPMS, known as ASCEND. The study had a duration of approximately two years and involved approximately 875 patients. SPMS is characterized by a steady progression of nerve damage, symptoms and disability.

1 In October 2015, the results of our Phase 3 ASCEND study did not achieve its primary and secondary endpoints, and the development of TYSABRI in SPMS was discontinued.

#### Hemophilia

##### ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein]

1 In March 2014, ALPROLIX was approved by the FDA for the treatment of hemophilia B.

1 Pediatric data was required as part of the MAA for ALPROLIX that we submitted to the EMA. In February 2015, we and Sobi announced positive top-line results of the Kids B-LONG Phase 3 clinical study that evaluated the safety, efficacy and pharmacokinetics of ALPROLIX in children under age 12 with severe hemophilia B. Following these results, we filed a MAA in the E.U., which was validated by the EMA in June 2015.

#### Neurodegeneration

##### Aducanumab (BIIB037)

1 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 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.

#### Other Programs

##### Nusinersen (IONIS-SMN<sub>Rx</sub>)

1 In August 2014, Ionis announced the initiation of a pivotal Phase 3 study evaluating nusinersen in infants with SMA, the most common genetic cause of infant mortality. This Phase 3 study, known as ENDEAR, is a randomized, double-blind, sham-procedure controlled thirteen month study in approximately 110 infants diagnosed with SMA. The study is evaluating the efficacy and safety of a 12mg dose of nusinersen with a primary endpoint of survival or permanent ventilation.



1 In November 2014, Ionis announced the initiation of a pivotal Phase 3 study evaluating the efficacy and safety of nusinersen in non-ambulatory children with SMA. This Phase 3 study, known as CHERISH, is a randomized, double-blind, sham-procedure controlled fifteen month study in approximately 120 children with SMA. The study is evaluating the efficacy and safety of a 12mg dose of nusinersen with a primary endpoint of a change in the Hammersmith Functional Motor Scale-Expanded, a validated method to measure changes in muscle function in patients with SMA.

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Genentech Relationships

GAZYVA (obinutuzumab)

- 1 The Roche Group is managing the following Phase 3 studies of GAZYVA:
- GOYA: investigating the efficacy and safety of GAZYVA in combination with CHOP chemotherapy compared to RITUXAN with CHOP chemotherapy in previously untreated patients with CD20-positive diffuse large B-cell lymphoma.
- GALLIUM: investigating the efficacy and safety of GAZYVA in combination with chemotherapy followed by maintenance with GAZYVA compared to RITUXAN in combination with chemotherapy followed by maintenance with RITUXAN in previously untreated patients with indolent non-Hodgkin's lymphoma.
- GADOLIN: investigating the efficacy and safety of GAZYVA plus bendamustine compared with bendamustine alone in patients with RITUXAN-refractory, indolent non-Hodgkin's lymphoma. In February 2015, the Roche Group announced positive results from the Phase 3 GADOLIN study. At a pre-planned interim analysis, an independent data monitoring committee determined that the study met its primary endpoint early, showing that people lived significantly longer without disease worsening or death (progression-free survival) when treated with GAZYVA plus bendamustine followed by GAZYVA alone, compared to bendamustine alone.

Ocrelizumab

- 1 In June 2015, the Roche Group announced positive results from two Phase 3 studies evaluating ocrelizumab compared with interferon beta-1a in people with relapsing forms of MS. Treatment with ocrelizumab 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.
- 1 In September 2015, the Roche Group announced positive results from a Phase 3 study evaluating ocrelizumab in people with PPMS. Treatment with ocrelizumab significantly reduced the progression of clinical disability compared with placebo, as measured by the Expanded Disability Status Scale.

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

FLIXABI

- 1 Samsung Bioepis' MAA for FLIXABI, an infliximab biosimilars candidate referencing REMICADE, was validated and accepted by the EMA in March 2015. If approved, under our agreement with Samsung Bioepis, we have commercialization rights to FLIXABI in specified E.U. countries.

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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 Biotherapeutics, Inc.

We have a collaboration agreement with AbbVie Biotherapeutics, Inc. aimed at advancing the development and commercialization of ZINBRYTA in MS.

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

In 2015, we entered into a collaboration agreement with 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 ocrelizumab is approved, we will receive tiered royalty payments on sales of ocrelizumab.

Ionis Pharmaceuticals, Inc.

We have three separate exclusive, worldwide option and collaboration agreements with Ionis under which both companies will develop and commercialize antisense therapeutics for up to three gene targets, Ionis' product candidates for the treatment of myotonic dystrophy type 1, and the antisense investigational candidate, nusinersen for the treatment of SMA. We also have a six-year research collaboration agreement with Ionis, which we entered into in 2013, 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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Mitsubishi Tanabe Pharma Corporation

In 2015, we entered into an agreement with MTPC to exclusively license amiselimod, a late stage experimental medicine with potential in multiple autoimmune indications. Amiselimod is an oral compound that targets the sphingosine 1-phosphate receptor. Under the agreement, we obtained worldwide rights to amiselimod, excluding Asia. We are responsible for commercialization and are covering development costs outside of Asia. MTPC has the right to participate in our global clinical trials and has an option to co-promote non-MS indications in the U.S.

Samsung Bioepis

We and Samsung Biologics established a joint venture, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. In December 2013, we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, anti-TNF biosimilar product candidates in specified E.U. countries, and, in the case of BENEPALI, Japan. To date, Samsung Bioepis' MAA for BENEPALI, an etanercept biosimilar referencing ENBREL, has been approved by the EC, and the MAA for FLIXABI, an infliximab biosimilars candidate referencing REMICADE, has been validated by the EMA.

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's 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.

Sangamo BioSciences, Inc.

We have an exclusive, worldwide research, development and commercialization collaboration and license agreement with Sangamo BioSciences, Inc. (Sangamo) under which the companies will develop and commercialize product candidates using gene editing technologies for the treatment of two inherited blood disorders, sickle cell disease and beta-thalassemia.

Swedish Orphan Biovitrum AB (publ)

We collaborate with Sobi to jointly develop and commercialize Factor VIII and Factor IX hemophilia products, including ELOCTATE and ALPROLIX. We have commercial rights for North America and for rest of the world markets outside of the Sobi Territory. Sobi has assumed final development and commercialization of ELOCTA in the Sobi Territory, and, has elected to opt-in to assume final development and commercialization of ALPROLIX if the MAA is approved by the EMA.

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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 New Drug Application (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. 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.

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**Fast Track Status:** The FDA may grant “fast track” status to products that treat serious diseases or conditions and fill an unmet medical need. Fast track is a process designed to expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product’s development plan, more frequent written correspondence from the FDA about trial design, eligibility for accelerated approval, and rolling review, which allows submission of individually completed sections of a NDA or BLA for FDA review before the entire filing is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

**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 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:** Finally, the FDA may grant “priority review” status to products that offer major advances in treatment or provide a treatment where no adequate therapy exists. Priority review is intended to reduce the time it takes for the FDA to review a NDA or BLA.

## 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.

## 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.

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### 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, where most 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.

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.



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### 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 Affordable Care Act 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.

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.

### 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.

### 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. 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.

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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. For most brand name drugs, the amount of the basic rebate for each product is set by law as the greater of 23.1% (17.1% for clotting factors and certain other products) of the average manufacturer price (AMP) or the difference between AMP and the best price available from us to any customer (with limited exceptions). The rebate amount must be adjusted upward if AMP increases more than inflation (measured by the Consumer Price Index - Urban). This adjustment can cause the total rebate amount to exceed the minimum 23.1% (or 17.1%) basic rebate amount. 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. The current payment rate for Medicare Part B drugs is ASP plus 6%. The payment rates for drugs in the hospital outpatient setting are subject to periodic adjustment. The CMS also has the statutory authority to adjust payment rates for specific drugs outside the hospital outpatient setting

based on a comparison of ASP payment rates to widely available market prices or to AMP, which could decrease Medicare payment rates, but the authority has not yet been implemented. 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 manufacturers 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.



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**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 our 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.

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.



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### 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 Cambridge, Massachusetts and 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 have announced our plans to expand 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
Cambridge, MA	TYSABRI
	AVONEX
	ELOCTATE
Hillerød, Denmark	PLEGRIDY
	TYSABRI
	Biosimilars

In addition to our drug substance manufacturing facilities, in August 2015, we expanded our capabilities by completing the purchase from Eisai of 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 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.

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, and Acorda Therapeutics supplies FAMPYRA to us pursuant to its supply agreement with Alkermes, Inc.

## Third-Party Suppliers and Manufacturers

We principally use third parties to manufacture the active pharmaceutical ingredient (API), 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.

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 Cambridge and Hillerød facilities. 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, 2015, we had approximately 7,350 employees worldwide.

Our Executive Officers (as of February 3, 2016)

Name	Current Position	Age	Year Joined Biogen
George A. Scangos, Ph.D.	Chief Executive Officer	67	2010
Susan H. Alexander	Executive Vice President, Chief Legal Officer and Corporate Secretary	59	2006
Spyros Artavanis-Tsakonas, Ph.D.	Senior Vice President, Chief Scientific Officer	69	2012
Paul J. Clancy	Executive Vice President, Finance and Chief Financial Officer	54	2001
Gregory F. Covino	Vice President, Finance and Chief Accounting Officer	50	2012
John G. Cox	Executive Vice President, Pharmaceutical Operations and Technology	53	2003
Kenneth DiPietro	Executive Vice President, Human Resources	57	2012
Steven H. Holtzman	Executive Vice President, Corporate Development	61	2011
Adriana (Andi) Karaboutis	Executive Vice President, Technology, Business Solutions and Corporate Affairs	53	2014
Adam Koppel, M.D., Ph.D.	Executive Vice President, Strategy and Business Development	46	2014
Alfred W. Sandrock, Jr., M.D., Ph.D.	Chief Medical Officer and Executive Vice President of Neurology Discovery and Development	58	1998
George A. Scangos, Ph.D.			

## Experience

Dr. Scangos has served as our Chief Executive Officer since July 2010. Prior to that, he served as the President and Chief Executive Officer of Exelixis, Inc., a drug discovery and development company, from 1996 to July 2010. From 1993 to 1996, Dr. Scangos served as President of Bayer Biotechnology, where he was responsible for research, business development, process development, manufacturing, engineering and quality assurance of Bayer's biological products. Before joining Bayer in 1987, Dr. Scangos was a professor of biology at Johns Hopkins University for six years, where he is still an adjunct professor. Dr. Scangos served as non-executive Chairman of Anadys Pharmaceuticals, Inc., a biopharmaceutical company, from 2005 to July 2010 and was a director of the company from 2003 to July 2010. He also served as the Chair of the California Healthcare Institute in 2010 and was a member of the board of the Global Alliance for TB Drug Development until 2010.

## Public Company Boards

- 1 Board of Directors of Agilent Technologies, Inc., a provider of instruments, software, services and consumables for laboratories
- 1 Board of Directors of Exelixis, Inc., a drug discovery and development company

## Outside Affiliations

- 1 Chairman-elect of the Board of Directors of Pharmaceutical Research and Manufacturers of America
- 1 Board of Trustees of the Boston Museum of Science and the Biomedical Science Careers Program
- 1 National Board of Visitors of the University of California, Davis School of Medicine

## Education

- 1 Cornell University, B.A. in Biology
- 1 University of Massachusetts, Ph.D. in Microbiology
- 1 Yale University, Jane Coffin Childs Post-Doctoral Fellow

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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.

Education

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

Spyros Artavanis-Tsakonas, Ph.D.

Experience

Dr. Artavanis-Tsakonas has served as our Senior Vice President, Chief Scientific Officer since May 2013. Prior to that, Dr. Artavanis-Tsakonas served as our interim Chief Scientific Officer while on sabbatical from Harvard Medical School from March 2012 to May 2013. Dr. Artavanis-Tsakonas has been a Professor of Cell Biology at the Harvard Medical School since 1999. From 1999 through 2012, he was Professor, Collège de France, serving as Chair of Biology and Genetics of Development, and from 1999 to 2007, he was also the K.J. Isselbacher- P. Schwartz Professor at the Massachusetts General Hospital Cancer Center and Director of Developmental Biology and Cancer at the Harvard Medical School. Dr. Artavanis-Tsakonas is the scientific co-founder of Exelixis Pharmaceuticals, Inc., a drug discovery and development company, Cellzome, a drug discovery and development company, and Anadys Pharmaceuticals, Inc., a biopharmaceutical company.

Education

- 1 Federal Institute of Technology, Zurich, M.Sc. in Chemistry
- 1 University of Cambridge, England, Ph.D. in Molecular Biology
- 1 Biozentrum, University of Basel and Stanford University, postdoctoral research

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

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

Education

- 1 Babson College, B.S. in Finance
- 1 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

- 1 Bryant University, B.S. in Business Administration

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John G. Cox

Experience

Mr. Cox has served as our Executive Vice President, Pharmaceutical Operations and Technology since June 2010 and has been leading our Global Therapeutic Operations since October 2015. Mr. Cox joined Biogen, Inc. in 2003 and has held several senior executive positions with us, including Senior Vice President of Technical Operations, Senior Vice President of Global Manufacturing, and Vice President of Manufacturing and General Manager of Biogen's operations in RTP. Prior to that, Mr. Cox held a number of senior operational roles at Diosynth Inc., a life sciences manufacturing and services company, where he worked in technology transfer, validation and purification. Prior to that, Mr. Cox focused on the same areas at Wyeth Corporation, a life sciences company, from 1993 to 2000.

Public Company Boards

- 1 Board of Directors of Repligen Corporation, a life sciences company

Education

- 1 Arizona State University, B.S. in Biology
- 1 University of Michigan, M.B.A.
- 1 California State University, M.S. in Cell Biology

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

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

Education

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

Steven H. Holtzman

Experience

Mr. Holtzman has served as our Executive Vice President, Corporate Development since January 2011. Prior to that, Mr. Holtzman was a founder of Infinity Pharmaceuticals, Inc., a drug discovery and development company, where he served as Chair of the Board of Directors from company inception in 2001 to November 2012, Executive Chair of the Board of Directors in 2010 and as Chief Executive Officer from 2001 to December 2009. From 1994 to 2001, Mr. Holtzman was Chief Business Officer at Millennium Pharmaceuticals Inc., a biopharmaceutical company. From 1986 to 1994, he was a founder, member of the Board of Directors and Executive Vice President of DNX Corporation, a biotechnology company. From 1996 to 2001, Mr. Holtzman served as presidential appointee to the national Bioethics Advisory Commission.

Education

- 1 Michigan State University, B.A.
- 1 Oxford University, B.Phil. graduate degree, which he attended as a Rhodes Scholar

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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

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

Education

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

Adam Koppel, M.D., Ph.D.

Experience

Dr. Koppel has served as our Executive Vice President, Strategy and Business Development since November 2015. Prior to that, Dr. Koppel served as our Senior Vice President and Chief Strategy Officer from May 2014 to October 2015, responsible for leading corporate strategy and portfolio management. Prior to joining us, Dr. Koppel served as a Managing Director of Brookside Capital, the public-equity affiliate of Bain Capital, since November 2003. Prior to Brookside Capital, he served as Associate Principal with McKinsey & Company, where he consulted to companies in the pharmaceutical and biotechnology industries.

Public Company Boards

1 Board of Directors of PTC Therapeutics, Inc., a biopharmaceutical company

1 Board of Directors of Trevena, Inc., a biopharmaceutical company

Education

1 Harvard University, B.A.

1 Wharton School of the University of Pennsylvania, M.B.A.

1 University of Pennsylvania School of Medicine, M.D. and Ph.D.

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

Experience

Dr. Sandroock has served as our Chief Medical Officer and Executive Vice President of Neurology Discovery and Development since November 2015. Prior to that, Dr. Sandroock 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. Sandroock 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

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

Education

1 Stanford University, B.A. in Human Biology

1 Harvard Medical School, M.D.

1 Harvard University, Ph.D. in Neurobiology

1 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](http://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. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales and growth of TECFIDERA as we further expand into additional markets. 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, due to a number of factors, including governmental or regulatory requirements, increased competition, or changes in reimbursement policies and practices of payors and other third parties; or
- adverse legal, administrative, regulatory or legislative developments.

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;
- 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.

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Similarly, the hemophilia treatment market is highly competitive, with current treatments marketed by companies that have substantially greater financial resources and marketing expertise. Our ability to successfully compete in the hemophilia market and gain share in this market may be adversely affected due to a number of reasons, including: difficulty in penetrating this market if our therapies are not regarded as offering significant benefits over current treatments;

the introduction by other companies of longer-lasting or more efficacious, safer, less expensive or more convenient treatments than our therapies;

our limited marketing experience within the hemophilia treatment market, which may impact our ability to develop relationships with the associated medical and scientific community; or

if one of several companies that are working to develop additional treatments for hemophilia obtains marketing approval of its treatment in the E.U. before we do, our application for ALPROLIX with the EMA could be barred under operation of the EMA's orphan medicinal product regulation.

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 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 marketing of 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 operation, 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. Drug pricing and other health care costs continue to be subject to intense political and societal pressures which we anticipate will continue and escalate 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 Patient Protection and Affordable Care Act (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. 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 addition, under the PPACA, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers, including us, will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our products for this patient population, which could have an adverse impact on our sales and results of operations. 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 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 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 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 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.

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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, or 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.

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 substantially all 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 does 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.

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 manufacturing facilities in Cambridge, Massachusetts, RTP, North Carolina and Hillerød, Denmark 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. Reliance on collaborative relationships subjects us to a number of risks, including:

- we may be unable to control the resources our collaborator devotes to our programs or products;
- disputes may arise with respect to ownership of rights to technology developed with our collaborator, and the underlying contract with our collaborator may fail to provide significant protection or may fail to be effectively enforced if the collaborator fails to perform;
- our collaborator's interests may not always be aligned with our interests and a collaborator 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;
- collaborations often require the parties to cooperate, and failure to do so effectively could adversely affect product sales by our collaborator 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
- any failure on the part of our collaborator to comply with applicable laws and regulatory requirements in the marketing, sale and maintenance of the market authorization of our products or to fulfill any responsibilities our

collaborator 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.



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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.

We may fail to achieve the expected financial and operating benefits of our corporate restructuring and the restructuring may harm our business and financial results.

We face significant risks associated with our corporate restructuring actions that may impair our ability to achieve anticipated savings and operational efficiencies or that may otherwise harm our business. These risks include loss of workforce capabilities, loss of continuity, decreases in employee focus and morale, attrition of necessary or key employees, higher than anticipated separation expenses, litigation and the failure to meet financial and operational targets. In addition, the calculation of the anticipated cost savings and other benefits resulting from our corporate restructuring actions are subject to many estimates and assumptions. These estimates and assumptions are subject to significant business, economic, competitive and other uncertainties and contingencies, many of which are beyond our control. If these estimates and assumptions are incorrect or if we experience delays or unforeseen events, our business and financial results could be adversely affected.

Our business may be adversely affected if we do not manage our current growth and 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. The availability of high quality 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.

To manage our current and future potential growth effectively, we need to continue to enhance our operational, financial and management processes and to expand, train and manage our employee base. Our growth is also dependent upon our ability to attract and retain qualified scientific, information technology, manufacturing, sales and marketing and executive personnel and to develop and maintain relationships with qualified clinical researchers and key distributors in a highly competitive environment. We may face difficulty in attracting and retaining key talent for a number of reasons, such as the underperformance or discontinuation of one or more late stage programs or recruitment by competitors.

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 current growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

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. 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.



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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, we along with many other pharmaceutical and biotechnology companies 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. These risks may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have product distribution methods differing from those we currently utilize.

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.

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 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;



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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 which 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.

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.

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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.

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 manufacturing capacity to meet our near-term manufacturing requirements, it is probable that we would need additional manufacturing capacity to support future clinical and commercial manufacturing requirements for product candidates in our pipeline, if such candidates are successful and approved. We recently announced our intent to build a biologics manufacturing facility in Solothurn, Switzerland and our acquisition of an additional manufacturing facility in RTP, 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.

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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;

**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; 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. If we decide to fully or partially vacate a leased property, we may incur significant cost, including lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements. 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.

Our Board of Directors has approved stock repurchase programs and may approve additional repurchase programs in the future. 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, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are 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, 2015.

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 1,312,000 square feet in Massachusetts, which is summarized as follows:

- 909,000 square feet in Cambridge, Massachusetts, which is comprised of a 67,000 square foot biologics manufacturing facility and 842,000 square feet for our corporate headquarters, laboratory and additional office space;
- 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; and
- 46,000 square feet of warehouse space in Somerville, Massachusetts.

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;
- 475,000 square feet related to a large-scale biologics manufacturing facility;
- 405,000 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 10,000 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:

- 439,000 square feet of warehouse, utilities and support space;
- 70,000 square feet related to a label and packaging facility;
- 47,000 square feet of administrative space; and
- 50,000 square feet related to a laboratory facility.

Switzerland

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

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Other International

We lease office space in Zug, Switzerland, our international headquarters, the United Kingdom, Germany, France, Denmark, and numerous other countries. Our international lease agreements expire at various dates through the year 2023.

Item 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2015, 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, 2015 and 2014:

	Common Stock Price			
	2015		2014	
	High	Low	High	Low
First Quarter	\$480.18	\$334.40	\$358.89	\$270.62
Second Quarter	\$432.88	\$368.88	\$322.25	\$272.02
Third Quarter	\$412.24	\$265.00	\$349.00	\$298.31
Fourth Quarter	\$311.65	\$254.00	\$361.93	\$290.85

As of January 29, 2016, there were approximately 742 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 May 2015, our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2015 Share Repurchase Program).

The following table summarizes our common stock repurchase activity under our 2015 Share Repurchase Program during the fourth quarter of 2015:

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 2015	4,976,270	275.87	4,976,270	\$629.0
November 2015	2,131,417	295.12	2,131,417	\$—
December 2015	—	—	—	\$—
Total	7,107,687	281.64		

As of December 31, 2015, the 2015 Share Repurchase Program was completed and we repurchased and retired approximately 16.8 million shares of common stock at a cost of \$5.0 billion during the year ended December 31, 2015.

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, 2015 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, 2010 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

	2010	2011	2012	2013	2014	2015
Biogen Inc.	100.00	164.13	218.30	416.96	506.26	456.90
NASDAQ Pharmaceutical	100.00	107.59	123.00	166.89	203.30	214.35
S&P 500 Index	100.00	102.11	118.45	156.82	178.28	180.75
NASDAQ Biotechnology	100.00	112.09	148.78	247.01	331.99	371.06

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Item 6. Selected Financial Data  
 BIOGEN INC. AND SUBSIDIARIES  
 SELECTED FINANCIAL DATA

(In millions, except per share amounts)	For the Years Ended December 31,				
	2015 (3) (4)	2014	2013 (1) (2)	2012	2011 (1)
<b>Results of Operations</b>					
Product revenues, net	\$9,188.5	\$8,203.4	\$5,542.3	\$4,166.1	\$3,836.1
Revenues from unconsolidated joint business	1,339.2	1,195.4	1,126.0	1,137.9	996.6
Other revenues	236.1	304.5	263.9	212.5	215.9
Total revenues	10,763.8	9,703.3	6,932.2	5,516.5	5,048.6
Total cost and expenses	5,872.8	5,747.7	4,441.6	3,707.4	3,323.9
Gain on sale of rights	—	16.8	24.9	46.8	—
Income from operations	4,891.0	3,972.4	2,515.5	1,855.9	1,724.7
Other income (expense), net	(123.7	) (25.8	) (34.9	) (0.7	) (13.5
Income before income tax expense and equity in loss of investee, net of tax	4,767.3	3,946.6	2,480.6	1,855.1	1,711.2
Income tax expense	1,161.6	989.9	601.0	470.6	444.5
Equity in loss of investee, net of tax	12.5	15.1	17.2	4.5	—
Net income	3,593.2	2,941.6	1,862.3	1,380.0	1,266.7
Net income (loss) attributable to noncontrolling interests, net of tax	46.2	6.8	—	—	32.3
Net income attributable to Biogen Inc.	\$3,547.0	\$2,934.8	\$1,862.3	\$1,380.0	\$1,234.4
<b>Diluted Earnings Per Share</b>					
Diluted earnings per share attributable to Biogen Inc.	\$15.34	\$12.37	\$7.81	\$5.76	\$5.04
Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Inc.	231.2	237.2	238.3	239.7	245.0

(In millions)	As of December 31,				
	2015 (5) (6)	2014	2013	2012	2011
<b>Financial Condition</b>					
Cash, cash equivalents and marketable securities	\$6,188.9	\$3,316.0	\$1,848.5	\$3,742.4	\$3,107.4
Total assets	\$19,504.8	\$14,314.7	\$11,863.3	\$10,130.1	\$9,049.6
Notes payable, line of credit and other financing arrangements, less current portion	\$6,521.5	\$580.3	\$592.4	\$687.4	\$1,060.8
Total Biogen Inc. shareholders' equity	\$9,372.8	\$10,809.0	\$8,620.2	\$6,961.5	\$6,425.5

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.

Our share of revenues from unconsolidated joint business reflects charges of \$50.0 million in 2011 and \$49.7 (1) million in 2013 for damages and interest awarded to Hoechst in Genentech's arbitration with Hoechst for RITUXAN.





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- 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
- (2) terminated, and we no longer record collaboration profit sharing expense. We recognized collaboration profit sharing expense of \$85.4 million, \$317.9 million and \$317.8 million during the years ended December 31, 2013, 2012 and 2011, respectively. In addition, product and total revenues includes net revenues related to sales of TECFIDERA.
- (3) Other revenues reflects a decrease in royalty revenues due to the December 2014 expiration of U.S. patent rights that gave rise to royalty payments related to ANGIOMAX.
- Included in total cost and expenses is a restructuring charge of \$93.4 million incurred in connection with our
- (4) corporate restructuring announced on October 21, 2015, which included the termination of certain pipeline programs and an 11% reduction in workforce.
- (5) Notes payable, line of credit and other financing arrangements, less current portion reflects the issuance of our senior unsecured notes for an aggregate principal amount of \$6.0 billion on September 15, 2015.
- Biogen Inc.'s shareholders' equity reflects a reduction in additional paid in capital and retained earnings totaling
- (6) \$5.0 billion resulting from the repurchase and retirement of our common stock under our 2015 Share Repurchase Program.

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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 patients for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for multiple sclerosis (MS), ELOCTATE for hemophilia A and ALPROLIX for hemophilia B, and FUMADERM for the treatment of severe plaque psoriasis. We also have a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, which entitles us to 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 other potential anti-CD20 therapies.

Our current revenues depend upon continued sales of our principal products. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales and growth of TECFIDERA as we continue to expand into additional markets. 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 and assets originating from our research and development efforts, and successful execution of external business 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 to explore the utility of our existing products in treating disorders beyond those currently approved in their labels. In addition to our innovative drug development efforts, we aim to leverage our manufacturing capabilities and scientific expertise to extend our mission to improve the lives of patients living with serious diseases through the development, manufacture and marketing of biosimilars through

Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics).

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were \$15.34 for 2015, representing an increase of 24.0% over the same period in 2014.

As described below under "Results of Operations," our income from operations for the year ended December 31, 2015, reflects the following:

Total revenues were \$10,763.8 million for 2015, representing an increase of 10.9% over the same period in 2014.

Product revenues, net totaled \$9,188.5 million for 2015, representing an increase of 12.0% over the same period in 2014. This increase was driven by a 25.1% increase in worldwide TECFIDERA revenues as well as revenue from our recent product additions PLEGRIDY, ELOCTATE and ALPROLIX, partially offset by a decrease in worldwide AVONEX and TYSABRI revenues. In addition, product revenues, net for 2015, compared to the same period in 2014, were negatively impacted by foreign currency exchange losses of \$388.1 million, partially offset by comparative net gains recognized under our foreign currency hedging program of \$166.3 million.

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Our share of RITUXAN and GAZYVA operating profits totaled \$1,339.2 million for 2015, representing an increase of 12.0% over the same period in 2014. This increase was primarily due to a 4% increase in U.S. product sales of RITUXAN and price increases.

Other revenues totaled \$236.1 million for 2015, representing a decrease of 22.5% from the same period in 2014. This decrease was driven by a 73.1% decrease in royalty revenues primarily due to the expiration of U.S. patent rights that gave rise to royalty payments related to ANGIOMAX, partially offset by a 47.6% increase in corporate partner revenues primarily due to an increase in contract manufacturing activities.

Total cost and expenses totaled \$5,872.8 million for 2015, representing an increase of 2.2% compared to the same period in 2014. This increase was driven by a 6.3% increase in research and development expense, a 5.9% increase in cost of sales, losses recognized on fair value remeasurement of contingent consideration as well as the recognition of a \$93.4 million charge related to our recent corporate restructuring. These increases were partially offset by a 21.9% decrease in the amortization of acquired intangible assets and a 5.3% decrease in selling, general and administrative expenses.

We generated \$3,716.1 million of net cash flows from operations for 2015, which were primarily driven by earnings. Cash, cash equivalents and marketable securities totaled approximately \$6,188.9 million as of December 31, 2015.

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion.

During the year ended December 31, 2015, we repurchased and retired approximately 16.8 million shares of common stock at a cost of \$5.0 billion under our share repurchase programs.

### Restructuring

On October 21, 2015, we announced a corporate restructuring, which includes the termination of certain pipeline programs and an 11% reduction in workforce. For additional information, please read Restructuring set forth below in this Management's Discussion and Analysis of Financial Condition and Results of Operations.

### Acquisitions

On February 12, 2015, we completed the acquisition of all of the outstanding stock of Convergence Pharmaceuticals (Convergence), a clinical-stage biopharmaceutical company with a focus on developing product candidates for neuropathic pain. For additional information related to this transaction, please read Note 2, Acquisitions to our consolidated financial statements included in this report.

### Collaborative and Other Relationships

On July 2, 2015, we announced a collaboration and license agreement to develop gene-based therapies for multiple ophthalmic diseases with Applied Genetic Technologies Corporation (AGTC).

On September 9, 2015, we announced an agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) to exclusively license amiselimod (MT-1303), a late stage experimental medicine with potential in multiple autoimmune indications. Amiselimod is an oral compound that targets the sphingosine 1-phosphate receptor.

For additional information related to these transactions, please read Note 19, Collaborative and Other Relationships 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.

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.

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



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## Results of Operations

## Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31,			% Change		
	2015	2014	2013	2015 compared to 2014	2014 compared to 2013	
<b>Product Revenues:</b>						
United States	\$6,545.8	\$5,566.7	\$3,581.0	17.6	%	55.5 %
Rest of world	2,642.7	2,636.7	1,961.3	0.2	%	34.4 %
Total product revenues	9,188.5	8,203.4	5,542.3	12.0	%	48.0 %
Unconsolidated joint business revenues	1,339.2	1,195.4	1,126.0	12.0	%	6.2 %
Other revenues	236.1	304.5	263.9	(22.5)	)%	15.4 %
Total revenues	\$10,763.8	\$9,703.3	\$6,932.2	10.9	%	40.0 %

## Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31,			% Change		
	2015	2014	2013	2015 compared to 2014	2014 compared to 2013	
<b>Multiple Sclerosis:</b>						
TECFIDERA	\$3,638.4	\$2,909.2	\$876.1	25.1	%	232.1 %
Interferon*	2,968.7	3,057.6	3,005.5	(2.9)	)%	1.7 %
TYSABRI	1,886.1	1,959.5	1,526.5	(3.7)	)%	28.4 %
FAMPYRA	89.7	80.2	74.0	11.8	%	8.4 %
<b>Hemophilia:</b>						
ELOCTATE	319.7	58.4	—	447.4	%	**
ALPROLIX	234.5	76.0	—	208.6	%	**
<b>Other product revenues:</b>						
FUMADERM	51.4	62.5	60.2	(17.8)	)%	3.8 %
Total product revenues	\$9,188.5	\$8,203.4	\$5,542.3	12.0	%	48.0 %

\* Interferon includes AVONEX and PLEGRIDY.

\*\* Percentage not meaningful.

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Multiple Sclerosis (MS)

TECFIDERA

For 2015 compared to 2014, the increase in U.S. TECFIDERA revenues was primarily due to an increase 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 2014 compared to 2013, the increase in U.S. TECFIDERA revenues was primarily due to increases in unit sales volume.

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 additional 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 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.

For 2014 compared to 2013, rest of world TECFIDERA revenues increased as sales in Germany began in the first quarter of 2014.

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.

While we continue to see a strong uptake of TECFIDERA in newly launched territories, total market growth and patient switch rates in our maturing markets, such as the U.S. and Germany, have returned to historical averages for MS.

Interferon

AVONEX

For 2015 compared to 2014, the decrease in U.S. AVONEX revenues was primarily due to a decrease in unit sales volume of 17%, which was attributable in part to patients transitioning to PLEGRIDY and oral MS therapies, including TECFIDERA, partially offset by gross price increases.

For 2014 compared to 2013, the increase in U.S. AVONEX revenues was primarily due to price increases, partially offset by a decrease in unit sales volume of 10%, which was attributable in part to patients transitioning to PLEGRIDY and oral MS therapies, including TECFIDERA.

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For 2015 compared to 2014, the decrease in rest of world AVONEX revenues was primarily due to a decrease in unit sales volume of 11% primarily in Europe, attributable to patients transitioning to PLEGRIDY and oral MS therapies, including TECFIDERA. Rest of world AVONEX revenues for 2015 compared to 2014, were 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.

For 2014 compared to 2013, the decrease in rest of world AVONEX revenues was due to a 7% decrease in unit sales volume in Europe primarily attributable to patients transitioning to oral therapies including TECFIDERA, partially offset by a 6% increase in unit demand in the emerging markets region. Rest of world AVONEX revenue for 2014 compared to 2013 also reflects the negative impact of foreign currency exchange rate changes experienced in 2014, partially offset by gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program.

We expect that AVONEX revenues will continue to decline as a result of competition from our own products, including PLEGRIDY and TECFIDERA, and other MS therapies.

**PLEGRIDY**

For 2015 compared to 2014, the increase in PLEGRIDY revenues was primarily due to increases in unit sales volume. Sales of PLEGRIDY began in the E.U. and the U.S. in the third and fourth quarters of 2014, respectively.

We expect that PLEGRIDY revenues will increase as PLEGRIDY becomes commercially available in additional markets and as patients transition to PLEGRIDY from AVONEX and other therapies.

**TYSABRI**

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 2014 compared to 2013, the increase in U.S. TYSABRI revenues was primarily due to price increases and our recognition, starting in April 2013, of 100% of net revenues on TYSABRI in-market sales due to our acquisition of the remaining rights to TYSABRI from Elan, partially offset by a 4% decrease in unit sales volume.

Based on data reported by Elan for 2013 and our sales to third-party customers, total U.S. TYSABRI in-market sales were \$958.3 million. For 2014 compared to 2013, the increase in U.S. TYSABRI in-market sales was primarily due to price increases, partially offset by patients transitioning to oral MS therapies, including TECFIDERA.

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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.

For 2014 compared to 2013, the increase in rest of world TYSABRI revenues was primarily due to the recognition of \$53.5 million of revenue previously deferred in Italy relating to the pricing agreement with AIFA as discussed below, volume increases in Europe of 10% and in our emerging markets region of 18% and a favorable net price in Germany as the mandatory rebate percentage was reduced. Rest of world TYSABRI revenue for 2014 compared to 2013 also reflects the negative impact of foreign currency exchange rate changes experienced in 2014, partially offset by gains recognized in relation to the settlement of certain cash flow hedge instruments under our foreign currency hedging program.

We remain in discussions with AIFA about a resolution relating to a claim that sales of TYSABRI in Italy exceeded a reimbursement limit established pursuant to a Price Determination Resolution granted by AIFA in December 2006 for the period from mid-February 2009 through January 2013. We could recognize approximately EUR40 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 expect that TYSABRI revenues will continue to face competition from additional treatments for MS and certain other pipeline products, including ZINBRYTA and ocrelizumab.

Hemophilia

ELOCTATE

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

ALPROLIX

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



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We expect continued growth with ELOCTATE as there remains a significant portion of the patient population that can benefit from long-acting therapies. We also expect moderating patient additions for ALPROLIX.

## Unconsolidated Joint Business Revenues

Revenues from unconsolidated joint business are summarized as follows:

\*Biogen's share of pre-tax profits includes the reimbursement of selling and development expenses.

## 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.:

(In millions)	For the Years Ended		
	December 31,		
	2015	2014	2013
Product revenues, net	\$3,847.9	\$3,556.6	\$3,425.8
Cost and expenses	673.7	771.1	615.9
Pre-tax profits in the U.S.	\$3,174.2	\$2,785.5	\$2,809.9
Biogen's share of pre-tax profits*	\$1,269.8	\$1,117.1	\$1,087.3

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 price increases, partially offset by higher discounts and allowances.

For 2014 compared to 2013, the increase in U.S. product revenues was primarily due to price increases and an increase in RITUXAN unit sales volume, partially offset by the 2013 recognition of \$94.9 million in net revenues resulting from the July 2013 issuance by the Department of Health and Human Services of its final rule on the Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program. The issuance of the final rule by the Department of Health and Human Services did not have an impact on the amount we recorded as revenues from unconsolidated joint business in our consolidated statements of income because, through June 30, 2013, we had been increasing our share of profits in the U.S. to reflect our interpretation of the proposed 340B rule. The final rule was consistent with our prior interpretation.

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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Collaboration costs and expenses for 2014 compared to 2013 increased primarily due to the recognition of \$53.9 million of additional BPD fee expense, as discussed above, as well as GAZYVA sales and marketing and research and development expenses. Upon the first marketing approval of GAZYVA by the FDA in the U.S., we began recognizing all activity, including sales and marketing and research and development expenses related to the GAZYVA program in unconsolidated joint business in our consolidated statements of income. Prior to its first regulatory approval, we recognized our share of GAZYVA development and commercialization expenses as research and development expense and selling, general and administrative expense, respectively, in our consolidated statements of income. We expect our share of RITUXAN pre-tax profits in the U.S. to decrease to 39% from 40% if GAZYVA is approved by the FDA in RITUXAN-refractory indolent non-Hodgkin's lymphoma. For additional information related to our collaboration with Genentech, including information regarding the pre-tax profit sharing formula and its impact on future unconsolidated joint business revenues, 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 consists of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenue on sales outside the U.S. and Canada. For 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 and patent expirations.

For 2014 compared to 2013, revenue on sales in the rest of world for RITUXAN increased primarily due to the prior year recognition of a \$41.2 million charge for damages and interest awarded to Hoechst in its arbitration with Genentech.

The royalty period for sales in the rest of world is 11 years from the first commercial sale of such product on a country-by-country basis. The royalty periods for the substantial portion of the royalty-bearing sales in the rest of world markets expired during 2012 and 2013. We expect future revenue on sales of RITUXAN in the rest of world will be limited to our share of pre-tax co-promotion profits in Canada.

### Other Revenues

#### 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 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.

For 2014 compared to 2013, royalty revenues decreased due to a decrease in the net worldwide sales of ANGIOMAX subject to royalty payments.

#### Corporate Partner Revenues

Our corporate partner revenues include amounts earned under contract manufacturing agreements, including revenues related to our arrangements with Samsung Bioepis and other strategic partners.

For 2015 compared to 2014, the increase in corporate partner revenues was primarily due to higher contract manufacturing revenue and the start of product shipments to Sobi in relation to our collaboration agreement as Sobi has assumed final development and commercialization of ALPROLIX and ELOCTATE in Europe, North Africa, Russia, and certain markets in the Middle East.

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For 2014 compared to 2013, the increase in corporate partner revenues was primarily due to higher contract manufacturing revenue and increased revenue from our biosimilar arrangements, partially offset by lower revenue associated with our Zevalin supply agreement. Zevalin is a program we sold in 2007 but continued to manufacture in accordance with the amendment to our Zevalin supply agreement. We completed our manufacturing obligation under this amendment in the third quarter of 2014.

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

Reserves for Discounts and Allowances

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

Reserves established for these discounts and allowances 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). These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, 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 same the period. To date, such adjustments have not been significant.

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

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Reserves for discounts and allowances increased in each of the past three years due to increased sales associated with launches of TECFIDERA, PLEGRIDY, ELOCTATE and ALPROLIX. In addition, we began recognizing reserves for discounts and allowances for U.S. TYSABRI revenue in the second quarter of 2013 following our acquisition of all remaining rights to TYSABRI from Elan.

**Discounts**

Discounts include trade term discounts and wholesaler incentives.

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

For 2014 compared to 2013, the increase in discounts was primarily driven by our recent product additions.

**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 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.

For 2014 compared to 2013, the increase in contractual adjustments was primarily due to our recent product additions, increases in managed care rebates, U.S. governmental rebates and allowances as a result of price increases and additional managed care contracts.

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

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

For 2014 compared to 2013, return reserves increased primarily due to our acquisition of all remaining rights to TYSABRI, the start of commercial sales of TECFIDERA and increased return rates for prior year AVONEX shipments.

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:

(In millions, except percentages)	For the Years Ended December 31,			% Change			
	2015	2014	2013	2015 compared to 2014	2014 compared to 2013		
Cost of sales, excluding amortization of acquired intangible assets	\$1,240.4	\$1,171.0	\$857.7	5.9	% 36.5		%
Research and development	2,012.8	1,893.4	1,444.1	6.3	% 31.1		%
Selling, general and administrative	2,113.1	2,232.3	1,712.1	(5.3)	)% 30.4		%
Amortization of acquired intangible assets	382.6	489.8	342.9	(21.9)	)% 42.8		%
Restructuring charges	93.4	—	—	**	**		
Collaboration profit sharing	—	—	85.4	**	(100.0)		)%
(Gain) loss on fair value remeasurement of contingent	30.5	(38.9	) (0.5	) (178.4	)% **		

consideration

Total cost and expenses

\$5,872.8

\$5,747.7

\$4,441.6

2.2

% 29.4

%

\*\* Percentage not meaningful.

59

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

Product Cost of Sales

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. For 2014 compared to 2013, the increase in product cost of sales was driven by higher unit sales volume, including due to recent product launches and our contract and biosimilars manufacturing arrangements.

Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons totaled \$41.9 million, \$50.6 million, and \$47.3 million for the years ended December 31, 2015, 2014, and 2013, respectively.

Royalty Cost of Sales

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 the contingent payments due to Perrigo, please read Note 2, Acquisitions to our consolidated financial statements included in this report.

For 2014 compared to 2013, the increase in royalty cost of sales was primarily driven by our acquisition of all remaining rights to TYSABRI, partially offset by the expiration of a third-party royalty related to AVONEX.

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 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 nusinersen program for the treatment of SMA, partially offset by a decrease in costs related to ZINBRYTA, which is in registration stage, 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 Raxatrigine program for trigeminal neuralgia (TGN). These increases were partially offset by a decrease in costs incurred in connection with the nusinersen program for the treatment of SMA as the program advanced to a late stage program during the first quarter of 2015.

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For 2014 compared to 2013, the increase in research and development expense was primarily related to increases in costs incurred in connection with our early stage programs, milestone and upfront expenses, research and discovery and marketed products, partially offset by a decrease in costs incurred in connection with our late stage programs. Research and development expense related to our early stage programs increased in 2014 compared to 2013 primarily due to costs incurred in the advancement of our Anti-LINGO program in MS, our aducanumab program for Alzheimer's disease, the BAN2401 program for Alzheimer's disease related to our collaboration agreement with Eisai and an increase in spending incurred in connection with our development of STX-100 for the treatment of idiopathic pulmonary fibrosis.

The increase in spending associated with marketed products in 2014 compared to 2013 is related to ALPROLIX, ELOCTATE and PLEGRIDY, which were approved in 2014, and costs associated with TYSABRI, which previously were shared with Elan prior to our acquisition of all remaining rights to TYSABRI from Elan in April 2013.

The decrease in spending associated with our late stage product candidates in 2014 compared to 2013 was driven by approvals of ALPROLIX, ELOCTATE and PLEGRIDY in 2014 and GAZYVA in the fourth quarter of 2013, partially offset by costs incurred in the development of nusinersen for the treatment of SMA.

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, the nusinersen program, the amiselimod program and our Raxatrigine program.

Milestone and Upfront Expenses included in Research and Development Expense

Research and development expense for 2015 includes \$60.0 million recorded upon entering into our collaboration with MTPC, \$48.1 million recorded upon entering into our collaboration with 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, \$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.

Included in total research and development expense in 2013 were charges of \$75.0 million related to an upfront payment made to Ionis in September 2013 upon entering into a six year research collaboration with Ionis under which we both agreed to perform research and then seek to develop and commercialize antisense or other therapeutics for the treatment of neurological disorders, \$36.0 million related to upfront and milestone payments made to Samsung Bioepis in December 2013 upon entering into a development and commercialization agreement and a \$10.0 million milestone payment made to Ionis related to the selection and advancement of IONIS-DMPK<sub>Rx</sub> to treat myotonic dystrophy (DM1).

These payments are classified as research and development expense as the programs they relate to have not achieved regulatory approval.

Selling, General and Administrative

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.

For 2014 compared to 2013, the increase in selling, general and administrative expenses was primarily driven by costs associated with developing commercial capabilities for our recent product launches in 2014 along with an increase in sales and marketing activities in support of our MS products. The successful commercialization of new and potential new products requires significant investments, such as sales force build and





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development, training, marketing, and other related activities. The increase in selling, general, and administrative expense was also driven by an increase in corporate giving and the recognition of \$21.9 million of additional 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. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of either product.

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 2014 compared to 2013, the change in amortization of acquired intangible assets was primarily driven by a \$60.2 million increase in amortization of acquired and in-licensed rights and patents as we recognized a full year of expense related to our TYSABRI rights in 2014 versus nine months of expense in 2013, total impairment charges of \$50.9 million related to one of our out-licensed patents and one of our IPR&D intangible assets, and lower expected lifetime revenues of AVONEX.

Our most recent long range planning cycle was completed in the third quarter of 2015. Based upon this analysis, the estimated future amortization of acquired intangible assets is expected to be as follows:

(In millions)	As of December 31, 2015
2016	\$346.4
2017	318.6
2018	291.0
2019	275.1
2020	269.1
Total	\$1,500.2

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 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. Impairment charges related to our intangible assets during 2015 and 2013 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.



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## IPR&amp;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 idiopathic pulmonary fibrosis (IPF) and neuropathic pain, such as TGN, are highly competitive and can be affected by rapid changes to the market. There can be no assurance that we will be able to successfully develop STX-100 for the treatment of IPF or Raxatrigine for the treatment of TGN or that a successfully developed therapy will be able to secure sufficient pricing in a competitive market. We review amounts 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, 2015 resulted in no impairments.

## Restructuring Charges

On October 21, 2015, we announced a corporate restructuring, which includes the termination of certain pipeline programs and an 11% reduction in workforce. These changes are expected to reduce the current annual run rate of operating expenses by approximately \$250 million.

We expect to reinvest the savings resulting from the restructuring to support the advancement of our high potential pipeline candidates, including our programs in Alzheimer's disease, Anti-LINGO for MS, nusinersen for SMA, Raxatrigine and amiselimod, an oral S1P modulator, and to support key commercial activities, including TECFIDERA. We also have discontinued several programs, including our Phase 3 program for TECFIDERA in secondary progressive MS (SPMS), the development of anti-TWEAK in lupus nephritis, and certain activities in immunology and fibrosis research.

We anticipate making cash payments totaling approximately \$120 million under this program, which includes approximately \$15.9 million related to previously accrued 2015 incentive compensation, for a total net expected restructuring charge of \$105 million. These amounts will be substantially incurred and paid by the end of 2016. We recognized \$93.4 million of these charges during the fourth quarter of 2015, of which \$86.2 million was related to our workforce reduction and \$7.2 million was related to the pipeline program terminations.

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

(In millions)	Workforce Reduction	Pipeline Programs	Total
Restructuring charges incurred during the fourth quarter of 2015	\$86.2	\$7.2	\$93.4
Previously accrued incentive compensation	15.9	—	15.9
Reserves established	102.1	7.2	109.3
Amounts paid through December 31, 2015	(68.4	) (3.6	) (72.0
Restructuring reserve as of December 31, 2015	\$33.7	\$3.6	\$37.3

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Collaboration Profit Sharing

Upon the closing of our acquisition of all remaining rights to TYSABRI, our collaboration agreement with Elan was terminated, and we no longer record collaboration profit sharing. Collaboration profit sharing previously included the portion of rest of world net operating profits to be shared with Elan under the terms of our collaboration agreement for the development, manufacture and commercialization of TYSABRI. The amount also included the reimbursement for our portion of third-party royalties paid by Elan on behalf of the collaboration relating to rest of world sales. For additional information about this collaboration, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in this report.

(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 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.

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Other Income (Expense), Net

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 (2015 Senior Notes), higher foreign exchange losses and a decrease in net gains recognized on the sale of our strategic investments and marketable securities. For additional information, please read Note 17, Other Consolidated Financial Statement Detail, to our consolidated financial statements included in this report.

For 2014 compared to 2013, the change in other income (expense), net was due to lower non-income based state taxes, an increase in interest income due to higher average cash, cash equivalents and marketable securities balances, lower foreign exchange losses and decreased interest expense as we repaid our 6.0% Senior Notes in March 2013, partially offset by lower gains on investments.

We expect interest expense will continue to increase as a result of our issuance of the 2015 Senior Notes. For additional information related to our 2015 Senior Notes, please read Note 11, Indebtedness, to our consolidated financial statements included in this report.

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 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, described below.

Our effective tax rate for 2014 compared to 2013 increased primarily as a result of the absence of a benefit related to the 2013 change in our uncertain tax position related to our U.S. federal manufacturing deduction and our unconsolidated joint business described below under "Accounting for Uncertainty in Income Taxes", lower current year expenses eligible for the orphan drug credit and a lower relative manufacturing deduction due to unqualified products, partially offset by a higher percentage of our 2014 income being earned outside the U.S.

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Accounting for Uncertainty in Income Taxes

During 2013, we received updated technical guidance from the IRS concerning the calculation of our U.S. federal manufacturing deduction and overall tax classification of our unconsolidated joint business for the current and prior year filings. Based on this guidance we reevaluated the level of our unrecognized benefits related to uncertain tax positions and recorded a \$49.8 million income tax benefit. This benefit was for a previously unrecognized position and related to years 2005 through 2012. We recorded an offsetting expense of \$11.3 million for non-income based state taxes, which was recorded in other income (expense) in our consolidated statements of income. This uncertain tax position was then remeasured in 2015 resulting in a \$27.0 million benefit related to the state tax impacts of the IRS technical guidance.

For more information on our uncertain tax positions and income tax rate reconciliation for 2015, 2014 and 2013, please read Note 16, Income Taxes to our consolidated financial statements included in this report.

Share in 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 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 2014 compared to 2013, the decrease in equity in loss of investee, net of tax was due to the joint venture's clinical trial activity, partially offset by our recognition of a gain as Samsung Bioepis secured additional equity financing from Samsung Biologics from a financing in which we did participate.

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 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 SubOne AG (Neurimmune), partially offset by increases in research expenses attributable to noncontrolling interests.

For 2014 compared to 2013, the change in net income attributable to noncontrolling interests, net of tax, was related to a \$10.0 million milestone payment made to Neurimmune and the consolidation of the research activities of Ataxion, Inc.

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,		% Change	
	2015	2014	2015	compared to 2014
Financial assets:				
Cash and cash equivalents	\$1,308.0	\$1,204.9	8.6	%
Marketable securities — current	2,120.5	640.5	231.1	%
Marketable securities — non-current	2,760.4	1,470.7	87.7	%
Total cash, cash equivalents and marketable securities	\$6,188.9	\$3,316.0	86.6	%
Borrowings:				
Current portion of notes payable and other financing arrangements	\$4.8	\$3.1	54.8	%
Notes payable and other financing arrangements	6,521.5	580.3	**	
Total borrowings	\$6,526.3	\$583.4	**	
Working Capital:				
Current assets	\$6,700.3	\$4,535.0	47.7	%
Current liabilities	(2,577.7	) (2,218.1	) 16.2	%
Total working capital	\$4,122.6	\$2,316.9	77.9	%

\*\* Percentage not meaningful.



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

\$5,930.5 million in proceeds from the issuance of our 2015 Senior Notes;  
\$3,716.1 million in net cash flows provided by operating activities;  
\$5.0 billion used for share repurchases;  
\$1,674.8 million in total 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;  
\$184.0 million used for upfront payments made to AGTC and MTPC; and  
\$60.0 million milestone payment made to Neurimmune.

For the year ended December 31, 2014, certain significant cash flows were as follows:

\$2,942.1 million in net cash flows provided by operating activities;  
\$1,163.2 million in total payments for income taxes;  
\$886.8 million used for share repurchases;  
\$375.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;  
\$287.8 million used for purchases of property, plant and equipment; and  
\$286.3 million used for upfront and milestone payments in collaborative arrangements.

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### Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. On September 15, 2015, we issued our 2015 Senior Notes for an aggregate principal amount of \$6.0 billion. 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 and proceeds received from our 2015 Senior Notes. 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, 2015, approximately \$3.5 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 May 2015, our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2015 Share Repurchase Program). As of December 31, 2015, the 2015 Share Repurchase Program was completed and we repurchased and retired approximately 16.8 million shares of common stock at a cost of \$5.0 billion during the year ended December 31, 2015.

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. During 2014, we purchased approximately 2.9 million shares of common stock at a cost of \$886.8 million under our 2011 Share Repurchase Program. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program during the year ended December 31, 2015 and have approximately 1.3 million shares remaining available for repurchase under this authorization.

### 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 increase in cash, cash equivalents and marketable securities at December 31, 2015 from December 31, 2014 is primarily due to the issuance of our 2015 Senior Notes and net cash flows provided by operating activities, offset by purchases of our common stock, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, net purchases of property, plant and equipment and the acquisition of Convergence.



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Borrowings

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion, consisting of the following:

\$1.5 billion of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;

\$1.0 billion of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;

\$1.75 billion of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and

\$1.75 billion of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

In addition to the 2015 Senior Notes, we have \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 that were originally priced at 99.184% of par.

The discounts are amortized as additional interest expense over the period from issuance through maturity.

In August 2015, we entered into a \$1.0 billion, 5-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, 2015, we had no outstanding borrowings and were in compliance with all covenants under this facility.

In connection with our 2006 distribution agreement with Fumedica, we issued notes totaling 61.4 million Swiss Francs which were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a carrying value of 8.9 million Swiss Francs (\$9.0 million) and 11.6 million Swiss Francs (\$11.7 million) as of December 31, 2015 and 2014, respectively.

For a summary of the fair values of our outstanding borrowings as of December 31, 2015 and 2014, 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. In accordance with ASU No. 2015-17, at December 31, 2015 we reclassified \$137.1 million of our deferred tax assets classified as current to noncurrent and \$1.6 million of our deferred tax liabilities classified as current to noncurrent in our December 31, 2014 consolidated balance sheet, to conform our prior year presentation to our current year presentation. For additional information related to ASU No. 2015-17, please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements to our consolidated financial statements included in this report.

The increase in working capital at December 31, 2015 from December 31, 2014 reflects an increase in total current assets of \$2,165.3 million, partially offset by an increase in current liabilities of \$359.6 million. The increase in total current assets was primarily driven by an increase in cash, cash equivalents and marketable securities due to the issuance of our 2015 Senior Notes and an increase in cash from operating activities, partially offset by purchases of our common stock. The increase in total current liabilities primarily resulted from an increase in taxes payable and an increase in accrued expenses and other due to increases in the amount of short-term contingent consideration expected to be paid and revenue-related reserves for discounts and allowances.

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## Cash Flows

The following table summarizes our cash flow activity:

(In millions, except percentages)	For the Years Ended December 31,			% Change		
	2015	2014	2013	2015 compared to 2014	2014 compared to 2013	
Net cash flows provided by operating activities	\$3,716.1	\$2,942.1	\$2,345.1	26.3	% 25.5	%
Net cash flows used in by investing activities	\$(4,553.6)	\$(1,543.0)	\$(1,604.7)	195.1	% (3.8)	)%
Net cash flows provided by (used in) financing activities	\$986.4	\$(755.9)	\$(716.5)	(230.5)	)% 5.5	%

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

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.

For 2014 compared to 2013, the increase in cash provided by operating activities was primarily driven by higher net income, partially offset by an increase in accounts receivable resulting from increased product revenue.

## Investing Activities

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.

For 2014 compared to 2013, the decrease in net cash flows used in investing activities was primarily due to the prior year acquisition of all remaining rights to TYSABRI from Elan and a decrease in the net purchases of marketable securities, partially offset by the payment of contingent consideration to former shareholders of Fumapharm AG.

## Financing Activities

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.

For 2014 compared to 2013, the increase in net cash flows used in financing activities was primarily due to an increase in the amount of common stock we repurchased, partially offset by the prior year repayment of the aggregate principal amount of our 6.0% Senior Notes.

## Contractual Obligations and Off-Balance Sheet Arrangements

## Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2015, 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.

(In millions)	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Capital leases (1)	\$20.7	\$2.0	\$18.7	\$—	\$—
Non-cancellable operating leases (2), (3)	672.3	69.9	131.3	117.3	353.8
Long-term debt obligations (4)	10,563.7	282.6	1,095.9	1,983.3	7,201.9
Purchase and other obligations (5)	380.9	258.5	79.4	24.0	19.0
Defined benefit obligation	70.1	—	—	—	70.1
Total contractual obligations	\$11,687.0	\$611.0	\$1,306.6	\$2,124.6	\$7,644.8

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(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.

(3) Obligations are presented net of sublease income expected to be received for the vacated portion of our Weston, Massachusetts facility. For additional information, please read Note 10, Property, Plant and Equipment 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 and also includes approximately \$126.4 million in contractual commitments for the construction of a biologics manufacturing facility in Solothurn, Switzerland and approximately \$14.7 million related to the fair value of net liabilities on derivative contracts.

**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, 2015, we have approximately \$45.4 million of net liabilities associated with uncertain tax positions.

**Other Funding Commitments**

As of December 31, 2015, 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 \$25.0 million on our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2015. We have approximately \$559.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2015.

**Contingent Development, Regulatory and Commercial Milestone Payments**

Based on our development plans as of December 31, 2015, we could make potential future milestone payments to third parties of up to approximately \$2.8 billion as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2015, 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 \$150.0 million of milestone payments in 2016, provided various development, regulatory or commercial milestones are achieved.

**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.

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### Contingent Consideration related to Business Combinations

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

As the acquisitions of Convergence, Stromedix and BIN, formerly Panima Pharmaceuticals AG, occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately \$1.3 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.

#### BIH

In connection with our acquisition of BIH, formerly Syntonix, in 2007, we agreed to pay up to an additional \$80.0 million if certain milestone events associated with the development of BIH's lead product, ALPROLIX are achieved. The final \$20.0 million contingent payment will occur if, prior to the tenth anniversary of the closing date, a marketing authorization is granted by the EMA for ALPROLIX. This payment will be accounted for as an increase to intangible assets if achieved. In June 2015, the EMA validated our MAA for ALPROLIX for the treatment of hemophilia B.

#### 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 2015, we paid \$850.0 million in contingent payments as we reached the \$4.0 billion, \$5.0 billion and \$6.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2014, second quarter of 2015 and third quarter of 2015, respectively, and accrued \$300.0 million upon reaching \$7.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2015.

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. 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.

#### 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, 2015, 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.

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### 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.

#### Product Revenues

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery. The timing of distributor orders and shipments can cause variability in earnings.

#### Reserves for Discounts and Allowances

We establish reserves for trade term discounts, wholesaler incentives, Medicaid rebates, copay, VA and PHS discounts, managed care rebates, product returns and other governmental rebates or applicable 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. 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. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the 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 Unconsolidated Joint Business

Revenues from unconsolidated joint business consists 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) revenue on sales in the rest of world for RITUXAN, which consist of our share of pre-tax co-promotion profits in Canada and royalty revenue on sales outside the U.S. and Canada by the Roche Group and its sublicensees. Pre-tax co-promotion profits on RITUXAN are calculated and paid to us by Genentech in the U.S. and by the Roche Group in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian net sales to third-party customers less the cost 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 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. Additionally, 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 receivables 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 large 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 long 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.



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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.

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.

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, however, 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.

Impairment charges related to our long-lived assets during 2015 and 2013 were insignificant. For additional information on the impairment charges related to our long-lived assets during 2014, please read Note 6, Intangible Assets and Goodwill to our consolidated financial statements included in this report.

##### 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 2015, 2014 and 2013, 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 performance 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 within the consolidated statement 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 the consolidated statement of income when the asset transferred is sold to a third-party or otherwise recovered through amortization of the asset's remaining economic life. If the asset transferred becomes impaired, for example through the discontinuation of a research program, we will expense any remaining deferred charge or prepaid tax. As of December 31, 2015, the total deferred charges and prepaid taxes were \$697.9 million.



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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, 2015, our non-U.S. subsidiaries’ undistributed foreign earnings included in consolidated retained earnings and other basis differences aggregated to approximately \$6.0 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 \$1.5 billion to \$2.0 billion as of December 31, 2015.

**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. Further, we only enter into contracts with counterparties that have at least an "A" (or equivalent) credit rating. 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, Switzerland, Denmark, Japan, Australia, New Zealand and Central and South America. In addition, we receive royalty revenues based on sales of 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, Japanese yen and Australian dollar.



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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 the 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 the 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.

**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, 2015 and 2014, 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 \$185.0 million and \$160.0 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 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, 2015 and 2014, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately \$43.0 million and \$14.5 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.

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, 2015, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately \$6.8 million.



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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 and 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 and other government entities. We monitor the financial performance and creditworthiness of our large 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, 2015 and 2014, respectively. 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-71 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, 2015. 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, 2015 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, 2015. 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, 2015, 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, 2015 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

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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](http://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,” “Stock Ownership - Section 16(a) Beneficial Ownership Reporting Compliance” and “Miscellaneous - Stockholder Proposals” contained in the proxy statement for our 2016 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 and Related Information” and “Corporate Governance” contained in the proxy statement for our 2016 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 2016 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” contained in the proxy statement for our 2016 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 2016 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:

	Page Number
Financial Statements	
Consolidated Statements of Income	F-2
Consolidated Statements of Comprehensive Income	F-3
Consolidated Balance Sheets	F-4
Consolidated Statements of Cash Flows	F-5
Consolidated Statements of Equity	F-6
Notes to Consolidated Financial Statements	F-9
Report of Independent Registered Public Accounting Firm	F-71

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/ GEORGE A. SCANGOS  
George A. Scangos  
Chief Executive Officer

Date: February 3, 2016

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Pursuant to the requirements 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/ GEORGE A. SCANGOS George A. Scangos	Director and Chief Executive Officer (principal executive officer)	February 3, 2016
/S/ PAUL J. CLANCY Paul J. Clancy	Executive Vice President, Finance and Chief Financial Officer (principal financial officer)	February 3, 2016
/S/ GREGORY F. COVINO Gregory F. Covino	Vice President, Finance, Chief Accounting Officer (principal accounting officer)	February 3, 2016
/S/ STELIOS PAPADOPOULOS Stelios Papadopoulos	Director and Chairman of the Board of Directors	February 3, 2016
/S/ ALEXANDER J. DENNER Alexander J. Denner	Director	February 3, 2016
/S/ CAROLINE D. DORSA Caroline D. Dorsa	Director	February 3, 2016
/S/ NANCY L. LEAMING Nancy L. Leaming	Director	February 3, 2016
/S/ RICHARD C. MULLIGAN Richard C. Mulligan	Director	February 3, 2016
/S/ ROBERT W. PANGIA Robert W. Pangia	Director	February 3, 2016
/S/ BRIAN S. POSNER Brian S. Posner	Director	February 3, 2016
/S/ ERIC K. ROWINSKY Eric K. Rowinsky	Director	February 3, 2016
/S/ LYNN SCHENK Lynn Schenk	Director	February 3, 2016
/S/ STEPHEN A. SHERWIN Stephen A. Sherwin	Director	February 3, 2016

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BIOGEN INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Statements of Comprehensive Income	F-3
Consolidated Balance Sheets	F-4
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BIOGEN INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF INCOME  
 (In millions, except per share amounts)

	For the Years Ended December 31,		
	2015	2014	2013
Revenues:			
Product, net	\$9,188.5	\$8,203.4	\$5,542.3
Unconsolidated joint business	1,339.2	1,195.4	1,126.0
Other	236.1	304.5	263.9
Total revenues	10,763.8	9,703.3	6,932.2
Cost and expenses:			
Cost of sales, excluding amortization of acquired intangible assets	1,240.4	1,171.0	857.7
Research and development	2,012.8	1,893.4	1,444.1
Selling, general and administrative	2,113.1	2,232.3	1,712.1
Amortization of acquired intangible assets	382.6	489.8	342.9
Restructuring charges	93.4	—	—
Collaboration profit sharing	—	—	85.4
(Gain) loss on fair value remeasurement of contingent consideration	30.5	(38.9	) (0.5
Total cost and expenses	5,872.8	5,747.7	4,441.6
Gain on sale of rights	—	16.8	24.9
Income from operations	4,891.0	3,972.4	2,515.5
Other income (expense), net	(123.7	) (25.8	) (34.9
Income before income tax expense and equity in loss of investee, net of tax	4,767.3	3,946.6	2,480.6
Income tax expense	1,161.6	989.9	601.0
Equity in loss of investee, net of tax	12.5	15.1	17.2
Net income	3,593.2	2,941.6	1,862.3
Net income attributable to noncontrolling interests, net of tax	46.2	6.8	—
Net income attributable to Biogen Inc.	\$3,547.0	\$2,934.8	\$1,862.3
Net income per share:			
Basic earnings per share attributable to Biogen Inc.	\$15.38	\$12.42	\$7.86
Diluted earnings per share attributable to Biogen Inc.	\$15.34	\$12.37	\$7.81
Weighted-average shares used in calculating:			
Basic earnings per share attributable to Biogen Inc.	230.7	236.4	236.9
Diluted earnings per share attributable to Biogen Inc.	231.2	237.2	238.3

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,		
	2015	2014	2013
Net income attributable to Biogen Inc.	\$3,547.0	\$2,934.8	\$1,862.3
Other comprehensive income:			
Unrealized gains (losses) on securities available for sale:			
Unrealized gains (losses) recognized during the period, net of tax	(1.7	) 0.4	11.8
Less: reclassification adjustment for (gains) losses included in net income, net of tax	1.3	(6.4	) (10.4
Unrealized gains (losses) on securities available for sale, net of tax	(0.4	) (6.0	) 1.4
Unrealized gains (losses) on cash flow hedges:			
Unrealized gains (losses) recognized during the period, net of tax	110.8	101.7	(26.7
Less: reclassification adjustment for (gains) losses included in net income, net of tax	(172.3	) (6.3	) 13.7
Unrealized gains (losses) on cash flow hedges, net of tax	(61.5	) 95.4	(13.0
Unrealized gains (losses) on pension benefit obligation	(6.2	) (12.0	) 2.1
Currency translation adjustment	(96.4	) (109.2	) 37.1
Total other comprehensive income (loss), net of tax	(164.5	) (31.8	) 27.6
Comprehensive income attributable to Biogen Inc.	3,382.5	2,903.0	1,889.9
Comprehensive income attributable to noncontrolling interests, net of tax	46.2	6.8	—
Comprehensive income	\$3,428.7	\$2,909.8	\$1,889.9

See accompanying notes to these consolidated financial statements.

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Table of ContentsBIOGEN INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

(In millions, except per share amounts)

	As of December 31,	
	2015	2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,308.0	\$ 1,204.9
Marketable securities	2,120.5	640.5
Accounts receivable, net	1,227.0	1,292.4
Due from unconsolidated joint business, net	314.5	283.4
Inventory	893.4	804.0
Other current assets	836.9	309.8
Total current assets	6,700.3	4,535.0
Marketable securities	2,760.4	1,470.7
Property, plant and equipment, net	2,187.6	1,765.7
Intangible assets, net	4,085.1	4,028.5
Goodwill	2,663.8	1,760.2
Investments and other assets	1,107.6	754.6
Total assets	\$ 19,504.8	\$ 14,314.7
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Current portion of notes payable and other financing arrangements	\$ 4.8	\$ 3.1
Taxes payable	208.7	168.1
Accounts payable	267.4	229.2
Accrued expenses and other	2,096.8	1,817.7
Total current liabilities	2,577.7	2,218.1
Notes payable and other financing arrangements	6,521.5	580.3
Long-term deferred tax liability	124.9	52.2
Other long-term liabilities	905.8	650.1
Total liabilities	10,129.9	3,500.7
Commitments and contingencies		
Equity:		
Biogen Inc. shareholders' equity		
Preferred stock, par value \$0.001 per share	—	—
Common stock, par value \$0.0005 per share	0.1	0.1
Additional paid-in capital	—	4,196.2
Accumulated other comprehensive loss	(224.0	) (59.5
Retained earnings	12,208.4	9,283.9
Treasury stock, at cost; 22.6 million shares, respectively	(2,611.7	) (2,611.7
Total Biogen Inc. shareholders' equity	9,372.8	10,809.0
Noncontrolling interests	2.1	5.0
Total equity	9,374.9	10,814.0
Total liabilities and equity	\$ 19,504.8	\$ 14,314.7

See accompanying notes to these consolidated financial statements.



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

	For the Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income	\$3,593.2	\$2,941.6	\$1,862.3
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	600.4	688.1	531.7
Share-based compensation	161.4	155.3	136.3
Deferred income taxes	(145.6)	(308.2)	(245.1)
Other	82.2	(50.3)	(27.6)
Changes in operating assets and liabilities, net:			
Accounts receivable	29.0	(512.4)	(126.7)
Inventory	(174.4)	(185.9)	(243.9)
Other assets	(156.6)	(94.5)	(160.2)
Accrued expenses and other current liabilities	74.2	244.3	284.1
Current taxes payable	(410.2)	61.0	156.8
Other long-term liabilities and taxes payable	93.6	33.8	161.7
Due from unconsolidated joint business	(31.1)	(30.7)	15.7
Net cash flows provided by operating activities	3,716.1	2,942.1	2,345.1
Cash flows from investing activities:			
Proceeds from sales and maturities of marketable securities	4,063.0	2,718.9	5,190.1
Purchases of marketable securities	(6,864.9)	(3,583.1)	(3,278.1)
Acquisition of TYSABRI rights	—	—	(3,262.7)
Contingent consideration related to Fumapharm AG acquisition	(850.0)	(375.0)	(15.0)
Acquisitions of businesses	(198.8)	—	—
Purchases of property, plant and equipment	(643.0)	(287.8)	(246.3)
Other	(59.9)	(16.0)	7.3
Net cash flows used in investing activities	(4,553.6)	(1,543.0)	(1,604.7)
Cash flows from financing activities:			
Purchase of treasury stock	(5,000.0)	(886.8)	(400.3)
Proceeds from issuance of stock for share-based compensation arrangements	54.2	54.9	66.8
Excess tax benefit from share-based compensation	78.2	96.4	73.5
Proceeds from borrowings	5,930.5	—	—
Repayments of borrowings	(2.1)	(2.7)	(452.4)
Other	(74.4)	(17.7)	(4.1)
Net cash flows provided by (used in) financing activities	986.4	(755.9)	(716.5)
Net increase in cash and cash equivalents	148.9	643.2	23.9
Effect of exchange rate changes on cash and cash equivalents	(45.8)	(40.9)	8.0
Cash and cash equivalents, beginning of the year	1,204.9	602.6	570.7
Cash and cash equivalents, end of the year	\$1,308.0	\$1,204.9	\$602.6

See accompanying notes to these consolidated financial statements.



Table of ContentsBIOGEN INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF EQUITY

(In millions)

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

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

See accompanying notes to these consolidated financial statements.

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

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

Balance,  
December 31, —\$—257.1 \$0.1 \$4,196.2 \$(59.5 ) \$9,283.9 (22.6) \$(2,611.7) \$10,809.0 \$ 5.0 \$10,814.0  
2014

See accompanying notes to these consolidated financial statements.

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

	Preferred stock	Common stock	Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock Shares	Treasury stock Amount	Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity	
	Shares	Shares	Amount			Shares	Amount				
Balance, December 31, 2012	—	254.2	\$ 0.1	\$ 3,854.5	\$ (55.3 )	\$ 4,486.8	(17.7 )	\$(1,324.6)	\$ 6,961.5	\$ 2.3	\$ 6,963.8
Net income					1,862.3			1,862.3	—	1,862.3	
Other comprehensive income, net of tax				27.6				27.6	—	27.6	
Deconsolidation of noncontrolling interests								—	(1.7 )	(1.7 )	
Repurchase of common stock for Treasury pursuant to the 2011 Share Repurchase Program, at cost						(2.0 )	(400.3 )	(400.3 )		(400.3 )	
Issuance of common stock under stock option and stock purchase plans	0.8	—	66.7					66.7		66.7	
Issuance of common stock under stock award plan	1.0	—	(89.7 )					(89.7 )		(89.7 )	
Compensation expense related to share-based payments			146.2					146.2		146.2	
Tax benefit from share-based payments			45.9					45.9		45.9	
Balance, December 31, 2013	—	256.0	\$ 0.1	\$ 4,023.6	\$ (27.7 )	\$ 6,349.1	(19.7 )	\$(1,724.9)	\$ 8,620.2	\$ 0.6	\$ 8,620.8

See accompanying notes to these consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to patients for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for multiple sclerosis (MS), ELOCTATE for hemophilia A and ALPROLIX for hemophilia B, and FUMADERM for the treatment of severe plaque psoriasis. We also have a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, which entitles us to 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 other potential anti-CD20 therapies.

In addition to our innovative drug development efforts, we aim to leverage our manufacturing capabilities and scientific expertise to extend our mission to improve the lives of patients living with serious diseases through the development, manufacture and marketing of biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics).

Consolidation

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

In determining whether we are the primary beneficiary of an entity, we apply a qualitative approach that determines whether we have both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. These considerations impact the way we account for our existing collaborative relationships and other arrangements. We continuously assess whether we are the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in us consolidating or deconsolidating one or more of our collaborators or partners.

Use of Estimates

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

Revenue Recognition

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

Product Revenues

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery. Product revenues are recorded net of applicable reserves for discounts and allowances.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Reserves for Discounts and Allowances

We establish reserves for trade term discounts, wholesaler incentives, Medicaid rebates, co-payment assistance (copay), Veterans Administration (VA) and Public Health Service (PHS) discounts, managed care rebates, product returns and other governmental rebates or applicable allowances, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Reserves established for these discounts and allowances 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). These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

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

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

Contractual adjustments primarily relate to Medicaid and managed care rebates, patient copay assistance, VA and PHS discounts, specialty pharmacy program fees and other governmental rebates or applicable allowances.

Medicaid rebates relate to our estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in other current liabilities. Our liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid, and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end.

Governmental rebates or chargebacks, including VA and PHS discounts, represent our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices we charge to wholesalers which provide those products. The wholesaler charges us for the difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Rebate and chargeback reserves are established in the same period as the related revenue is recognized, resulting in a reduction in product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and we generally issue credits for such amounts within a few weeks of the wholesaler notifying us about the resale. Our reserves for VA, PHS and chargebacks consists of amounts that we expect to issue for inventory that exists at the wholesalers that we expect will be sold to qualified healthcare providers and chargebacks that wholesalers have claimed for which we have not issued a credit.

Managed care rebates represent our estimated obligations to third parties, primarily pharmacy benefit managers. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses and other current liabilities. These rebates result from performance-based goals, formulary position and price increase limit allowances (price protection). The calculation of the accrual for these rebates is based on an estimate of the customer's buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period.

Copay represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The calculation of the accrual for copay is based on an estimate of claims and the cost per claim that we expect to receive associated with inventory that exists in the distribution channel at period end.

Other governmental rebates or applicable allowances primarily relate to mandatory rebates and discounts in international markets where government-sponsored healthcare systems are the primary payors for healthcare.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Product returns are established for returns expected to be made by wholesalers and are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to product expiration. Expired product return reserves are estimated through a comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product. In addition to the discounts, rebates and product returns described above and classified as a reduction of revenue, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services, which are generally reflected as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services, we classify these payments in selling, general and administrative expenses.

**Revenues from Unconsolidated Joint Business**

Revenues from unconsolidated joint business consists 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) revenue on sales in the rest of world for RITUXAN, which consist of our share of pre-tax co-promotion profits in Canada and royalty revenue on sales outside the U.S. and Canada by the Roche Group and its sublicensees. Pre-tax co-promotion profits on RITUXAN are calculated and paid to us by Genentech in the U.S. and by the Roche Group in Canada. Pre-tax co-promotion profits consist of U.S. and Canadian net sales to third-party customers less the cost 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 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. Additionally, our share of the pre-tax profits on RITUXAN and GAZYVA in the U.S. includes estimates made by Genentech and those estimates are subject to change. Actual results may differ from our estimates. For additional information related to our collaboration with Genentech, please read Note 19, Collaborative and Other Relationships, to these consolidated financial statements.

**Royalty Revenues**

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

**Multiple-Element Revenue Arrangements**

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

**Fair Value Measurements**

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

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Level 1 — Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access;

Level 2 — Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Level 3 — Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

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

We validate the prices provided by our third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources and analyzing pricing data in certain instances. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2015 and 2014, respectively.

Other

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

Cash and Cash Equivalents

We consider only those investments which are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. As of December 31, 2015 and 2014, cash equivalents were comprised of money market funds and commercial paper, overnight reverse repurchase agreements, and other debt securities with maturities less than 90 days from the date of purchase.

Accounts Receivable

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

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

The credit and economic conditions in certain countries in the E.U. continue to remain uncertain and have, from time to time, led to a lengthening of time to collect our accounts receivable in some of these countries. In recent years, our collection efforts in Portugal and select regions of Spain have been subject to significant payment delays due to government funding and reimbursement practices. As a result, a portion of these receivables have been routinely collected beyond our contractual payment terms and over periods in excess of one year. Our accounts receivable collection efforts in Portugal and Spain have improved during 2015 with our receivables in Spain now expected to be collected within one year. Our net accounts receivable balance from product sales in Portugal and Spain totaled \$62.4 million and \$90.2 million as of December 31, 2015 and 2014, respectively, of which \$6.1 million and \$12.6 million were classified as non-current and included in investments and other assets in our consolidated balance sheets.



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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Concentration of Credit Risk

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

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

As of December 31, 2015 and 2014, two wholesale distributors individually accounted for approximately 35.4% and 23.1%, and 34.4% and 23.3%, of accounts receivable, net, respectively.

Marketable Securities and Other Investments

Marketable Debt Securities

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

Marketable Equity Securities

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

Non-Marketable Equity Securities

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

Evaluating Investments for Other-than-Temporary Impairments

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

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair

value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in earnings as an impairment loss.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

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

Equity Method of Accounting

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

Inventory

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

Capitalization of Inventory Costs

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

Obsolescence and Unmarketable Inventory

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

estimated net realizable value. Amounts written-down due to unmarketable inventory are charged to cost of sales.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Property, Plant and Equipment

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

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

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

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

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

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

## Intangible Assets

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

Intangible assets related to acquired and in-licensed rights and patents, developed technology and out-licensed patents are amortized over their estimated useful lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated.

Amortization is recorded as amortization of acquired intangible assets in our consolidated statements of income.

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





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

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

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

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

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

**Goodwill**

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

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

**Impairment of Long-Lived Assets**

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

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



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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Contingent Consideration

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

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

Derivative Instruments and Hedging Activities

We recognize all derivative instruments as either assets or liabilities at fair value in our consolidated balance sheets. Changes in the fair value of derivatives are recorded each period in current earnings or accumulated other comprehensive income (loss), depending on whether a derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. We classify the cash flows from these instruments in the same category as the cash flows from the hedged items. We do not hold or issue derivative instruments for trading or speculative purposes. We assess, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows or fair values of the hedged items. We also assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

Translation of Foreign Currencies

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

Translation adjustments of these subsidiaries are included in other income (expense), net, in net income.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Royalty Cost of Sales

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

## Accounting for Share-Based Compensation

Our share-based compensation programs grant awards that have included stock options, restricted stock units which vest based on stock performance known as market stock units (MSUs), performance-vested restricted stock units which settle in cash (CSPUs), time-vested restricted stock units (RSUs), performance-vested restricted stock units which can be settled in cash or shares of our common stock (PUs) at the sole discretion of the Compensation and Management Development Committee of the Board of Directors and shares issued under our employee stock purchase plan (ESPP). We charge the estimated fair value of awards against income over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance, where a portion of the award vests upon retirement eligibility), we estimate and recognize expense based on the period from the grant date to the date on which the employee is retirement eligible.

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

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

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

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

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

## Research and Development Expenses

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities, which include compensation and benefits, facilities and overhead expenses, clinical trial expenses and fees paid to contract research organizations (CROs), clinical supply and manufacturing expenses, write-offs of inventory that was previously capitalized in anticipation of product launch and determined to no longer be realizable, and other outside expenses. Research and development expenses are expensed as incurred. Payments we make for research and development services prior to the services being rendered are

recorded as prepaid assets on our consolidated balance sheets and are expensed as the services are provided. We also accrue the costs of ongoing clinical trials associated with programs that have been terminated or discontinued for which there is no future economic benefit at the time the decision is made to terminate or discontinue the program.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

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

**Selling, General and Administrative Expenses**

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

Advertising costs are expensed as incurred. For the years ended December 31, 2015, 2014 and 2013, advertising costs totaled \$108.6 million, \$92.9 million and \$72.7 million, respectively.

**Income Taxes**

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

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

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

**Contingencies**

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

on our consolidated results of operations and financial position.

Earnings per Share

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

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

New Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-11, Transfers and Servicing (Topic 860): Repurchase-to-Maturity Transactions, Repurchase Financings, and Disclosure. The new standard expanded secured borrowing accounting to include repurchase-to-maturity transactions and repurchase financings and set forth new disclosure requirements for repurchase agreements, securities lending transactions, and repurchase-to-maturity transactions that are accounted for as secured borrowings. We adopted this standard on April 1, 2015 and expanded our disclosures presented in Note 8, Financial Instruments to these consolidated financial statements. The adoption of this standard did not have an impact on our financial position or results of operations.

In April 2015, the FASB issued ASU No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, Interest - Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements, which clarified that debt issuance costs related to line-of-credit arrangements can be presented in the balance sheet as an asset and amortized over the term of the line-of-credit arrangement. We adopted these standards as of September 30, 2015 with retroactive application. The adoption of these standards did not have a significant impact on our financial position or results of operations. For additional information, please read Note 11, Indebtedness to these consolidated financial statements.

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

In May 2015, the FASB issued ASU No. 2015-07, Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent). The new standard removes the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share practical expedient. The new standard will be effective for us on January 1, 2016. Early application is permitted. We maintain investments in certain venture capital funds which primarily invest in small, privately-owned, venture-backed biotechnology companies. The value of our investments in these venture capital funds is estimated using the net asset value of the fund and has been included in the fair value hierarchy disclosure as a Level 3 measurement. These venture capital investments are not material to our financial position or results of

operations. We adopted this standard as of June 30, 2015 and our investments in venture capital funds are no longer included in our disclosures reflected in Note 7, Fair Value Measurements to these consolidated financial statements.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

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

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. We adopted this standard as of December 31, 2015 with retroactive application. As a result, we reclassified our deferred tax assets classified as current to noncurrent and our deferred tax liabilities classified as current to noncurrent in our December 31, 2014 consolidated balance sheet, to conform our prior year presentation to our current year presentation. For additional information, please read Note 16, Income Taxes to these consolidated financial statements.

## 2. Acquisitions

## Convergence Pharmaceuticals

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

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

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

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

(In millions)

Cash portion of consideration	\$200.1
Contingent consideration	274.5
Total purchase price	\$474.6

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

respectively. Our revised purchase price allocation is reflected in the chart below. Our purchase price allocation is substantially complete.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Subsequent changes in the fair value of the contingent consideration obligation will be recognized as adjustments to contingent consideration and reflected in our consolidated statements of income. For additional information related to the fair value of this obligation, please read Note 7, Fair Value Measurements to these consolidated financial statements.

The following table summarizes the estimated fair values of the separately identifiable assets acquired and liabilities assumed as of February 12, 2015, as adjusted:

(In millions)

In-process research and development	\$424.6	
Other intangible assets	7.6	
Goodwill	128.3	
Deferred tax liability	(84.9	)
Other, net	(1.0	)
Total purchase price	\$474.6	

Our estimate of the fair value of the IPR&D programs acquired was determined through a probability adjusted discounted cash flow analysis utilizing a discount rate of 11%. This valuation was primarily driven by the value associated with the lead candidate, Raxatrigine, which is in development for the treatment of TGN and is expected to be completed no earlier than 2020, at a remaining cost of approximately \$145.0 million. The fair value associated with Raxatrigine for the treatment of TGN was \$200.0 million. We have recorded additional IPR&D assets related to the use of Raxatrigine in two additional neuropathic pain indications, with a total estimated value of \$220.0 million. The remaining cost of development for these two indications is approximately \$415.0 million, with an expected completion date of no earlier than 2021. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

We have attributed the goodwill recognized to the Convergence workforce's expertise in chronic pain research and clinical development and to establishing a deferred tax liability for the acquired IPR&D intangible assets which have no tax basis. The goodwill is not tax deductible.

Pro forma results of operations would not be materially different as a result of the acquisition of Convergence and therefore are not presented. Subsequent to the acquisition date, our results of operations include the results of operations of Convergence.

**TYSABRI**

On April 2, 2013, we acquired full ownership of all remaining rights to TYSABRI from Elan that we did not already own or control. Upon the closing of the transaction, we made an upfront payment of \$3.25 billion to Elan, which was funded from our existing cash, and our collaboration agreement with Elan was terminated.

We accounted for this transaction as the acquisition of an asset as we did not acquire any employees from Elan nor did we acquire any significant processes that we did not previously perform or manage under the collaboration agreement. Under the collaboration agreement, we manufactured TYSABRI and collaborated with Elan on the product's marketing, commercial, regulatory, distribution and ongoing development activities. The collaboration agreement was designed to effect an equal sharing of worldwide profits and losses generated by the activities of the collaboration. For additional information related to this collaboration, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

The \$3.25 billion upfront payment was capitalized in the second quarter of 2013 as an intangible asset in our consolidated balance sheet as TYSABRI had reached technological feasibility. We adjusted the value of this intangible asset by \$84.4 million related to deferred revenue from two sales-based milestones previously paid by Elan as well as transaction costs. The net intangible asset capitalized was \$3.18 billion. Commencing in the second quarter of 2013, we began amortizing this intangible asset over the estimated useful life using an economic consumption method based on actual and expected revenue generated from the sales of our TYSABRI product.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Following the April 2, 2013 closing of the transaction, we began recording 100% of U.S. revenues, cost of sales and operating expenses related to TYSABRI in our consolidated statements of income. Under the terms of the acquisition agreement, we continued to share TYSABRI profits with Elan on an equal basis until April 30, 2013. We recorded the profit split for the month ended April 30, 2013, as cost of sales in our consolidated statements of income as we controlled TYSABRI effective April 2, 2013. Between May 1, 2013 and April 30, 2014, we made contingent payments to Elan of 12% on worldwide net sales of TYSABRI. Commencing May 1, 2014 and thereafter, we will 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. In 2014, the \$2.0 billion threshold was pro-rated for the portion of 2014 remaining after the first 12 months expired. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013. Following that acquisition, we began making these royalty payments to Perrigo. Royalty payments to Perrigo and other third parties are recognized as cost of sales in our consolidated statements of income.

## 3. Restructuring

On October 21, 2015, we announced a corporate restructuring, which includes the termination of certain pipeline programs and an 11% reduction in workforce. We anticipate making cash payments totaling approximately \$120 million under this program, which includes approximately \$15.9 million related to previously 2015 accrued incentive compensation, for a total net expected restructuring charge of \$105 million. These amounts will be substantially incurred and paid by the end of 2016.

We recognized \$93.4 million of these charges during the fourth quarter of 2015, of which \$86.2 million was related to our workforce reduction and \$7.2 million was related to the pipeline program terminations. Our restructuring reserve is included in accrued expenses and other in our consolidated balance sheets.

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

(In millions)	Workforce Reduction	Pipeline Programs	Total
Restructuring charges incurred during the fourth quarter of 2015	\$86.2	\$7.2	\$93.4
Previously accrued incentive compensation	15.9	—	15.9
Reserves established	102.1	7.2	109.3
Amounts paid through December 31, 2015	(68.4	) (3.6	) (72.0
Restructuring reserve as of December 31, 2015	\$33.7	\$3.6	\$37.3

## 4. Reserves for Discounts and Allowances

As a result of our acquisition of all remaining rights to TYSABRI from Elan, we began recognizing reserves for discounts and allowances for U.S. TYSABRI revenue in the second quarter of 2013. In addition, following our recently launched products, we began recognizing reserves for discounts and allowances related to these products' revenue.

An analysis of the change in reserves is summarized as follows:

(In millions)	Discounts	Contractual Adjustments	Returns	Total
2015				
Beginning balance	\$47.6	\$387.1	\$49.1	\$483.8
Current provisions relating to sales in current year	459.7	1,732.1	37.6	2,229.4
Adjustments relating to prior years	(1.3	) (16.3	) (14.7	) (32.3
Payments/returns relating to sales in current year	(405.9	) (1,258.1	) (2.6	) (1,666.6
Payments/returns relating to sales in prior years	(44.0	) (296.1	) (11.5	) (351.6
Ending balance	\$56.1	\$548.7	\$57.9	\$662.7





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(In millions)	Discounts	Contractual Adjustments	Returns	Total
2014				
Beginning balance	\$47.0	\$345.5	\$33.7	\$426.2
Current provisions relating to sales in current year	347.3	1,265.4	39.1	1,651.8
Adjustments relating to prior years	(1.0)	) (28.5)	) 13.5	(16.0)
Payments/returns relating to sales in current year	(299.7)	) (933.4)	) (4.1)	) (1,237.2)
Payments/returns relating to sales in prior years	(46.0)	) (261.9)	) (33.1)	) (341.0)
Ending balance	\$47.6	\$387.1	\$49.1	\$483.8
(In millions)	Discounts	Contractual Adjustments	Returns	Total
2013				
Beginning balance	\$14.3	\$196.0	\$26.8	\$237.1
Current provisions relating to sales in current year	236.3	861.3	22.9	1,120.5
Adjustments relating to prior years	(0.7)	) (16.4)	) 1.1	(16.0)
Payments/returns relating to sales in current year	(189.7)	) (560.4)	) —	(750.1)
Payments/returns relating to sales in prior years	(13.2)	) (135.0)	) (17.1)	) (165.3)
Ending balance	\$47.0	\$345.5	\$33.7	\$426.2

The total revenue-related reserves above, included in our consolidated balance sheets, are summarized as follows:

(In millions)	As of December 31,	
	2015	2014
Reduction of accounts receivable	\$144.6	\$124.6
Component of accrued expenses and other	518.1	359.2
Total revenue-related reserves	\$662.7	\$483.8

## 5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of December 31,	
	2015	2014
Raw materials	\$213.0	\$128.3
Work in process	577.6	511.5
Finished goods	143.0	164.2
Total inventory	\$933.6	\$804.0

## Balance Sheet Classification:

Inventory	\$893.4	\$804.0
Investments and other assets	40.2	—
Total inventory	\$933.6	\$804.0

Inventory included in investments and other assets in our consolidated balance sheets primarily consisted of work in process.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As of December 31, 2015, our inventory included \$24.7 million associated with our ZINBRYTA program, \$18.4 million associated with our BENEPALI program and \$24.2 million associated with our FLIXABI program, which have been capitalized in advance of regulatory approval. In January 2016, the European Commission (EC) approved the marketing authorization application (MAA) for BENEPALI for marketing in the E.U. As of December 31, 2014, our inventory included \$6.3 million associated with our ZINBRYTA program, which has been capitalized in advance of regulatory approval. For information on our pre-approval inventory policy, please read Note 1, Summary of Significant Accounting Policies to these consolidated financial statements

Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons are charged to cost of sales, and totaled \$41.9 million, \$50.6 million, and \$47.3 million for the years ended December 31, 2015, 2014, and 2013, respectively.

## 6. Intangible Assets and Goodwill

## Intangible Assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments, are summarized as follows:

(In millions)	Estimated Life	As of December 31, 2015			As of December 31, 2014		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	\$543.3	\$ (506.0 )	\$37.3	\$543.3	\$ (481.7 )	\$61.6
Developed technology	15-23 years	3,005.3	(2,552.9 )	452.4	3,005.3	(2,396.8 )	608.5
In-process research and development	Indefinite until commercialization	730.5	—	730.5	314.1	—	314.1
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	6-18 years	3,303.2	(502.3 )	2,800.9	3,280.4	(300.1 )	2,980.3
Total intangible assets		\$7,646.3	\$ (3,561.2 )	\$4,085.1	\$7,207.1	\$ (3,178.6 )	\$4,028.5

Amortization of acquired intangible assets totaled \$382.6 million, \$489.8 million, and \$342.9 million for the years ended December 31, 2015, 2014 and 2013, respectively. Amortization of acquired intangible assets during 2014 included total impairment charges of \$34.7 million related to one of our out-licensed patents and \$16.2 million related to one of our IPR&D intangible assets.

## Out-licensed Patents

Out-licensed patents to third-parties primarily relate to patents acquired in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. During 2014, we recorded a charge of \$34.7 million related to the impairment of one of our out-licensed patents to reflect a change in its estimated fair value, due to a change in the underlying competitive market for that product. The charge was included in amortization of acquired intangible assets. The fair value of the intangible asset was based on a discounted cash flow calculated using Level 3 fair value measurements and inputs including estimated revenues. There were no impairment charges related to our out-licensed patents during 2015.

## Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of December 31, 2015, was \$443.9 million.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## IPR&amp;D

IPR&D represents the fair value assigned to research and development assets that we acquire that have not reached technological feasibility at the date of acquisition. Upon commercialization, we determine the estimated useful life. In connection with our acquisition of Convergence in February 2015, we acquired IPR&D programs with an estimated fair value of \$424.6 million. This amount has and will be adjusted for foreign exchange rate fluctuations. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

An analysis of anticipated lifetime revenues and anticipated development costs is performed annually during our long-range planning cycle, which was updated in the third quarter of 2015. This analysis is based upon certain assumptions that we evaluate on a periodic basis, including anticipated future product sales, the expected impact of changes in the amount of development costs and the probabilities of our programs succeeding, the introduction of new products by our competitors and changes in our commercial and pipeline product candidates.

During the third quarter of 2014, we updated the probabilities of success related to the early stage programs acquired through our recent acquisitions. The change in probability of success, combined with a delay in one of the projects, resulted in an impairment loss of \$16.2 million in one of our IPR&D assets during 2014.

## Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan. The net book value of this asset as of December 31, 2015 was \$2,742.9 million. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

## Estimated Future Amortization of Intangible Assets

Our amortization expense is based on the economic consumption of intangible assets. Our most significant intangible assets are related to our AVONEX and TYSABRI products. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of AVONEX and TYSABRI. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of either product.

Our most recent long range planning cycle was completed in the third quarter of 2015. Based upon this analysis, the estimated future amortization of acquired intangible assets is expected to be as follows:

(In millions)	As of December 31, 2015
2016	\$346.4
2017	318.6
2018	291.0
2019	275.1
2020	269.1
Total	\$1,500.2

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Goodwill

The following table provides a roll forward of the changes in our goodwill balance:

(In millions)	As of December 31,	
	2015	2014
Goodwill, beginning of year	\$ 1,760.2	\$ 1,232.9
Increase to goodwill	908.1	527.3
Other	(4.5	) —
Goodwill, end of year	\$ 2,663.8	\$ 1,760.2

The increase in goodwill during 2015 was related to \$900.0 million in contingent milestones achieved (exclusive of \$120.2 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights and \$128.3 million related to our acquisition of Convergence. Other includes changes related to foreign exchange rate fluctuations. The increase in goodwill during 2014 was related to \$600.0 million in contingent milestones achieved (exclusive of \$72.7 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights.

For additional information related to future contingent payments to the former shareholders of Fumapharm AG, please read Note 21, Commitments and Contingencies to these consolidated financial statements. For additional information related to our acquisition of Convergence, please read Note 2, Acquisitions to these consolidated financial statements. As of December 31, 2015, we had no accumulated impairment losses related to goodwill.

## 7. Fair Value Measurements

The tables below present information about our assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques we utilized to determine such fair value:

(In millions)	As of December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 909.5	\$ —	\$ 909.5	\$ —
<b>Marketable debt securities:</b>				
Corporate debt securities	1,510.9	—	1,510.9	—
Government securities	2,875.9	—	2,875.9	—
Mortgage and other asset backed securities	494.1	—	494.1	—
Marketable equity securities	37.5	37.5	—	—
Derivative contracts	27.2	—	27.2	—
Plan assets for deferred compensation	40.1	—	40.1	—
<b>Total</b>	<b>\$ 5,895.2</b>	<b>\$ 37.5</b>	<b>\$ 5,857.7</b>	<b>\$ —</b>
<b>Liabilities:</b>				
Derivative contracts	\$ 14.7	\$ —	\$ 14.7	\$ —
Contingent consideration obligations	506.0	—	—	506.0
<b>Total</b>	<b>\$ 520.7</b>	<b>\$ —</b>	<b>\$ 14.7</b>	<b>\$ 506.0</b>

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(In millions)	As of December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$716.3	\$—	\$716.3	\$—
Marketable debt securities:				
Corporate debt securities	1,063.0	—	1,063.0	—
Government securities	849.8	—	849.8	—
Mortgage and other asset backed securities	198.3	—	198.3	—
Marketable equity securities	6.9	6.9	—	—
Derivative contracts	72.7	—	72.7	—
Plan assets for deferred compensation	36.9	—	36.9	—
Total	\$2,943.9	\$6.9	\$2,937.0	\$—
Liabilities:				
Derivative contracts	\$5.4	\$—	\$5.4	\$—
Contingent consideration obligations	215.5	—	—	215.5
Total	\$220.9	\$—	\$5.4	\$215.5

The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities were determined through third-party pricing services. For a description of our validation procedures related to prices provided by third-party pricing services, refer to Note 1, Summary of Significant Accounting Policies: Fair Value Measurements, to these consolidated financial statements.

**Debt Instruments**

The fair values of our debt instruments, which are Level 2 liabilities, are summarized as follows:

(In millions)	As of December 31,	
	2015	2014
Notes payable to Fumedica	\$9.4	\$12.6
6.875% Senior Notes due March 1, 2018	602.6	634.6
2.900% Senior Notes due September 15, 2020	1,497.5	—
3.625% Senior Notes due September 15, 2022	1,014.2	—
4.050% Senior Notes due September 15, 2025	1,764.6	—
5.200% Senior Notes due September 15, 2045	1,757.6	—
Total	\$6,645.9	\$647.2

The fair value of our notes payable to Fumedica was estimated using market observable inputs, including current interest and foreign currency exchange rates. The fair values of each of our series of Senior Notes were determined through market, observable, and corroborated sources. For additional information related to our debt instruments, please read Note 11, Indebtedness to these consolidated financial statements.

**Contingent Consideration Obligations**

The following table provides a roll forward of the fair values of our contingent consideration obligations which includes Level 3 measurements:

(In millions)	As of December 31,	
	2015	2014
Fair value, beginning of year	\$215.5	\$280.9
Additions	274.5	—
Changes in fair value	30.5	(38.9)

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Payments	(14.5	) (26.5	)
Fair value, end of year	\$506.0	\$215.5	

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As of December 31, 2015 and 2014, approximately \$301.3 million and \$200.0 million, respectively, of the fair value of our total contingent consideration obligations was reflected as a component of other long-term liabilities in our consolidated balance sheets with the remaining balance reflected as a component of accrued expenses and other. There were no changes in valuation techniques or transfers between fair value measurement levels during the years ended December 31, 2015 and 2014. During the third quarter 2014, we updated the probabilities of success related to the early stage programs acquired through our recent acquisitions. We adjusted the value of our contingent consideration liabilities to reflect these changes. The change in probability of success, combined with a delay in one of the projects, resulted in a net gain of \$49.4 million during 2014, which was recorded in (gain) loss on fair value remeasurement of contingent consideration and reduced the fair value of our contingent consideration obligations. The fair values of the intangible assets and contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenues and probabilities of success. For additional information related to the valuation techniques and inputs utilized in valuation of our financial assets and liabilities, please read Note 1, Summary of Significant Accounting Policies to these consolidated financial statements.

In connection with our acquisition of Convergence in February 2015, we recorded a liability of \$274.5 million, representing the fair value of the contingent consideration. This valuation was based on probability weighted net cash outflow projections of \$450.0 million, discounted using a rate of 2%, which was the estimated cost of debt financing for market participants. This liability reflects the revised estimate from the date of acquisition for our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements. As of December 31, 2015, the fair value of this contingent consideration obligation was \$297.5 million, discounted using a rate of 3%, and approximately \$197.2 million is reflected as a component of accrued expenses and other in our consolidated balance sheets as we expect to make the payment within a year.

In connection with our acquisition of Stromedix in March 2012, we recorded a contingent consideration obligation of \$122.2 million. As of December 31, 2015 and 2014, the fair value of this contingent consideration obligation was \$131.5 million and \$130.5 million, respectively. Our most recent valuation was determined based upon probability weighted net cash outflow projections of \$419.0 million, discounted using a rate of 2%, which is a measure of the credit risk associated with settling the liability. For 2015 compared to 2014, the net increase in the fair value of this obligation was primarily due to changes in the discount rate, partially offset by changes in the expected timing related to the achievement of certain remaining developmental milestones.

Upon completion of our purchase of the noncontrolling interest in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH in September 2011, we recorded a contingent consideration obligation of \$38.8 million. As of December 31, 2015 and 2014, the fair value of this contingent consideration obligation was \$0.0 million and \$15.5 million, respectively. For 2015 compared to 2014, the net decrease in the fair value of this obligation was primarily due to payments of \$14.5 million of sales-based milestones. Our obligations under this agreement were completed as of December 31, 2015.

In connection with our acquisition of Biogen Idec International Neuroscience GmbH (BIN), formerly Panima Pharmaceuticals AG (Panima), in December 2010, we recorded a contingent consideration obligation of \$81.2 million. As of December 31, 2015 and 2014, the fair value of this contingent consideration obligation was \$77.0 million and \$69.5 million, respectively. Our most recent valuation was determined based upon probability weighted net cash outflow projections of \$365.0 million, discounted using a rate of 3%, which is a measure of the credit risk associated with settling the liability. For 2015 compared to 2014, the net increase in the fair value of this obligation was primarily due to changes in the probability and expected timing related to the achievement of certain remaining developmental milestones and in the discount rate.





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Acquired IPR&amp;D

In connection with our acquisition of Convergence, we also allocated \$424.6 million of the total purchase price to acquired IPR&D, which was capitalized as an intangible asset. The amount allocated to acquired IPR&D was based on significant inputs not observable in the market and thus represented a Level 3 fair value measurement. This estimate was also adjusted from our preliminary estimate as of the date of acquisition to reflect revised estimates to our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. These assets will be tested for impairment annually until commercialization, after which time the IPR&D will be amortized over its estimated useful life. For a more detailed description of this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

## 8. Financial Instruments

The following table summarizes our financial assets with maturities of less than 90 days from the date of purchase included in cash and cash equivalents on the accompanying consolidated balance sheet:

(In millions)	As of December 31,	
	2015	2014
Commercial paper	\$21.9	\$54.2
Overnight reverse repurchase agreements	134.7	305.0
Money market funds	673.8	321.2
Short-term debt securities	79.1	35.9
Total	\$909.5	\$716.3

The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and our short-term debt securities approximate fair value due to their short term maturities. Our overnight reverse repurchase agreements are collateralized with agency-guaranteed mortgage-backed securities and represent approximately 0.7% and 2.1% of total assets as of December 31, 2015 and 2014, respectively.

The following tables summarize our marketable debt and equity securities:

As of December 31, 2015 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	\$394.3	\$—	\$(0.5)	) \$394.8
Non-current	1,116.6	0.1	(4.1)	) 1,120.6
Government securities				
Current	1,723.4	0.1	(1.1)	) 1,724.4
Non-current	1,152.5	—	(3.1)	) 1,155.6
Mortgage and other asset backed securities				
Current	2.8	—	—	) 2.8
Non-current	491.3	0.1	(1.8)	) 493.0
Total marketable debt securities	\$4,880.9	\$0.3	\$(10.6)	) \$4,891.2
Marketable equity securities, non-current	\$37.5	\$9.2	\$—	) \$28.3

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As of December 31, 2014 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	\$370.4	\$—	\$(0.2)	) \$370.6
Non-current	692.6	0.2	(1.5)	) 693.9
Government securities				
Current	269.9	—	(0.1)	) 270.0
Non-current	579.9	0.3	(0.4)	) 580.0
Mortgage and other asset backed securities				
Current	0.2	—	—	) 0.2
Non-current	198.1	0.2	(0.2)	) 198.1
Total marketable debt securities	\$2,111.1	\$0.7	\$(2.4)	) \$2,112.8
Marketable equity securities, non-current	\$6.9	\$1.2	\$(0.2)	) \$5.9

## Summary of Contractual Maturities: Available-for-Sale Securities

The estimated fair value and amortized cost of our marketable debt securities available-for-sale by contractual maturity are summarized as follows:

(In millions)	As of December 31, 2015		As of December 31, 2014	
	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	\$2,120.5	\$2,122.0	\$640.5	\$640.8
Due after one year through five years	2,575.9	2,583.9	1,343.7	1,345.2
Due after five years	184.5	185.3	126.9	126.8
Total available-for-sale securities	\$4,880.9	\$4,891.2	\$2,111.1	\$2,112.8

The average maturity of our marketable debt securities available-for-sale as of December 31, 2015 and 2014, was 16 months and 15 months, respectively.

## Proceeds from Marketable Debt Securities

The proceeds from maturities and sales of marketable debt securities and resulting realized gains and losses are summarized as follows:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Proceeds from maturities and sales	\$4,063.0	\$2,718.9	\$5,190.1
Realized gains	\$1.5	\$0.7	\$6.6
Realized losses	\$3.5	\$0.5	\$2.1

Realized losses for the year ended December 31, 2015, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities. Realized losses for the year ended December 31, 2014, primarily relate to sales of agency mortgage-backed securities and government securities. Realized losses for the year ended December 31, 2013, primarily relate to sales of agency mortgage-backed securities and corporate securities.

## Strategic Investments

As of December 31, 2015 and 2014, our strategic investment portfolio was comprised of investments totaling \$96.0 million and \$47.8 million, respectively, which are included in investments and other assets in our consolidated balance sheets. Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and investments in venture capital funds where the underlying investments are in equity securities of biotechnology companies.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 9. Derivative Instruments

## Foreign Currency Forward Contracts - Hedging Instruments

Due to the global nature of our operations, portions of our revenues and operating expenses are recorded in currencies other than the U.S. dollar. The value of revenues and operating expenses measured in U.S. dollars is therefore subject to changes in foreign currency exchange rates. In order to mitigate these changes we use foreign currency forward contracts to lock in exchange rates associated with a portion of our forecasted international revenues and operating expenses.

Foreign currency forward contracts in effect as of December 31, 2015 and 2014, had durations of 1 to 18 months and 1 to 15 months, respectively. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses for the effective portion of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized and, beginning in the fourth quarter of 2015, in operating expenses when the expense in the currency being hedged is recorded. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net.

The notional value of foreign currency forward contracts that were entered into to hedge forecasted revenues and expenses is summarized as follows:

Foreign Currency: (In millions)	Notional Amount	
	As of December 31,	
	2015	2014
Euro	\$945.5	\$1,174.6
Swiss francs	80.8	—
Canadian dollar	76.7	56.7
British pound sterling	—	34.5
Australian dollar	—	19.9
Japanese yen	—	16.6
Total foreign currency forward contracts	\$1,103.0	\$1,302.3

The portion of the fair value of these foreign currency forward contracts that was included in accumulated other comprehensive income (loss) in total equity reflected gains of \$1.8 million and \$72.1 million and losses of \$23.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. We expect all contracts to be settled over the next 18 months and any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of December 31, 2015 and 2014, credit risk did not change the fair value of our foreign currency forward contracts. The following table summarizes the effect of foreign currency forward contracts designated as hedging instruments on our consolidated statements of income related to our forecasted revenues:

For the Years Ended December 31,

Net Gains/(Losses)				Net Gains/(Losses)			
Reclassified from AOCI into Net Income				Recognized into Net Income			
(Effective Portion)				(Ineffective Portion)			
Location	2015	2014	2013	Location	2015	2014	2013
Revenue	\$173.2	\$6.8	\$(13.2)	Other income	\$4.9	\$(1.5)	\$(0.2)
			)	(expense)		)	)

The effect of foreign currency forward contracts designated as hedging instruments on our consolidated statements of income related to our forecasted operating expenses was immaterial for 2015.

## Interest Rate Contracts - Hedging Instruments

We have entered into interest rate lock contracts or interest rate swap contracts on certain borrowing transactions to manage our exposure to interest rate changes and to reduce our overall cost of borrowing.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Interest Rate Lock Contracts

During 2015, we entered into treasury rate locks, with an aggregated notional amount of \$1.1 billion, that were designated as cash flow hedges to hedge against changes in the 10-year and 30-year U.S. treasury interest rates that could have impacted our anticipated debt offering. In connection with the issuance of our 4.05% and 5.20% Senior Notes, as described in Note 11, Indebtedness, we settled the treasury rate locks and realized an \$8.5 million gain. As the hedging relationship was effective, the gain was recorded in AOCI and will be recognized in other income (expense), net over the life of the 4.05% and 5.20% Senior Notes.

## Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes, as described in Note 11, Indebtedness, we entered into interest rate swaps with an aggregate notional amount of \$675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in the 2.90% Senior Notes attributable to changes in interest rates. Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recorded as a component of the 2.90% Senior Notes with no net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recognized as a component of interest expense in our consolidated statements of income.

## Foreign Currency Forward Contracts - Other Derivatives

We also enter into other foreign currency forward contracts, usually with one month durations, to mitigate the foreign currency risk related to certain balance sheet positions. We have not elected hedge accounting for these transactions. The aggregate notional amount of these outstanding foreign currency contracts was \$721.0 million and \$365.2 million as of December 31, 2015 and 2014, respectively. Net losses of \$23.8 million and \$15.5 million and net gains of \$5.2 million related to these contracts were recognized as a component of other income (expense), net, for the years ended December 31, 2015, 2014 and 2013, respectively.

## Summary of Derivatives

While certain of our derivatives are subject to netting arrangements with our counterparties, we do not offset derivative assets and liabilities in our consolidated balance sheets.

The following table summarizes the fair value and presentation in our consolidated balance sheets for our outstanding derivatives including those designated as hedging instruments:

(In millions)	Balance Sheet Location	Fair Value As of December 31, 2015
<b>Hedging Instruments:</b>		
Asset derivatives	Other current assets	\$16.6
	Investments and other assets	\$0.3
Liability derivatives	Accrued expenses and other	\$10.2
	Other long-term liabilities	\$2.5
<b>Other Derivatives:</b>		
Asset derivatives	Other current assets	\$10.3
Liability derivatives	Accrued expenses and other	\$2.0
		Fair Value
(In millions)	Balance Sheet Location	As of December 31, 2014
<b>Hedging Instruments:</b>		
Asset derivatives	Other current assets	\$69.5
	Investments and other assets	\$1.9
<b>Other Derivatives:</b>		

Asset derivatives	Other current assets	\$1.3
Liability derivatives	Accrued expenses and other	\$5.4

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 10. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Components of property, plant and equipment, net are summarized as follows:

(In millions)	As of December 31,	
	2015	2014
Land	\$74.7	\$56.9
Buildings	1,035.6	947.7
Leasehold improvements	166.6	155.5
Machinery and equipment	1,079.6	1,011.3
Computer software and hardware	647.1	547.8
Furniture and fixtures	72.9	64.3
Construction in progress	441.2	168.6
Total cost	3,517.7	2,952.1
Less: accumulated depreciation	(1,330.1	) (1,186.4
Total property, plant and equipment, net	\$2,187.6	\$1,765.7

Depreciation expense totaled \$217.9 million, \$198.4 million and \$187.8 million for 2015, 2014 and 2013, respectively.

For 2015, 2014 and 2013, we capitalized interest costs related to construction in progress totaling approximately \$10.4 million, \$6.4 million and \$7.8 million, respectively.

## Research Triangle Park Facility Purchase

On August 24, 2015, we purchased from Eisai, Inc. (Eisai) its drug product manufacturing facility and supporting infrastructure in Research Triangle Park (RTP), North Carolina for \$104.8 million. The purchase price consisted of the following:

(In millions)	
Buildings	\$58.6
Machinery and equipment	25.9
Land	20.3
Total purchase price	\$104.8

On August 24, 2015, we also amended our existing 10 year lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. As amended, the lease provides for a 3 year term and our agreement to purchase the facility upon expiration of the lease term and Eisai's completion of certain activities. Accordingly, we recorded the assets along with a corresponding financing obligation on our consolidated balance sheet for \$20.3 million, the net present value of the future minimum lease payments. The assets were recorded as a component of buildings and machinery and equipment. We expect to complete the purchase of the oral solid products manufacturing facility at the end of the lease term in the third quarter of 2018.

## Solothurn, Switzerland Facility

On December 1, 2015, we purchased land in Solothurn, Switzerland for 64.4 million Swiss Francs (approximately \$62.5 million). We plan to build a biologics manufacturing facility on this land in the Commune of Luterbach over the next several years. As of December 31, 2015, we have approximately \$99.0 million capitalized in construction in progress related to the construction of this facility.

## Weston Exit Costs

As a result of our decision to relocate our corporate headquarters to Cambridge, Massachusetts, we vacated part of our Weston, Massachusetts facility in the fourth quarter of 2013. We incurred a charge of \$27.2 million in connection with this move. This charge represented our remaining lease obligation for the vacated portion of our Weston, Massachusetts facility, net of sublease income expected to be received. The term of our sublease for the





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

vacated portion of our Weston, Massachusetts facility started in January 2014 and will continue through the remaining term of our lease agreement.

## 11. Indebtedness

Our indebtedness is summarized as follows:

(In millions)	As of December 31,	
	2015	2014
Current portion:		
Notes payable to Fumedica	\$3.1	\$3.1
Financing arrangement for the purchase of the RTP facility	1.7	—
Current portion of notes payable and other financing arrangements	\$4.8	\$3.1
Non-current portion:		
2008 Senior Notes		
6.875% Senior Notes due March 1, 2018	\$565.3	\$571.7
2015 Senior Notes		
2.900% Senior Notes due September 15, 2020	1,485.5	—
3.625% Senior Notes due September 15, 2022	992.2	—
4.050% Senior Notes due September 15, 2025	1,733.4	—
5.200% Senior Notes due September 15, 2045	1,721.1	—
Notes payable to Fumedica	5.9	8.6
Financing arrangement for the purchase of the RTP facility	18.1	—
Non-current portion of notes payable and other financing arrangements	\$6,521.5	\$580.3

The following is a summary description of our principal indebtedness as of December 31, 2015:

## 2015 Senior Notes

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion, consisting of the following:

\$1.5 billion of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;

\$1.0 billion of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;

\$1.75 billion of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and

\$1.75 billion of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

These notes are senior unsecured obligations and may be redeemed at our option at any time at 100% of the principal amount plus accrued interest and a specified make-whole amount. The notes also contain a change of control provision that may require us to purchase the notes at a price equal to 101% of the principal amount plus accrued and unpaid interest to the date of purchase under certain circumstances.

The costs associated with this offering of approximately \$47.5 million have been recorded as a reduction to the carrying amount of the debt on our consolidated balance sheet. These costs along with the discounts will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity.

Interest on the notes is payable March 15 and September 15 of each year.

In connection with this offering, we also entered into interest rate swaps. The carrying value of the 2.90% Senior Notes includes approximately \$1.8 million related to changes in the fair value of the interest rate swaps. For additional information, please read Note 9, Derivative Instruments, to these consolidated financial statements.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 2008 Senior Notes

On March 4, 2008, we issued \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 that were originally priced at 99.184% of par. The discount is amortized as additional interest expense over the period from issuance through maturity. These notes are senior unsecured obligations. Interest on the notes is payable March 1 and September 1 of each year. The notes may be redeemed at our option at any time at 100% of the principal amount plus accrued interest and a specified make-whole amount. The notes contain a change of control provision that may require us to purchase the notes under certain circumstances. There is also an interest rate adjustment feature that requires us to pay interest at an increased rate on the notes if the credit rating on the notes declines below investment grade. In accordance with ASU No. 2015-03, during 2015, we reclassified \$1.8 million of our debt issuance costs related to our 6.875% Senior Notes from an asset to a reduction to the carrying amount of the 6.875% Senior Notes in our 2014 consolidated balance sheet.

Upon the issuance of the 6.875% Senior Notes due in 2018, we entered into interest rate swap contracts where we received a fixed rate and paid a variable rate. These contracts were terminated in December 2008. Upon termination of these swaps, the carrying amount of the 6.875% Senior Notes due in 2018 was increased by \$62.8 million and is being amortized using the effective interest rate method over the remaining life of the Senior Notes and is being recognized as a reduction of interest expense. As of December 31, 2015, \$17.8 million remains to be amortized.

## Notes Payable to Fumedica

In connection with our 2006 distribution agreement with Fumedica, we issued notes totaling 61.4 million Swiss Francs which were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a carrying value of 8.9 million Swiss Francs (\$9.0 million) and 11.6 million Swiss Francs (\$11.7 million) as of December 31, 2015 and 2014, respectively.

## Credit Facility

In August 2015, we entered into a \$1.0 billion, 5-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, 2015, we had no outstanding borrowings and were in compliance with all covenants under this facility. In March 2013, we entered into a \$750.0 million 364-day senior unsecured revolving credit facility. In March 2014, the revolving credit facility expired and was not renewed.

## Financing Arrangement

During 2015 we recorded a financing obligation in relation to the amendment of our lease agreement of Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. As of December 31, 2015, the financing obligation totaled approximately \$19.8 million. For additional information, please read Note 10, Property, Plant and Equipment to these consolidated financial statements.

## Debt Maturity

The total gross payments, excluding our financing arrangement, due under our debt arrangements are as follows:

(In millions)	As of December 31,
	2015
2016	\$3.2
2017	3.2
2018	553.2
2019	—
2020	1,500.0
2021 and thereafter	4,500.0
Total	\$6,559.6

The fair value of our debt is disclosed in Note 7, Fair Value Measurements to these consolidated financial statements.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 12. Equity

## Preferred Stock

We have 8.0 million shares of Preferred Stock authorized, of which 1.75 million shares are authorized as Series A, 1.0 million shares are authorized as Series X junior participating and 5.25 million shares are undesignated. Shares may be issued without a vote or action of stockholders from time to time in classes or series with the designations, powers, preferences, and the relative, participating, optional or other special rights of the shares of each such class or series and any qualifications, limitations or restrictions thereon as set forth in the instruments governing such shares. Any such Preferred Stock may rank prior to common stock as to dividend rights, liquidation preference or both, and may have full or limited voting rights and may be convertible into shares of common stock. No shares of Preferred Stock were issued and outstanding during 2015, 2014 and 2013.

## Common Stock

The following table describes the number of shares authorized, issued and outstanding of our common stock as of December 31, 2015 and 2014:

(In millions)	As of December 31, 2015			As of December 31, 2014		
	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding
Common stock	1,000.0	241.2	218.6	1,000.0	257.1	234.6

## Share Repurchases

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). As of December 31, 2015, the 2015 Share Repurchase Program was completed and we repurchased and retired approximately 16.8 million shares of common stock at a cost of \$5.0 billion during the year ended December 31, 2015.

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. During 2014, we purchased approximately 2.9 million shares of common stock at a cost of \$886.8 million under our 2011 Share Repurchase Program. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program during the year ended December 31, 2015 and have approximately 1.3 million shares remaining available for repurchase under this authorization.

## 13. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss), net of tax by component:

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	Unrealized Gains (Losses) on Cash Flow Hedges	Unfunded Status of Postretirement Benefit Plans	Translation Adjustments	Total
Balance, December 31, 2014	\$(0.4)	\$71.7	\$(31.6)	\$(99.2)	\$(59.5)
Other comprehensive income (loss) before reclassifications	(1.7)	110.8	(6.2)	(96.4)	6.5
Amounts reclassified from accumulated other comprehensive income (loss)	1.3	(172.3)	—	—	(171.0)
Net current period other comprehensive income (loss)	(0.4)	(61.5)	(6.2)	(96.4)	(164.5)
Balance, December 31, 2015	\$(0.8)	\$10.2	\$(37.8)	\$(195.6)	\$(224.0)



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	Unrealized Gains (Losses) on Cash Flow Hedges	Unfunded Status of Postretirement Benefit Plans	Translation Adjustments	Total
Balance, December 31, 2013	\$5.6	\$(23.7	) \$(19.6	) \$10.0	\$(27.7
Other comprehensive income (loss) before reclassifications	0.4	101.7	(12.0	) (109.2	) (19.1
Amounts reclassified from accumulated other comprehensive income (loss)	(6.4	) (6.3	) —	—	(12.7
Net current period other comprehensive income (loss)	(6.0	) 95.4	(12.0	) (109.2	) (31.8
Balance, December 31, 2014	\$(0.4	) \$71.7	\$(31.6	) \$(99.2	) \$(59.5

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	Unrealized Gains (Losses) on Cash Flow Hedges	Unfunded Status of Postretirement Benefit Plans	Translation Adjustments	Total
Balance, December 31, 2012	\$4.2	\$(10.7	) \$(21.7	) \$(27.1	) \$(55.3
Other comprehensive income (loss) before reclassifications	11.8	(26.7	) 2.1	37.1	24.3
Amounts reclassified from accumulated other comprehensive income (loss)	(10.4	) 13.7	—	—	3.3
Net current period other comprehensive income (loss)	1.4	(13.0	) 2.1	37.1	27.6
Balance, December 31, 2013	\$5.6	\$(23.7	) \$(19.6	) \$10.0	\$(27.7

The following table summarizes the amounts reclassified from accumulated other comprehensive income:

(In millions)	Income Statement Location	Amounts Reclassified from Accumulated Other Comprehensive Income For the Years Ended December 31,		
		2015	2014	2013
Gains (losses) on securities available for sale	Other income (expense)	\$(2.0	) \$9.9	\$15.9
	Income tax benefit (expense)	0.7	(3.5	) (5.5
Gains (losses) on cash flow hedges	Revenues	173.2	6.8	(13.2
	Other income (expense)	(0.1	) —	—
	Income tax benefit (expense)	(0.8	) (0.5	) (0.5
Total reclassifications, net of tax		\$171.0	\$12.7	\$(3.3

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 14. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Numerator:			
Net income attributable to Biogen Inc.	\$3,547.0	\$2,934.8	\$1,862.3
Denominator:			
Weighted average number of common shares outstanding	230.7	236.4	236.9
Effect of dilutive securities:			
Stock options and employee stock purchase plan	0.1	0.1	0.3
Time-vested restricted stock units	0.3	0.5	0.8
Market stock units	0.1	0.2	0.3
Dilutive potential common shares	0.5	0.8	1.4
Shares used in calculating diluted earnings per share	231.2	237.2	238.3

Amounts excluded from the calculation of net income per diluted share because their effects were anti-dilutive were insignificant.

Earnings per share for the years ended December 31, 2015, 2014 and 2013, reflects, on a weighted average basis, the repurchase of 4.6 million shares, 1.0 million shares and 0.9 million shares, respectively, of our common stock under our share repurchase authorizations.

## 15. Share-based Payments

## Share-based Compensation Expense

The following table summarizes share-based compensation expense included in our consolidated statements of income:

(In millions)	For the Years Ended December 31,			
	2015	2014	2013	
Research and development	\$88.6	\$102.1	\$95.6	
Selling, general and administrative	127.3	150.3	160.3	
Reversal of previously accrued incentive compensation included in restructuring charges	(8.6	) —	—	
Subtotal	207.3	252.4	255.9	
Capitalized share-based compensation costs	(11.0	) (10.0	) (9.8	)
Share-based compensation expense included in total cost and expenses	196.3	242.4	246.1	
Income tax effect	(55.8	) (72.2	) (73.3	)
Share-based compensation expense included in net income attributable to Biogen Inc.	\$140.5	\$170.2	\$172.8	



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes share-based compensation expense associated with each of our share-based compensation programs:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Stock options	\$—	\$—	\$0.6
Market stock units	38.1	37.4	32.8
Time-vested restricted stock units	119.0	115.4	103.5
Cash settled performance units	22.4	65.5	109.8
Performance units	13.9	21.9	—
Employee stock purchase plan	13.9	12.2	9.2
Subtotal	207.3	252.4	255.9
Capitalized share-based compensation costs	(11.0	) (10.0	) (9.8
Share-based compensation expense included in total cost and expenses	\$196.3	\$242.4	\$246.1

Windfall tax benefits from vesting of stock awards, exercises of stock options and ESPP participation were \$78.2 million, \$96.4 million and \$73.5 million in 2015, 2014 and 2013, respectively. These amounts have been calculated under the alternative transition method.

As of December 31, 2015, unrecognized compensation cost related to unvested share-based compensation was approximately \$184.3 million, net of estimated forfeitures. We expect to recognize the cost of these unvested awards over a weighted-average period of 1.8 years.

**Share-Based Compensation Plans**

We have three share-based compensation plans pursuant to which awards are currently being made: (i) the Biogen Inc. 2006 Non-Employee Directors Equity Plan (2006 Directors Plan); (ii) the Biogen Inc. 2008 Amended and Restated Omnibus Equity Plan (2008 Omnibus Plan); and (iii) the Biogen Inc. 2015 Employee Stock Purchase Plan (ESPP).  
**Directors Plan**

In May 2006, our stockholders approved the 2006 Directors Plan for share-based awards to our directors. Awards granted from the 2006 Directors Plan may include stock options, shares of restricted stock, restricted stock units, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the plan. We have reserved a total of 1.6 million shares of common stock for issuance under the 2006 Directors Plan. The 2006 Directors Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares reserved under the plan in a 1.5-to-1 ratio. In June 2015, our stockholders approved an amendment to extend the term of the 2006 Directors Plan until June 10, 2025.

**Omnibus Plans**

In June 2008, our stockholders approved the 2008 Omnibus Plan for share-based awards to our employees. Awards granted from the 2008 Omnibus Plan may include stock options, shares of restricted stock, restricted stock units, performance shares, shares of phantom stock, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the plan. Shares of common stock available for issuance under the 2008 Omnibus Plan consist of 15.0 million shares reserved for this purpose, plus shares of common stock that remained available for issuance under our 2005 Omnibus Equity Plan on the date that our stockholders approved the 2008 Omnibus Plan, plus shares that were subject to awards under the 2005 Omnibus Equity Plan which remain unissued upon the cancellation, surrender, exchange or termination of such awards. The 2008 Omnibus Equity Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares available under the plan in a 1.5-to-1 ratio.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

We have not made any awards pursuant to the 2005 Omnibus Equity Plan since our stockholders approved the 2008 Omnibus Plan, and do not intend to make any awards pursuant to the 2005 Omnibus Equity Plan in the future, except that unused shares under the 2005 Omnibus Equity Plan have been carried over for use under the 2008 Omnibus Plan.

**Stock Options**

We currently do not grant stock options to our employees or directors. Outstanding stock options previously granted to our employees and directors generally have a ten-year term and vest over a period of between one and four years, provided the individual continues to serve at Biogen through the vesting dates. Options granted under all plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the options' vesting periods. The fair value of the stock options granted in 2010 was estimated as of the date of grant using a Black-Scholes option valuation model. There were no grants of stock options made in 2015, 2014 and 2013. As of December 31, 2015, all outstanding options were exercisable.

The expected life of options granted is derived using assumed exercise rates based on historical exercise patterns and represents the period of time that options granted are expected to be outstanding. Expected stock price volatility is based upon implied volatility for our exchange-traded options and other factors, including historical volatility. After assessing all available information on either historical volatility, implied volatility, or both, we have concluded that a combination of both historical and implied volatility provides the best estimate of expected volatility. The risk-free interest rate used is determined by the market yield curve based upon risk-free interest rates established by the Federal Reserve, or non-coupon bonds that have maturities equal to the expected term. The dividend yield of zero is based upon the fact that we have not historically granted cash dividends, and do not expect to issue dividends in the foreseeable future. Stock options granted prior to January 1, 2006 were valued based on the grant date fair value of those awards, using the Black-Scholes option pricing model, as previously calculated for pro-forma disclosures.

The following table summarizes our stock option activity:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2014	221,000	\$56.98
Granted	—	\$—
Exercised	(114,000	) \$59.82
Cancelled	—	\$—
Outstanding at December 31, 2015	107,000	\$53.94

The total intrinsic values of options exercised in 2015, 2014 and 2013 totaled \$38.0 million, \$42.7 million, and \$86.2 million, respectively. The aggregate intrinsic values of options outstanding as of December 31, 2015 totaled \$27.0 million. The weighted average remaining contractual term for options outstanding as of December 31, 2015 was 3.2 years.

The following table summarizes the amount of tax benefit realized for stock options and cash received from the exercise of stock options:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Tax benefit realized for stock options	\$11.9	\$13.0	\$29.4
Cash received from the exercise of stock options	\$6.3	\$8.5	\$28.1

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Market Stock Units (MSUs)

MSUs awarded to employees prior to 2014 vested in four equal annual increments beginning on the first anniversary of the grant date. Participants may ultimately earn between 0% and 150% of the target number of units granted based on actual stock performance.

MSUs awarded to employees in 2014 and 2015 vest in three equal annual increments beginning on the first anniversary of the grant date, and participants may ultimately earn between 0% and 200% of the target number of units granted based on actual stock performance.

The vesting of these awards is subject to the respective employee's continued employment. The number of MSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain market-based criteria involving our stock price. The number of MSUs earned is calculated at each annual anniversary from the date of grant over the respective vesting periods, resulting in multiple performance periods. Accordingly, additional MSUs may be issued or currently outstanding MSUs may be cancelled upon final determination of the number of awards earned. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our MSU activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2014	403,000	\$219.29
Granted (a)	185,000	\$493.43
Vested	(277,000)	) \$165.63
Forfeited	(42,000)	) \$294.85
Unvested at December 31, 2015	269,000	\$339.89

MSUs granted in 2015 include approximately 8,000, 19,000, 24,000 and 34,000 MSUs issued in 2015 based upon the attainment of performance criteria set for 2014, 2013, 2012 and 2011, respectively, in relation to awards (a) granted in those years. The remainder of MSUs granted during 2015 include awards granted in conjunction with our annual awards made in February 2015 and MSUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

We value grants of MSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, including the 60 calendar day average closing stock price on grant date for MSUs awarded prior to 2014, the 30 calendar day average closing stock price on the date of grant for MSUs awarded in 2014 and 2015, expected volatility of our stock price, risk-free rates of return and expected dividend yield. The assumptions used in our valuation are summarized as follows:

	For the Years Ended December 31,		
	2015	2014	2013
Expected dividend yield	—%	—%	—%
Range of expected stock price volatility	31.0% - 33.2%	31.7% - 35.1%	21.7% - 25.7%
Range of risk-free interest rates	0.2% - 1.0%	0.1% - 0.7%	0.1% - 0.7%
30 calendar day average stock price on grant date	\$277.35 - \$426.27	\$280.88 - \$335.65	**
60 calendar day average stock price on grant date	**	**	\$150.33 - \$240.14
Weighted-average per share grant date fair value	\$493.43	\$395.22	\$193.45

The total fair values of MSUs vested in 2015, 2014 and 2013 totaled \$109.0 million, \$117.4 million, and \$50.9 million, respectively.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Cash Settled Performance Units (CSPUs)

CSPUs awarded to employees vest in three equal annual increments beginning on the first anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment with such awards settled in cash. The number of CSPUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional CSPUs may be issued or currently outstanding CSPUs may be cancelled upon final determination of the number of units earned. CSPUs awarded prior to 2014 are settled in cash based on the 60 calendar day average closing stock price through each vesting date once the actual vested and earned number of units is known. CSPUs awarded in 2014 and 2015 will be settled in cash based on the 30 calendar day average closing stock price through each vesting date, once the actual vested and earned number of units is known. Since no shares are issued, these awards do not dilute equity.

Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our CSPU activity:

	Shares	
Unvested at December 31, 2014	335,000	
Granted (a)	115,000	
Vested	(222,000)	)
Forfeited	(36,000)	)
Unvested at December 31, 2015	192,000	

CSPUs granted in 2015 include approximately 48,000 CSPUs issued in 2015 based upon the attainment of performance criteria set for 2014 in relation to awards granted in 2014. The remainder of the CSPUs granted in (a)2015 include awards granted in conjunction with our annual awards made in February 2015 and CSPUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

The total cash paid in settlement of CSPUs vested in 2015, 2014 and 2013 totaled \$79.8 million, \$92.8 million, and \$48.3 million, respectively.

## Performance-vested Restricted Stock Units (PUs)

Beginning in the first quarter of 2014, we revised our long term incentive program to include a new type of award granted to certain employees in the form of restricted stock units that may be settled in cash or shares of our common stock at the sole discretion of the Compensation and Management Development Committee of our Board of Directors. These awards are structured and accounted for the same way as the cash settled performance units, and vest in three equal annual increments beginning on the first anniversary of the grant date. The number of PUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional PUs may be issued or currently outstanding PUs may be cancelled upon final determination of the number of units earned. PUs settling in cash are based on the 30 calendar day average closing stock price through each vesting date once the actual vested and earned number of units is known. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our PU activity:

	Shares	
Unvested at December 31, 2014	57,000	
Granted (a)	89,000	
Vested	(33,000)	)
Forfeited	(10,000)	)

Unvested at December 31, 2015

103,000

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

PU's granted in 2015 include approximately 42,000 PU's issued in 2015 based upon the attainment of performance criteria set for 2014 in relation to awards granted in 2014. The remainder of the PU's granted in 2015 include (a) awards granted in conjunction with our annual awards made in February 2015 and PU's granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant. During 2015, 32,000 PU's were converted to share settlements, of which approximately 11,000 shares were vested and issued. All other PU's that vested in 2015 were settled in cash totaling \$12.4 million.

**Time-Vested Restricted Stock Units (RSUs)**

RSUs awarded to employees generally vest no sooner than one-third per year over three years on the anniversary of the date of grant, or upon the third anniversary of the date of the grant, provided the employee remains continuously employed with us, except as otherwise provided in the plan. Shares of our common stock will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. RSUs awarded to directors for service on our Board of Directors vest on the first anniversary of the date of grant, provided in each case that the director continues to serve on our Board of Directors through the vesting date. Shares of our common stock will be delivered to the director upon vesting and are not subject to any withholding taxes. The fair value of all RSUs is based on the market value of our stock on the date of grant. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

The following table summarizes our RSU activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2014	1,137,000	\$221.01
Granted (a)	459,000	\$388.88
Vested	(626,000)	) \$190.65
Forfeited	(160,000)	) \$302.35
Unvested at December 31, 2015	810,000	\$323.87

RSUs granted in 2015 primarily represent RSUs granted in conjunction with our annual awards made in February (a) 2015 and awards made in conjunction with the hiring of new employees. RSUs granted in 2015 also include approximately 7,000 RSUs granted to our Board of Directors.

RSUs granted in 2014 and 2013 had weighted average grant date fair values of \$321.72 and \$176.53, respectively. The total fair values of RSUs vested in 2015, 2014 and 2013 totaled \$239.7 million, \$281.1 million, and \$209.7 million, respectively.

**Employee Stock Purchase Plan (ESPP)**

In June 2015, our stockholders approved the Biogen Inc. 2015 ESPP (2015 ESPP). The 2015 ESPP, which became effective on July 1, 2015, replaced the Biogen Idec Inc. 1995 ESPP (1995 ESPP), which expired on June 30, 2015. The maximum aggregate number of shares of our common stock that may be purchased under the 2015 ESPP is 6.2 million.

The following table summarizes our ESPP activity:

(In millions, except share amounts)	For the Years Ended December 31,		
	2015	2014	2013
Shares issued under the 2015 ESPP	78,000	**	**
Shares issued under the 1995 ESPP	98,000	180,000	245,000
Cash received under the 2015 ESPP	\$19.3	**	**
Cash received under the 1995 ESPP	\$30.0	\$46.4	\$38.7





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 16. Income Taxes

## Income Tax Expense

Income before income tax provision and the income tax expense consist of the following:

(In millions)	For the Years Ended December 31,			
	2015	2014	2013	
Income before income taxes (benefit):				
Domestic	\$3,386.7	\$2,557.4	\$1,953.0	
Foreign	1,380.6	1,389.2	527.6	
Total	\$4,767.3	\$3,946.6	\$2,480.6	
Income tax expense (benefit):				
Current:				
Federal	\$1,214.1	\$1,159.5	\$700.9	
State	38.6	65.2	98.4	
Foreign	54.5	73.4	46.8	
Total	1,307.2	1,298.1	846.1	
Deferred:				
Federal	\$(129.6	) \$(280.9	) \$(200.6	)
State	(1.9	) (21.0	) (35.9	)
Foreign	(14.1	) (6.3	) (8.6	)
Total	(145.6	) (308.2	) (245.1	)
Total income tax expense	\$1,161.6	\$989.9	\$601.0	

## Deferred Tax Assets and Liabilities

Significant components of our deferred tax assets and liabilities are summarized as follows:

(In millions)	As of December 31,		
	2015	2014	
Deferred tax assets:			
Tax credits	\$189.3	\$69.0	
Inventory, other reserves, and accruals	243.9	217.3	
Intangibles, net	328.3	251.7	
Net operating loss	24.7	20.6	
Share-based compensation	63.8	86.0	
Other	35.8	60.0	
Valuation allowance	(14.1	) (11.5	)
Total deferred tax assets	\$871.7	\$693.1	
Deferred tax liabilities:			
Purchased intangible assets	\$(440.1	) \$(432.8	)
Depreciation, amortization and other	(102.7	) (107.0	)
Total deferred tax liabilities	\$(542.8	) \$(539.8	)

In accordance with ASU No. 2015-17, at December 31, 2015 we reclassified \$137.1 million of our deferred tax assets classified as current to noncurrent and \$1.6 million of our deferred tax liabilities classified as current to noncurrent in our December 31, 2014 consolidated balance sheet, to conform our prior year presentation to our current year presentation.

In addition to deferred tax assets and liabilities, we have recorded prepaid tax and deferred charges related to intercompany transactions. As of December 31, 2015 and 2014, the total deferred charges and prepaid taxes were \$697.9 million and \$238.9 million, respectively.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

During 2013, we recorded a deferred charge of \$203.7 million in connection with an intercompany transfer of the intellectual property for ZINBRYTA. The net book value of this deferred charge as of December 31, 2015 and 2014 was \$166.3 million and \$179.9 million, respectively. The deferred charge will be amortized to income tax expense over the economic life of the ZINBRYTA program. Our regulatory submissions in Europe and the U.S. have been accepted for review by the relevant authorities. If the ZINBRYTA applications are not approved, we may have to accelerate the amortization of this deferred charge and record an expense equal to its remaining net book value.

**Tax Rate**

A reconciliation between the U.S. federal statutory tax rate and our effective tax rate is summarized as follows:

	For the Years Ended December 31,					
	2015		2014		2013	
Statutory rate	35.0	%	35.0	%	35.0	%
State taxes	0.5		1.2		3.1	
Taxes on foreign earnings	(10.0)	)	(9.5)	)	(6.7)	)
Credits and net operating loss utilization	(1.3)	)	(1.1)	)	(2.6)	)
Purchased intangible assets	1.0		1.2		1.5	
Manufacturing deduction	(1.8)	)	(1.8)	)	(6.6)	)
Other permanent items	0.7		0.5		0.8	
Contingent consideration and other	0.3		(0.4)	)	(0.3)	)
Effective tax rate	24.4	%	25.1	%	24.2	%

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, described below under "Accounting for Uncertainty in Income Taxes".

Our effective tax rate for 2014 compared to 2013 increased primarily as a result of the absence of a benefit related to the 2013 change in our uncertain tax position related to our U.S. federal manufacturing deduction and our unconsolidated joint business described below under "Accounting for Uncertainty in Income Taxes", lower current year expenses eligible for the orphan drug credit and a lower relative manufacturing deduction due to unqualified products, partially offset by a higher percentage of our 2014 income being earned outside the U.S.

As of December 31, 2015, we had net operating losses and general business credit carry forwards for federal income tax purposes of approximately \$25.3 million and \$127.6 million, respectively, which begin to expire in 2020.

Additionally, for state income tax purposes, we had net operating loss carry forwards of approximately \$91.7 million, which begin to expire in 2016. For state income tax purposes, we also had research and investment credit carry forwards of approximately \$125.5 million, which begin to expire in 2016. For foreign income tax purposes, we had \$53.4 million of net operating loss carryforwards, which begin to expire in 2021.

In assessing the realizability of our deferred tax assets, we have considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial reporting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. Our estimates of future taxable income take into consideration, among other items, our estimates of future income tax deductions related to the exercise of stock options. Based upon the level of historical taxable income and income tax liability and projections for future taxable income over the periods in which the deferred tax assets are utilizable, we believe it is more likely than not that we will realize the benefits of the deferred tax assets of our wholly owned subsidiaries. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

As of December 31, 2015, undistributed foreign earnings of non-U.S. subsidiaries included in consolidated retained earnings and other basis differences aggregated approximately \$6.0 billion. We intend to reinvest these earnings indefinitely in operations outside the U.S. The residual U.S. tax liability, if cumulative amounts were repatriated, would be between \$1.5 billion to \$2.0 billion as of December 31, 2015.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Accounting for Uncertainty in Income Taxes

A reconciliation of the beginning and ending amount of our unrecognized tax benefits is summarized as follows:

(In millions)	2015	2014	2013
Balance at January 1,	\$131.5	\$110.1	\$125.9
Additions based on tax positions related to the current period	10.5	20.8	11.9
Additions for tax positions of prior periods	19.5	86.1	71.7
Reductions for tax positions of prior periods	(49.9)	) (23.4	) (92.1
Statute expirations	(1.2)	) (1.6	) (1.9
Settlements	(42.5)	) (60.5	) (5.4
Balance at December 31,	\$67.9	\$131.5	\$110.1

We and our subsidiaries are routinely examined by various taxing authorities. We file income tax returns in the U.S. federal jurisdiction, various U.S. states, and foreign jurisdictions. With few exceptions, including the proposed disallowance we discuss below, we are no longer subject to U.S. federal tax examination for years before 2013 or state, local, or non-U.S. income tax examinations for years before 2004.

Included in the balance of unrecognized tax benefits as of December 31, 2015, 2014 and 2013 are \$15.7 million, \$53.6 million and \$32.5 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in future periods.

We recognize potential interest and penalties accrued related to unrecognized tax benefits in income tax expense. In 2015, we recognized a net interest expense of \$3.1 million. During 2014, we recognized net interest expense of \$4.1 million. In 2013, we recognized a net interest expense of approximately \$4.5 million. We have accrued approximately \$12.5 million and \$17.6 million for the payment of interest as of December 31, 2015 and 2014, respectively.

In March 2015, we received a final assessment from the Danish Tax Authority (SKAT) for fiscal 2009, regarding withholding taxes and the treatment of certain intercompany transactions involving our Danish affiliate and another of our affiliates. The audits of our tax filings for 2010 through 2013 are not completed but have been prepared in a manner consistent with prior filings, with similar transactions. In December 2015, we received draft assessments for these periods. The total amount assessed for all periods is \$60.9 million, including interest. For all periods potentially under dispute, we believe that positions taken in our tax filings are valid and we are contesting the assessment vigorously.

## Federal Uncertain Tax Positions

During 2013, we received updated technical guidance from the IRS concerning our current and prior year filings and calculation of our U.S. federal manufacturing deduction and overall tax classification of our unconsolidated joint business. Based on this guidance we reevaluated the level of our unrecognized benefits related to uncertain tax positions, and recorded a \$49.8 million income tax benefit. This benefit is for a previously unrecognized position and relates to years 2005 through 2012. We recorded an offsetting expense of \$11.3 million for non-income based state taxes, which is recorded in other income (expense) in our consolidated statements of income.

In October 2011, in conjunction with our examination, the IRS proposed a disallowance of approximately \$130 million in deductions for tax years 2007, 2008 and 2009 related to payments for services provided by our wholly owned Danish subsidiary located in Hillerød, Denmark. We believe that these items represent valid deductible business expenses and are vigorously defending our position. We have initiated a mutual agreement procedure between the IRS and SKAT for the years 2001 through 2009, in an attempt to reach agreement on the issue. In addition, we have applied for a bilateral advanced pricing agreement for the years 2010 through 2014 to resolve similar issues for the subsequent years.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

During the year ended December 31, 2015, the net effect of adjustments to our uncertain tax positions was a net benefit of approximately \$25.0 million. It is reasonably possible that we will adjust the value of our uncertain tax positions related to our unconsolidated joint business and certain transfer pricing issues as we receive additional information from various taxing authorities, including reaching settlements with the authorities. In addition, the IRS and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

## 17. Other Consolidated Financial Statement Detail

## Supplemental Cash Flow Information

Supplemental disclosure of cash flow information for the years ended December 31, 2015, 2014 and 2013, is as follows:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Cash paid during the year for:			
Interest	\$39.1	\$41.2	\$53.6
Income taxes	\$1,674.8	\$1,163.2	\$643.2

## Non-cash Investing and Financing Activity

In the fourth quarter of 2015, we accrued \$300.0 million upon reaching \$7.0 billion in total cumulative sales of Fumapharm Products. The amount, net of tax benefit, was accounted for as an increase to goodwill in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm and is expected to be paid in the first quarter of 2016. For additional information related to this transaction, please read Note 21, Commitment and Contingencies to these consolidated financial statements.

In connection with the construction of our manufacturing facility in Solothurn, Switzerland, we accrued charges related to processing equipment and engineering services of approximately \$59.1 million in our consolidated balance sheet. For additional information related to this transaction, please read Note 10, Property, Plant and Equipment to these consolidated financial statements.

In February 2015, upon completion of our acquisition of Convergence, we recorded a contingent consideration obligation of \$274.5 million as part of the purchase price. For additional information related to this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

In July and November 2013, the construction of two office buildings in Cambridge, Massachusetts was completed and we started leasing the facilities. Upon completion of the construction of the buildings, we determined that we were no longer considered the owner of the buildings because we did not have any unusual or significant continuing involvement. Consequently, we derecognized the buildings and their associated financing obligation of approximately \$161.5 million from our consolidated balance sheet.

## Other Income (Expense), Net

Components of other income (expense), net, are summarized as follows:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Interest income	\$22.1	\$12.2	\$8.2
Interest expense	(95.5	) (29.5	) (31.9
Impairments on investments	—	—	(2.8
Gain (loss) on investments, net	(3.8	) 11.8	21.7
Foreign exchange gains (losses), net	(32.7	) (11.6	) (15.2
Other, net	(13.8	) (8.7	) (14.9
Total other income (expense), net	\$(123.7	) \$(25.8	) \$(34.9





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Other Current Assets

Other current assets includes prepaid taxes totaling approximately \$550.6 million and \$57.6 million as of December 31, 2015 and 2014, respectively.

## Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of December 31,	
	2015	2014
Revenue-related reserves for discounts and allowances	\$518.1	\$359.2
Current portion of contingent consideration obligations	504.7	265.5
Employee compensation and benefits	270.8	393.8
Royalties and licensing fees	167.9	172.4
Deferred revenue	55.7	120.9
Other	579.6	505.9
Total accrued expenses and other	\$2,096.8	\$1,817.7

## Other Long-Term Liabilities

Other long-term liabilities consists of the following:

(In millions)	As of December 31,	
	2015	2014
Contingent consideration obligation	\$301.3	\$200.0
Employee compensation and benefits	235.4	200.7
Other	369.1	249.4
Total other long-term liabilities	\$905.8	\$650.1

## Pricing of TYSABRI in Italy - AIFA

In the fourth quarter of 2011, Biogen Italia SRL (formerly Biogen Idec Italia SRL), our Italian subsidiary, received a notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 through mid-February 2011 exceeded by EUR30.7 million a reimbursement limit established pursuant to a Price Determination Resolution granted by AIFA in December 2006. In December 2011, we filed an appeal against AIFA in administrative court in Rome, Italy seeking a ruling that the reimbursement limit in the Price Determination Resolution should apply as written to only “the first 24 months” of TYSABRI sales, which ended in mid-February 2009. That appeal is still pending. Since being notified in the fourth quarter of 2011 that AIFA believed a reimbursement limit was still in effect, we deferred revenue on sales of TYSABRI as if the reimbursement limit were in effect for each biannual period beginning in mid-February 2009.

In July 2013, we negotiated an agreement in principle with AIFA's Price and Reimbursement Committee that would have resolved all of AIFA's claims relating to sales of TYSABRI in excess of the reimbursement limit for the periods from February 2009 through January 2013 for an aggregate repayment of EUR33.3 million. The agreement was sent to the Avvocatura Generale dello Stato (Attorney General) for its opinion. As a result of this agreement in principle, we recorded a liability and reduction to revenue of EUR15.4 million at June 30, 2013, which approximated 50% of the claim related to the period from mid-February 2009 through mid-February 2011. In October 2014, we proposed a revised settlement for the period from February 2009 through January 2013 of EUR35.6 million to be paid in one payment. AIFA and Biogen Italia SRL are still discussing a possible resolution for the period from February 2009 through January 2013.

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

We have approximately EUR75 million recorded as accrued expenses and long-term deferred revenue in our consolidated balance sheets for this matter as of December 31, 2015 and 2014, respectively.



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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

18. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

Our consolidated financial statements include the financial results of variable interest entities in which we are the primary beneficiary. The following are our significant variable interest entities.

Neurimmune SubOne AG

In 2007, we entered into a collaboration agreement with Neurimmune SubOne AG (Neurimmune), a subsidiary of Neurimmune AG, for the development and commercialization of antibodies for the treatment of Alzheimer's disease. Neurimmune conducts research to identify potential therapeutic antibodies and we are responsible for the development, manufacturing and commercialization of all products. Our anti-amyloid beta antibody, aducanumab (BIIB037), for the treatment of Alzheimer's disease resulted from this collaboration. In September 2015, we announced that the first patient had been enrolled in a Phase 3 trial for aducanumab, which triggered a \$60.0 million milestone payment due to Neurimmune. As we consolidate the financial results of Neurimmune, we recognized this payment as a charge to noncontrolling interest in the third quarter of 2015. Based upon our current development plans for aducanumab, we may pay Neurimmune up to \$275.0 million in remaining milestone payments. We may also pay royalties in the low-to-mid-teens on sales of any resulting commercial products.

We determined that we are the primary beneficiary of Neurimmune because we have the power through the collaboration to direct the activities that most significantly impact the entity's economic performance and are required to fund 100% of the research and development costs incurred in support of the collaboration agreement. Accordingly, we consolidate the results of Neurimmune.

Amounts that are incurred by Neurimmune for research and development expenses in support of the collaboration that we reimburse are reflected in research and development expense in our consolidated statements of income. During the years ending December 31, 2015, 2014 and 2013, these amounts were immaterial. Future milestone payments and royalties, if any, will be reflected in our consolidated statements of income as a charge to noncontrolling interest, net of tax, when such milestones are achieved.

The assets and liabilities of Neurimmune are not significant to our financial position or results of operations as it is a research and development organization. We have provided no financing to Neurimmune other than previously contractually required amounts.

Rodin Therapeutics, Inc.

In December 2015, we paid \$8.0 million for preferred stock in Rodin Therapeutics, Inc. (Rodin) and entered into an option and collaboration agreement which gives us the right to purchase all remaining outstanding shares of Rodin, at any time until 35 days after acceptance of an Investigational New Drug (IND) application by the FDA. Rodin is a discovery-stage biotechnology company developing novel therapeutics for neurological disorders. We committed to make additional investments in Rodin's preferred shares of \$4.0 million, if certain development milestones are achieved. If we exercise our option to purchase the outstanding shares of Rodin, we could pay additional amounts upon achievement of clinical and commercial milestones.

Through our fixed price option to purchase Rodin, purchases of equity, our collaboration and presence on the program advisory committee and Rodin Board of Directors, we are deemed to be the primary beneficiary of Rodin, a variable interest entity. Therefore, we consolidate the results of Rodin. As part of the initial consolidation of Rodin, we recorded an IPR&D intangible asset of approximately \$8.7 million and assigned approximately \$10.9 million to minority interest in our stockholder's equity.

The assets and liabilities of Rodin are not significant to our financial position or results of operations as it is a research and development organization. We have provided no financing to Rodin other than contractually required amounts.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Unconsolidated Variable Interest Entities

We have relationships with other variable interest entities that we do not consolidate as we lack the power to direct the activities that significantly impact the economic success of these entities. These relationships include investments in certain biotechnology companies and research collaboration agreements.

As of December 31, 2015 and 2014, the total carrying value of our investments in biotechnology companies totaled \$29.2 million and \$7.9 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

We have entered into research collaboration agreements with certain variable interest entities where we are required to fund certain development activities. These development activities are included in research and development expense in our consolidated statements of income, as they are incurred. We have provided no financing to these variable interest entities other than previously contractually required amounts.

19. Collaborative and Other Relationships

In connection with our business strategy, we have entered into various collaboration agreements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. Terms of the various collaboration agreements may require us to make milestone payments upon the achievement of certain product research and development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

Depending on the collaborative arrangement, we may record funding receivables or payable balances with our partners, based on the nature of the cost-sharing mechanism and activity within the collaboration. Our significant collaboration arrangements are discussed below.

Genentech (Roche Group)

We collaborate with Genentech on the development and commercialization of RITUXAN. In addition, in the U.S., we share operating profits and losses relating to GAZYVA with Genentech. The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacturing and commercialization of GAZYVA in the U.S. Our collaboration agreement will continue in effect until we mutually agree to terminate the collaboration, except that if we undergo a change in control, as defined in the collaboration agreement, Genentech has the right to present an offer to buy the rights to RITUXAN and we must either accept Genentech's offer or purchase Genentech's rights on the same terms as its offer. Genentech will also be deemed concurrently to have purchased our rights to any other anti-CD20 products in development in exchange for a royalty and our rights to GAZYVA in exchange for the compensation described in the table below. Our collaboration with Genentech was created through a contractual arrangement and not through a joint venture or other legal entity.

RITUXAN

Genentech is responsible for the worldwide manufacturing of RITUXAN. Development and commercialization rights and responsibilities under this collaboration are divided as follows:

U.S.

We share with Genentech co-exclusive rights to develop, commercialize and market RITUXAN in the U.S.

Canada

We and Genentech have assigned our rights under our collaboration agreement with respect to Canada to the Roche Group.

Outside the U.S. and Canada

We have granted Genentech exclusive rights to develop, commercialize and market RITUXAN outside the U.S. and Canada. Under the terms of separate sublicense agreements between Genentech and the Roche Group, development and commercialization of RITUXAN outside the U.S. and Canada is the responsibility of the Roche Group and its sublicensees. We do not have any direct contractual arrangements with the Roche Group or its sublicensees.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Under the terms of the collaboration agreement, the Roche Group pays us royalties between 10% and 12% on sales of RITUXAN outside the U.S. and Canada, with the royalty period lasting 11 years from the first commercial sale of RITUXAN on a country-by-country basis. The royalty periods for the substantial portion of the royalty-bearing sales in the rest of world markets expired during 2012 and 2013. We expect future revenue on sales of RITUXAN in the rest of world will be limited to our share of pre-tax co-promotion profits in Canada.

**GAZYVA**

Prior to FDA approval of GAZYVA, we recognized 35% of the development and commercialization expenses as research and development expense and selling, general and administrative expense, respectively, in our consolidated statements of income. After GAZYVA was approved by the FDA in the fourth quarter of 2013, we began to recognize our share of the development and commercialization expenses as a reduction of our share of pre-tax profits in revenues from unconsolidated joint business.

Commercialization of GAZYVA will impact our percentage of the co-promotion profits for RITUXAN, as summarized in the table below.

**Ocrelizumab**

Genentech is solely responsible for development and commercialization of ocrelizumab, a humanized anti-CD20 monoclonal antibody currently in development for MS, and funding future costs. Genentech cannot develop ocrelizumab in CLL, NHL or RA. We will receive tiered royalties between 13.5% and 24% on U.S. net sales of ocrelizumab if approved for commercial sale by the FDA. There will be a 50% reduction to these royalties if a biosimilar to ocrelizumab is approved in the U.S. In addition, we will receive a 3% royalty on worldwide net sales of ocrelizumab outside the U.S., with the royalty period lasting 11 years from the first commercial sale of ocrelizumab on a country-by-country basis.

Commercialization of ocrelizumab will not impact the percentage of the co-promotion profits we receive for RITUXAN or GAZYVA.

**Profit-sharing Formulas****RITUXAN Profit Share**

Our current pretax co-promotion profit-sharing formula for RITUXAN provides for a 30% share on the first \$50.0 million of co-promotion operating profits earned each calendar year. Our share of annual co-promotion profits in excess of \$50.0 million varies, as summarized in the table below, upon the following events:

Until GAZYVA First Non-CLL FDA Approval	40.0	%
After GAZYVA First Non-CLL FDA Approval until First GAZYVA Threshold Date	39.0	%
After First GAZYVA Threshold Date until Second GAZYVA Threshold Date	37.5	%
After Second GAZYVA Threshold Date	35.0	%

First Non-CLL GAZYVA FDA Approval means the FDA's first approval of GAZYVA in an indication other than CLL.

First GAZYVA Threshold Date means the earlier of (1) the date of the First Non-CLL GAZYVA FDA approval if U.S. gross sales of GAZYVA for the preceding consecutive 12 month period were at least \$150.0 million or (2) the first day of the calendar quarter after the date of the First Non-CLL GAZYVA FDA Approval that U.S. gross sales of GAZYVA within any consecutive 12 month period have reached \$150.0 million.

Second GAZYVA Threshold Date means the first day of the calendar quarter after U.S. gross sales of GAZYVA within any consecutive 12 month period have reached \$500.0 million. The Second GAZYVA Threshold Date can be achieved regardless of whether GAZYVA has been approved in a non-CLL indication.

We expect our share of RITUXAN pre-tax profits in the U.S. to decrease to 39% from 40% if GAZYVA is approved by the FDA in RITUXAN-refractory indolent non-Hodgkin's lymphoma.

In addition, should the FDA approve an anti-CD20 product other than ocrelizumab or GAZYVA that is acquired or developed by Genentech and subject to the collaboration agreement, our share of the co-promotion operating profits would be between 30% and 38% based on certain events.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## GAZYVA Profit Share

Our current pretax profit-sharing formula for GAZYVA provides for a 35% share on the first \$50.0 million of operating profits earned each calendar year. Our share of annual profits in excess of \$50.0 million varies, as summarized in the table below, upon the following events:

Until First GAZYVA Threshold Date	39.0	%
After First GAZYVA Threshold Date until Second GAZYVA Threshold Date	37.5	%
After Second GAZYVA Threshold Date	35.0	%

In 2015, 2014, and 2013, our share of operating losses on GAZYVA was 35%.

## Unconsolidated Joint Business Revenues

During the first quarter of 2013, we reduced our share of RITUXAN revenues from unconsolidated joint business by approximately \$49.7 million, of which revenue on sales in the rest of world for RITUXAN was reduced by \$41.2 million and pre-tax profits in the U.S. were reduced by \$8.5 million, to reflect our share of the royalties and interest awarded to Hoechst in its arbitration with Genentech.

Revenues from unconsolidated joint business are summarized as follows:

(In millions)	For the Years Ended December 31,		
	2015	2014	2013
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA, including the reimbursement of selling and development expenses (1)	\$1,269.8	\$1,117.1	\$1,087.3
Revenue on sales in the rest of world for RITUXAN	69.4	78.3	38.7
Total unconsolidated joint business revenues	\$1,339.2	\$1,195.4	\$1,126.0

(1) GAZYVA sales began in the fourth quarter of 2013.

In 2015, 2014, and 2013, the 40% profit-sharing threshold was met during the first quarter.

Prior to regulatory approval, we record our share of the expenses incurred by the collaboration for the development of anti-CD20 products in research and development expense in our consolidated statements of income. We incurred \$25.7 million in development expense for 2013. After an anti-CD20 product is approved, we record our share of the development expenses related to that product as a reduction of our share of pre-tax profits in revenues from unconsolidated joint business.

## Elan

On April 2, 2013, we acquired full ownership of all remaining rights to TYSABRI from Elan that we did not already own or control. Upon the closing of the transaction, our collaboration agreement with Elan was terminated. For additional information related to this transaction, please read Note 2, Acquisitions to these consolidated financial statements.

We previously collaborated with Elan on the development, manufacture and commercialization of TYSABRI. Under the terms of our collaboration agreement, we manufactured TYSABRI and collaborated with Elan on the product's marketing, commercial distribution and ongoing development activities. The agreement was designed to effect an equal sharing of profits and losses generated by the activities of our collaboration. Under the agreement, however, once sales of TYSABRI exceeded specific thresholds, Elan was required to make milestone payments to us in order to continue sharing equally in the collaboration's results.

In the U.S., we previously sold TYSABRI to Elan who then sold the product to third-party distributors. Our sales price to Elan in the U.S. was set prior to the beginning of each quarterly period to effect an approximate equal sharing of the gross profit between Elan and us. We recognized revenue for sales in the U.S. of TYSABRI upon Elan's shipment of the product to the third-party distributors, at which time all revenue recognition criteria had been met. We incurred manufacturing and distribution costs, research and development expenses, commercial expenses, and general and administrative expenses related to TYSABRI. We recorded these expenses to their respective line items in our consolidated statements of income when they were incurred. Research and development and sales and marketing



expenses were shared equally with Elan and the reimbursement of these expenses was recorded as

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

reductions of the respective expense categories. During 2013, we recorded \$11.7 million as a reduction of research and development expense resulting from reimbursements from Elan. In addition, for 2013, we recorded \$20.6 million as a reduction of selling, general and administrative expense resulting from reimbursements from Elan.

In the rest of world, we previously were responsible for distributing TYSABRI to customers and were primarily responsible for all operating activities. Generally, we recognized revenue for sales of TYSABRI in the rest of world at the time of product delivery to our customers. We made payments to Elan which effected an equal sharing of rest of world collaboration operating profits. These payments also included the reimbursement we paid to Elan for half of the third-party royalties that Elan paid on behalf of the collaboration relating to rest of world sales. These amounts were reflected in the collaboration profit sharing line in our consolidated statements of income. For 2013, \$85.4 million was reflected in the collaboration profit sharing line for our collaboration with Elan.

**Acorda**

In 2009, we entered into a collaboration and license agreement with Acorda Therapeutics, Inc. (Acorda) to develop and commercialize products containing fampridine in markets outside the U.S. We also have responsibility for regulatory activities and the future clinical development of related products in those markets.

Under the terms of the collaboration and license agreement, we pay Acorda tiered royalties based on the level of ex-U.S. net sales. We may pay up to \$375.0 million of additional milestone payments to Acorda, based on the successful achievement of certain regulatory and commercial milestones. The next expected milestone would be \$15.0 million, due if ex-U.S. net sales reach \$100.0 million over a period of four consecutive quarters. We will capitalize these additional milestones as intangible assets upon achievement of the milestone which will then be amortized utilizing an economic consumption model and recognized as amortization of acquired intangible assets. Royalty payments are recognized as a cost of goods sold.

In connection with the collaboration and license agreement, we have also entered into a supply agreement with Acorda for the commercial supply of FAMPRYA. This agreement is a sublicense arrangement of an existing agreement between Acorda and Alkermes, who acquired Elan Drug Technologies, the original party to the license with Acorda. During the years ending December 31, 2015, 2014 and 2013, total cost of sales related to royalties and commercial supply of FAMPRYA reflected in our consolidated statement of income were \$30.6 million, \$29.2 million and \$24.3 million, respectively.

**Swedish Orphan Biovitrum AB (publ)**

In January 2007, we acquired 100% of the stock of Syntonix. Syntonix had previously entered into a collaboration agreement with Swedish Orphan Biovitrum AB (publ) (Sobi) to jointly develop and commercialize Factor VIII and Factor IX hemophilia products, including ELOCTATE and ALPROLIX. In February 2010, we restructured the collaboration agreement and assumed full development responsibilities and costs, as well as manufacturing rights. In addition, the cross-royalty rates were reduced and commercial rights for certain territories were changed. As a result, we have commercial rights for North America (the Biogen North America Territory) and for rest of the world markets outside of, essentially, Europe, North Africa, Russia and certain countries in the Middle East (the Biogen Direct Territory). Subject to the exercise of an option right that Sobi controls, Sobi will have commercial rights in, essentially, Europe, North Africa, Russia and certain countries in the Middle East (the Sobi Territory). The collaboration agreement was amended and restated in April 2014. (References to the collaboration agreement refer to the amended and restated collaboration agreement).

In November 2014, Sobi exercised its option to assume final development and commercialization activities in the Sobi Territory for ELOCTA (the trade name for ELOCTATE in the E.U.). In July 2015, Sobi exercised its option to assume final development and commercialization of ALPROLIX within the Sobi Territory. Upon each exercise of opt-in right under the terms of the collaboration agreement, Sobi made a \$10.0 million payment in escrow.

Upon EMA regulatory approval of each such product, Sobi will be liable to reimburse us 50% of the sum of all shared manufacturing and development expenses incurred by us from October 1, 2009 through the earlier of the date on which Sobi is registered as the marketing authorization holder for the applicable product or 90 days post-regulatory

approval, as well as 100% of certain development expenses incurred exclusively for the benefit of the Sobi Territory (the Opt-In Consideration). This reimbursement will be recognized in proportion to collaboration revenues, over a ten year period, consistent with the initial patent terms of the products.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

ELOCTA was approved by the EC in November 2015. Through December 31, 2015, approximately \$200 million in expenditures for ELOCTA, net of the \$10.0 million escrow payment discussed above, are reimbursable by Sobi under the collaboration agreement due to its election to assume final development and commercialization of ELOCTA within the Sobi Territory. Approximately \$175 million in expenditures for ALPROLIX may be reimbursable by Sobi under the collaboration agreement due to its election to assume final development and commercialization of ALPROLIX within the Sobi Territory. The escrow payment made with respect to ALPROLIX will be applied to the amount of the Opt-In Consideration to be reimbursed by Sobi upon EMA regulatory approval.

To effect Sobi's reimbursement to us for the Opt-In Consideration exceeding the escrow payment for the applicable product, the cross-royalty cash payment structure for direct sales in each company's respective territories will be adjusted until the Opt-In Consideration is paid in full (the Reimbursement Period). The mechanism for reimbursement is outlined in the table below.

Under the collaboration agreement, cash payments are as follows:

Royalty and Net Revenue Share Rates: Method	Rate prior to 1st commercial sale in the Sobi Territory:	Rates post Sobi Opt-In <sup>(3)</sup>		
		Base Rate following 1st commercial sale in the Sobi Territory:	Rate during the Reimbursement Period:	
Sobi rate to Biogen on net sales in the Sobi Territory	Royalty	N/A	10 or 12%	Base Rate plus 5%
Biogen rate to Sobi on net sales in the Biogen North America Territory	Royalty	2%	10 or 12%	Base Rate less 5%
Biogen rate to Sobi on net sales in the Biogen Direct Territory	Royalty	2%	15 or 17%	Base Rate less 5%
Biogen rate to Sobi on net revenue <sup>(1)</sup> from the Biogen Distributor Territory <sup>(2)</sup>	Net Revenue Share	10%	50%	Base Rate less 15%

(1) Net revenue represents Biogen's pre-tax receipts from third-party distributors, less expenses incurred by Biogen in the conduct of commercialization activities supporting the distributor activities.

(2) The Biogen Distributor Territory represents Biogen territories where sales are derived utilizing a third-party distributor.

A credit will be issued to Sobi against its reimbursement of the Opt-in Consideration in an amount equal to the (3) difference in the rate paid by Biogen to Sobi on sales in the Biogen territories for certain periods prior to the first commercial sale in the Sobi Territory versus the rate that otherwise would have been payable on such sales.

If the reimbursement of the Opt-in Consideration has not been achieved within six years of the first commercial sale of such product, we maintain the right to require Sobi to pay any remaining balances due to us within 90 days of the six year anniversary date of the first commercial sale.

We expect to recognize the effect of the cash reimbursement as an adjustment to the Base Rate in the table above. Should Sobi terminate the collaboration agreement with respect to ALPROLIX, we will obtain full worldwide development and commercialization rights and we will be obligated to pay royalties to Sobi subject to separate terms, as defined in the collaboration agreement. In addition, if EMA approval for ALPROLIX is not granted within 18 months of the filing date, Sobi shall have the right to require that the escrow payment be refunded and revoke its option right for such product.

AbbVie Biotherapeutics, Inc.

We have a collaboration agreement with AbbVie Biotherapeutics, Inc., a subsidiary of AbbVie, Inc. (AbbVie) aimed at advancing the development and commercialization of ZINBRYTA in MS.

Under the agreement, we and AbbVie will conduct ZINBRYTA co-promotion activities in the E.U., U.S. and Canada territories (Collaboration Territory), where development and commercialization costs and profits are shared equally. We are responsible for all manufacturing activities in the Collaboration Territory. In the U.S., AbbVie will recognize revenues on sales to third parties and we will recognize our 50% share of the co-promotion profits or losses as a component of total revenues in our consolidated statements of income.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In the E.U. and Canada, we will reflect revenues on sales to third parties in product revenues, net in our consolidated statements of income. We will record the related cost of revenues and sales and marketing expenses to their respective line items in our consolidated statements of income when these costs are incurred. The reimbursement with AbbVie for the 50% sharing of the co-promotion profits or losses in the E.U. and Canada will be recognized in our total costs and expenses.

Outside of the Collaboration Territory, we are solely responsible for development and commercialization where we will pay a tiered royalty to AbbVie on net sales in the low to high teens.

We are the responsible party for manufacturing and research and development activities in both the Collaboration Territory and outside the Collaboration Territory and will record these activities to their respective lines in our consolidated statements of income, net of any reimbursement of research and development expenditures from AbbVie.

During 2015, we made milestone payments of \$16.0 million for the development of ZINBRYTA as a result of filing for regulatory approval in the U.S. and E.U. during the year. These payments were recorded as research and development expense in our consolidated statements of income. We may incur up to an additional \$32.0 million of milestone payments related to the development of ZINBRYTA, of which \$20.0 million is due upon regulatory approval in the U.S. and \$12.0 million is due upon regulatory approval in the E.U. These future payments will be capitalized as an intangible asset in our consolidated balance sheets.

A summary of activity related to this collaboration is as follows:

(In millions)	For the Years Ended		
	December 31,		
	2015	2014	2013
Total development expense incurred by the collaboration	\$113.8	\$117.8	\$133.4
Biogen's share of development expense reflected in our consolidated statements of income	\$60.8	\$67.4	\$71.0

Ionis Pharmaceuticals, Inc.

#### Long-Term Strategic Research Collaboration

In September 2013, we entered into a six year research collaboration with Ionis Pharmaceuticals, Inc. (Ionis), formerly known as Isis Pharmaceuticals Inc. under which both companies collaborate to perform discovery level research and then develop and commercialize antisense or other therapeutics for the treatment of neurological disorders. Under the collaboration, Ionis will perform research on a set of neurological targets identified within the agreement. Once the research has reached a specific stage of development, we will make the determination whether antisense is the preferred approach to develop a therapeutic candidate or whether another modality is preferred. If antisense is selected, Ionis will continue development and identify a product candidate. If another modality is used, we will assume the responsibility for identifying a product candidate and developing it.

Under the terms of this agreement, we paid Ionis an upfront amount of \$100.0 million. Of this payment, we recorded prepaid research and discovery services of approximately \$25.0 million, representing the value of the Ionis full time equivalent employee resources which are required by the collaboration to provide research and discovery services to us over the next six years. The remaining \$75.0 million of the upfront payment was recorded as research and development expense as it represented the purchase of intellectual property that had not reached technological feasibility.

Ionis is also eligible to receive milestone payments, license fees and royalty payments for all product candidates developed through this collaboration, with the specific amount dependent upon the modality of the product candidate advanced by us. During the years ending December 31, 2015 and 2014, we triggered milestones of \$20.0 million and \$20.0 million, respectively, related to the advancement of IONIS-SOD1<sub>Rx</sub> for the treatment of ALS and other neurological targets identified.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

For non-ALS antisense product candidates, Ionis will be responsible for global development through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. For ALS antisense product candidates, we are responsible for global development, clinical trial design and regulatory strategy. We have an option to license a product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a \$70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive additional milestone payments upon the achievement of certain regulatory milestones of up to \$130.0 million, plus additional amounts related to the cost of clinical trials conducted by Ionis under the collaboration, and royalties on future sales if we successfully develop the product candidate after option exercise.

For product candidates using a different modality, we will be responsible for global development through all stages and will pay Ionis up to \$90.0 million upon the achievement of certain regulatory milestones and royalties on future sales if we successfully develop the product candidate.

**Product Collaborations**

In December, June and January 2012, we entered into three separate exclusive, worldwide option and collaboration agreements with Ionis under which both companies will develop and commercialize antisense therapeutics for up to three gene targets, Ionis' product candidates for the treatment of myotonic dystrophy type 1 (DM1), and the antisense investigational candidate nusinersen (ISIS-SMN<sub>Rx</sub>) for the treatment of spinal muscular atrophy (SMA), respectively.

**Antisense Therapeutics**

Under the terms of the December 2012 agreement relating to the development and commercialization of up to three gene targets we provided Ionis with an upfront payment of \$30.0 million and will make potential additional payments, prior to licensing, of up to \$10.0 million based on the development of the selected product candidate as well as a mark-up of the cost estimate of the Phase 1 and Phase 2 trials. During 2015, we triggered a \$10.0 million milestone payment. Ionis will be responsible for global development of any product candidate through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. We have an option to license the product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a \$70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive up to another \$130.0 million in milestone payments upon the achievement of certain regulatory milestones as well as royalties on future sales if we successfully develop the product candidate after option exercise.

**IONIS-DMPK<sub>Rx</sub>**

Under the terms of the June 2012 agreement for the DM1 candidate, we provided Ionis with an upfront payment of \$12.0 million and agreed to make potential additional payments, prior to licensing, of up to \$59.0 million based on the development of the selected product candidate. During 2015, we amended the agreement to adjust the amount of potential additional payments by an additional \$4.2 million due to changes in the clinical trial design.

During 2015, 2014 and 2013, we triggered milestones of \$2.8 million, \$14.0 million and \$10.0 million, respectively, related to the selection and advancement of IONIS-DMPK<sub>Rx</sub> to treat DM1. Ionis will be responsible for global development of any product candidate through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. We also have an option to license the product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a \$70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive up to another \$130.0 million in milestone payments upon the achievement of certain regulatory milestones as well as royalties on future sales if we successfully develop the product candidate after option exercise.

During the years ending December 31, 2015, 2014 and 2013, \$9.0 million, \$10.9 million and \$11.2 million, respectively, were reflected in research and development expense in our consolidated statements of income.



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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Nusinersen

Under the terms of the January 2012 agreement for the antisense investigational drug candidate, nusinersen, we paid Ionis \$29.0 million as an upfront payment.

During 2014, we amended the agreement to adjust the amount of potential additional payments and terms of the exercise of our opt-in right to license nusinersen. Consistent with the initial agreement, Ionis remains responsible for conducting the pivotal/Phase 3 trials. We are providing input on the clinical trial design and regulatory strategy for the development of nusinersen. During 2015 and 2014, we triggered clinical trial payments of \$42.8 million and \$57.3 million related to the advancement of the program. We are recognizing these payments as research and development expenses as the trial costs are incurred.

During 2015, we amended the agreement and may pay up to an additional \$92.0 million due to changes in the clinical trial design.

We may exercise our opt-in right upon completion of and data review of the first successful Phase 2/3 trial or completion of both Phase 2/3 trials. An amendment in December 2014 provided for additional opt-in scenarios, based on the filing or the acceptance of a new drug application or marketing authorization application with the FDA or EMA. Under the amended collaboration agreement, we may pay Ionis up to approximately \$325.0 million in a license fee and payments, including \$100.0 million in payments associated with the clinical development of nusinersen prior to licensing, a license fee and \$150.0 million in milestone payments upon the achievement of certain regulatory milestones as well as royalties on future sales of nusinersen if we successfully develop nusinersen after option exercise.

During the years ending December 31, 2015, 2014 and 2013, \$74.9 million, \$27.7 million and \$13.6 million, respectively, were reflected in research and development expense in our consolidated statements of income.

Eisai Co., Ltd.

BAN2401 and E2609 Collaboration

On March 4, 2014, we entered into a collaboration agreement with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize two Eisai product candidates for the treatment of Alzheimer's disease, BAN2401, a monoclonal antibody that targets amyloid-beta aggregates, and E2609, a BACE inhibitor, (Eisai Collaboration Agreement). Under the Eisai Collaboration Agreement, Eisai serves as the global operational and regulatory lead for both compounds and all costs, including research, development, sales and marketing expenses, will be shared equally by us and Eisai.

Following marketing approval in major markets, such as the U.S., the E.U. and Japan, we will co-promote BAN2401 and E2609 with Eisai and share profits equally. In smaller markets, Eisai will distribute these products and pay us a royalty. The Eisai Collaboration Agreement also provides the parties with certain rights and obligations in the event of a change in control of either party.

The Eisai Collaboration Agreement also provides Eisai an option to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for Alzheimer's disease (Aducanumab Option) and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). Upon exercise of each of the Aducanumab Option and the Anti-Tau Option, we will execute a separate collaboration agreement with Eisai on terms and conditions that mirror the Eisai Collaboration Agreement.

Aducanumab Option

Eisai may exercise the Aducanumab Option after either (i) completion of both the current Phase 1b clinical trial for aducanumab and the current Phase 2 clinical trial for BAN2401 (Post-Phase 2 Aducanumab Option), or (ii) completion of the Phase 3 clinical trial for aducanumab (Post-Phase 3 Aducanumab Option) under certain conditions. The consideration we will receive if Eisai exercises the Post-Phase 2 Aducanumab Option depends on the development status of BAN2401. If BAN2401 is then determined to advance to Phase 3, we will be entitled to receive a single payment from Eisai upon regulatory approval of aducanumab and we will no longer be required to pay Eisai any milestone payments for products containing BAN2401 under the Eisai Collaboration Agreement. If the development of BAN2401 has instead been terminated, we will receive development and commercial milestone

payments from Eisai (Post-Phase 2 Aducanumab Milestone Payments). If Eisai does not exercise its Post-Phase 2 Aducanumab Option, we may elect to terminate the Eisai Collaboration Agreement with respect to BAN2401 but, under certain conditions, will have the option to reinstate the Eisai Collaboration Agreement after completion of a BAN2401 Phase 3 clinical trial.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

If Eisai exercises its Post-Phase 3 Aducanumab Option, Eisai will be required to pay us all Phase 3 development and commercialization costs plus a mark-up and an amount equal to any unpaid Post-Phase 2 Aducanumab Milestone Payments that would have been payable if Eisai had exercised its Post-Phase 2 Aducanumab Option.

**Anti-Tau Option**

Eisai may exercise the Anti-Tau Option after completion of the Phase 1 clinical trial of such anti-tau monoclonal antibody. If Eisai exercises its Anti-Tau Option, we will receive an upfront payment from Eisai and will be entitled to additional development and commercial milestone payments.

Upon the effective date of the Eisai Collaboration Agreement, we paid Eisai \$100.0 million and recorded \$17.7 million, reflecting the fair value of the options granted under the Eisai Collaboration Agreement, both of which were classified as research and development expense in our consolidated statements of income. During the second quarter of 2014, Eisai exercised its option under the Eisai Collaboration Agreement to expand the joint development and commercialization activities to include Japan. Upon such exercise, we paid Eisai an additional \$35.0 million, and recorded \$21.6 million as research and development expense in our consolidated statements of income, which represented the difference between the payment made upon exercise of the option and the fair value of that option recorded as research and development expense upon closing of the agreement in the first quarter of 2014. We could pay Eisai up to an additional \$1.0 billion under the Eisai Collaboration Agreement based on the future achievement of certain development, regulatory and commercial milestones.

In addition to our arrangements with Eisai, Neurimmune is entitled to milestone and royalty payments related to the development and commercialization of aducanumab and certain anti-tau antibodies. For additional information regarding our agreement with Neurimmune, please see Note 18, Investments in Variable Interest Entities to these consolidated financial statements.

A summary of activity related to this collaboration is as follows:

(In millions)	For the Years Ended		
	December 31,		
	2015	2014	2013
Total development expense incurred by the collaboration	\$84.1	\$57.5	\$—
Biogen's share of development expense, excluding upfront and milestone payments, reflected in our consolidated statements of income	\$40.4	\$29.1	\$—

**Sangamo BioSciences, Inc.**

On February 22, 2014, we completed an exclusive worldwide research, development and commercialization collaboration and license agreement with Sangamo BioSciences, Inc. (Sangamo) under which both companies will develop and commercialize product candidates for the treatment of two inherited blood disorders, sickle cell disease and beta-thalassemia. The collaboration is currently in the research stage of development.

Under the terms of the agreement, we paid Sangamo an upfront payment of \$20.0 million in cash, with additional payments of up to approximately \$300.0 million based on the achievement of certain development, regulatory and commercial milestones, plus royalties based on sales. We recorded the \$20.0 million upfront payment as research and development expense. Under this arrangement, Sangamo will be responsible for identifying a product candidate for the treatment of beta-thalassemia and advancing that candidate through a completed Phase 1 human clinical trial, at which point we would assume responsibility for development. We will jointly develop a sickle cell disease candidate through the potential filing of an investigative new drug application, after which we would assume clinical responsibilities. We will lead the global development and commercialization efforts and Sangamo will have the option to assume co-promotion responsibilities in the U.S.

During the years ending December 31, 2015 and 2014, \$13.6 million and \$28.9 million, respectively, of expense was reflected in our consolidated statements of income.



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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Applied Genetic Technologies Corporation

On July 2, 2015, we announced a collaboration and license agreement to develop gene-based therapies for multiple ophthalmic diseases with Applied Genetic Technologies Corporation (AGTC). The collaboration will focus on the development of a portfolio of AGTC's therapeutic programs, including both a clinical-stage candidate for X-linked Retinoschisis (XLRS) and a pre-clinical candidate for the treatment of X-Linked Retinitis Pigmentosa (XLRP). The agreement also includes options for early stage discovery programs in two ophthalmic diseases and one non-ophthalmic condition, as well as an equity investment in AGTC.

During the third quarter of 2015, we made an upfront payment of \$124.0 million, which included a \$30.0 million equity investment in AGTC, prepaid research and development expenditures of \$58.4 million and total licensing and other fees of \$35.6 million. The \$58.4 million of prepaid research and development expenditures were recorded in investments and other assets in our consolidated balance sheets and will be expensed as the services are provided. During 2015, we recorded \$54.5 million as research and development expense associated with AGTC in our consolidated statements of income, including the \$35.6 million total licensing and other fees, \$6.5 million in research and development services, a \$7.5 million premium on our equity investment and a \$5.0 million clinical development milestone related to XLRS.

AGTC is eligible to receive development, regulatory and commercial milestone payments aggregating in excess of \$1.1 billion, which includes up to \$472.5 million collectively for the two lead programs and up to \$592.5 million across the discovery programs. AGTC is also eligible to receive royalties in the mid-single digit to mid-teen percentages of annual net sales.

We were granted worldwide commercialization rights for the XLRS and XLRP programs. AGTC has an option to share development costs and profits after the initial clinical trial data are available, and an option to co-promote the second of these products to be approved in the U.S. AGTC will lead the clinical development programs of XLRS through product approval and of XLRP through the completion of first-in-human trials. We will support the clinical development costs, subject to certain conditions, following the first-in-human study for XLRS and IND-enabling studies for XLRP. Under the manufacturing license, we have received an exclusive license to use AGTC's proprietary technology platform to make AAV vectors for up to six genes, three of which are in AGTC's discretion, in exchange for payment of milestones and royalties.

Mitsubishi Tanabe Pharma Corporation

On September 9, 2015, we announced an agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) to exclusively license amiselimod (MT-1303), a late stage experimental medicine with potential in multiple autoimmune indications. Amiselimod is an oral compound that targets the sphingosine 1-phosphate receptor. Under the terms of the agreement, we will receive worldwide rights to amiselimod, excluding Asia. We will be responsible for global commercialization and development costs except for costs related to the Asian territories, which are the responsibility of MTPC.

During the fourth quarter of 2015, the agreement became effective and we made an upfront payment of \$60.0 million, which was recorded as research and development expense in our consolidated statements of income. In the future we may pay up to approximately \$484.0 million in milestone payments for multiple indications and territories, along with average royalties in the mid- to high-teen percentages of annual net sales. MTPC has the right to participate in our global clinical trials related to amiselimod and has an option to co-promote non-MS indications in the U.S.

Other Research and Discovery Arrangements

During the years ended December 31, 2015 and 2014, we entered into several research, discovery and other related arrangements that resulted in \$9.7 million and \$40.0 million, respectively, recorded as research and development expense in our consolidated statements of income.

These additional arrangements include the potential for future milestone payments based on clinical and commercial development over a period of several years.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Samsung Bioepis

In February 2012, we entered into a joint venture agreement with Samsung BioLogics Co. Ltd. (Samsung Biologics), establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. Samsung Biologics contributed 280.5 billion South Korean won (approximately \$250.0 million) for an 85% stake in Samsung Bioepis and we contributed approximately 49.5 billion South Korean won (approximately \$45.0 million) for the remaining 15% ownership interest. Under the joint venture agreement, we have no obligation to provide any additional funding and our ownership interest may be diluted due to financings in which we do not participate. As of December 31, 2015, our ownership interest is approximately 9%, which reflects our additional contribution of 6.3 billion South Korean won (approximately \$5.7 million) in the first quarter of 2015 and the effect of additional equity financings in which we did not participate. We maintain an option to purchase additional stock in Samsung Bioepis that would allow us to increase our ownership percentage up to 49.9%. The exercise of this option is within our control and is based on paying for 49.9% of the total investment made by Samsung Biologics into Samsung Bioepis in excess of what we have already contributed under the agreement plus a rate that will represent their return on capital. Samsung Biologics has the power to direct the activities of Samsung Bioepis which will most significantly and directly impact its economic performance. We account for this investment under the equity method of accounting as we maintain the ability to exercise significant influence over Samsung Bioepis through a presence on the entity's Board of Directors and our contractual relationship. Under the equity method, we recorded our original investment at cost and subsequently adjust the carrying value of our investment for our share of equity in the entity's income or losses according to our percentage of ownership. During 2015, our share of losses exceed the carrying value of our investment. We suspended recognizing additional losses and will continue to do so unless we commit to providing additional funding. As of December 31, 2014, the carrying value of our investment in Samsung Bioepis totaled 9.1 billion South Korean won (approximately \$8.6 million), which was classified as a component of investments and other assets in our consolidated balance sheets. We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears when the results of the entity become available, which is reflected as equity in loss of investee, net of tax in our consolidated statements of income. During the years ended December 31, 2015, 2014 and 2013, we recognized a loss on our investment of \$12.5 million, \$15.1 million and \$17.2 million, respectively.

## Commercial Agreement

On December 17, 2013, pursuant to our rights under the joint venture agreement with Samsung Biologics, we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, anti-tumor necrosis factor (TNF) biosimilar product candidates in Europe and in the case of one anti-TNF biosimilar, Japan. Under the terms of this agreement, we have paid \$46.0 million, which has been recorded as a research and development expense in our consolidated statements of income as the programs they relate to had not achieved regulatory approval. Samsung Bioepis is eligible to receive an additional \$75.0 million in additional milestones, including \$25.0 million upon the regulatory approval of each anti-TNF biosimilar product candidate in the E.U. In January 2016, the EC approved the MAA for BENEPALI for marketing in the E.U.

Upon commercialization, we will reflect revenues on sales to third parties in product revenues, net in our consolidated statements of income. We will record the related cost of revenues and sales and marketing expenses in our consolidated statements of income to their respective line items when these costs are incurred. A 50% profit share with Samsung Bioepis will be recognized in costs and expenses.

## License Agreement

Simultaneous with the formation of Samsung Bioepis, we entered into a license agreement with Samsung Bioepis. Under the terms of the agreement, we granted Samsung Bioepis an exclusive license to use, develop, manufacture, and commercialize biosimilar products created by Samsung Bioepis using Biogen product-specific technology. In exchange, we will receive single digit royalties on all biosimilar products developed and commercialized by Samsung Bioepis.





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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Other Services

In addition, we entered into a technical development services agreement and a manufacturing agreement with Samsung Bioepis. Under the terms of the technical development services agreement, we provide Samsung Bioepis technical development and technology transfer services, which include, but are not limited to, cell culture development, purification process development, formulation development, and analytical development. Under the terms of our manufacturing agreement, we manufacture clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis pursuant to contractual terms. Under limited circumstances, we may also supply Samsung Bioepis with quantities of drug product of biosimilar products for use in clinical trials through arrangements with third-party contract manufacturers.

For the years ended December 31, 2015, 2014 and 2013, we recognized \$62.9 million, \$58.5 million and \$43.1 million, respectively, in revenues in relation to these services, which is reflected as a component of other revenues in our consolidated statement of income.

20. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies regarding contingencies, see Note 1, Summary of Significant Accounting Policies.

Patent Matters

Forward Pharma German Patent Litigation

On November 18, 2014 Forward Pharma A/S (Forward Pharma) filed suit against us in the Regional Court of Dusseldorf, Germany alleging that TECFIDERA infringes German Utility Model DE 20 2005 022 112 U1, which was issued in April 2014 and expired in October 2015. Forward Pharma subsequently extended its allegations to assert that TECFIDERA infringes Forward Pharma's European Patent No. 2,801,355, which was issued in May 2015 and expires in October 2025. Forward Pharma seeks declarations of infringement and damages for our sales of TECFIDERA in Germany. Under German law, disgorgement of profits on infringing sales is a measure of damages. A hearing has been scheduled for early 2016.

Interference Proceeding with Forward Pharma

In April 2015, the U.S. Patent and Trademark Office (USPTO) declared an interference between Forward Pharma's pending U.S. Patent Application No. 11/576,871 and our U.S. Patent No. 8,399,514 (the '514 patent). The '514 patent includes claims covering the treatment of multiple sclerosis with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. A hearing has been scheduled for early 2017.

Inter Partes Review Proceeding

On September 28, 2015, the Coalition for Affordable Drugs V LLC, an entity associated with a hedge fund, filed a petition with the USPTO for inter partes review of the '514 patent, which we opposed. The USPTO has not yet decided whether to institute review.

European Patent Office Oppositions

Several parties have filed oppositions in the European Patent Office requesting revocation of our European patent number 2 137 537 (the '537 patent), which includes claims covering the treatment of multiple sclerosis with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. The '537 patent expires in 2028. A hearing has been scheduled for early 2016.

Patent Licensing Matter

We are in discussions with Pfizer regarding its proposal that we take a license to its U.S. Patent No. 8,603,777 (Expression of Factor VII and IX Activities in Mammalian Cells) and pay royalties on sales of ALPROLIX. An estimate of the possible loss or range of loss cannot be made at this time.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Patent Revocation Matter

In December 2015, Swiss Pharma International AG brought an action in the Patents Court of the United Kingdom to revoke the UK counterpart of our European Patent Number 1 485 127 (“Administration of agents to treat inflammation”) (the '127 patent), which was issued in June 2011 and concerns administration of natalizumab (TYSABRI) to treat multiple sclerosis. The patent expires in February 2023. On January 11, 2016 the same entity brought an action in the District Court of The Hague seeking to revoke the Dutch counterpart of the '127 patent. A hearing has been scheduled in the Dutch action for early 2017. No hearing has yet been scheduled in the UK action.

'755 Patent Litigation

On May 28, 2010, Biogen MA Inc. (formerly Biogen Idec MA Inc.) filed a complaint in the U.S. District Court for the District of New Jersey alleging infringement by Bayer Healthcare Pharmaceuticals Inc. (Bayer) (manufacturer, marketer and seller of BETASERON and manufacturer of EXTAVIA), EMD Serono, Inc. (manufacturer, marketer and seller of REBIF), Pfizer Inc. (co-marketer of REBIF), and Novartis Pharmaceuticals Corp. (marketer and seller of EXTAVIA) of our U.S. Patent No. 7,588,755 ('755 Patent), which claims the use of interferon beta for immunomodulation or treating a viral condition, viral disease, cancers or tumors. The complaint seeks monetary damages, including lost profits and royalties. Bayer had previously filed a complaint against us in the same court, on May 27, 2010, seeking a declaratory judgment that it does not infringe the '755 Patent and that the patent is invalid, and seeking monetary relief in the form of attorneys' fees, costs and expenses. The court has consolidated the two lawsuits, and we refer to the two actions as the “Consolidated '755 Patent Actions.”

Bayer, Pfizer, Novartis and EMD Serono have all filed counterclaims in the Consolidated '755 Patent Actions seeking declaratory judgments of patent invalidity and non-infringement, and seeking monetary relief in the form of costs and attorneys' fees, and EMD Serono and Bayer have each filed a counterclaim seeking a declaratory judgment that the '755 Patent is unenforceable based on alleged inequitable conduct. Bayer has also amended its complaint to seek such a declaration. No trial date has been set.

Italian National Medicines Agency

In the fourth quarter of 2011, Biogen Italia SRL received notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. On December 23, 2011, we filed an appeal in the Regional Administrative Tribunal of Lazio (Il Tribunale Amministrativo Regionale per il Lazio) in Rome, Italy seeking a ruling that the reimbursement limit in the Price Resolution should apply as written to only “the first 24 months” of TYSABRI sales, which ended in mid-February 2009. The appeal is still pending. In June 2014, AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. AIFA and Biogen Italia SRL are discussing a possible resolution for the period from February 2009 through January 2013.

Government Matters

We have learned that state and federal governmental authorities are investigating our sales and promotional practices and have received related subpoenas. We are cooperating with the government in this matter.

We also received a subpoena from the federal government for documents relating to our relationship with certain pharmacy benefit managers, with which we cooperated. We do not anticipate any further involvement.

Qui Tam Litigation

On July 6, 2015, four qui tam actions filed against us by relators suing on behalf of the United States and certain states were unsealed by the U.S. District Court for the District of Massachusetts. The actions, which have been administratively consolidated, allege sales and promotional activities in violation of the federal False Claims Act and state law counterparts, and seek single and treble damages, civil penalties, interest, attorneys' fees and costs. The United States declined to intervene in two of the actions, both of which have since been voluntarily dismissed, and has not made an intervention decision in the other two actions, which we have moved to dismiss. An estimate of the possible loss or range of loss cannot be made at this time.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Securities Litigation

We and certain current and former officers are defendants in In re Biogen Inc. Securities Litigation, filed by a shareholder on August 18, 2015 in the U.S. District Court for the District of Massachusetts. The amended complaint alleges violations of federal securities laws under 15 U.S.C. §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5. The lead plaintiff seeks a declaration of the action as a class action, certification as a representative of the class and its counsel as class counsel, and an award of damages, interest, and attorneys' fees. An estimate of the possible loss or range of loss cannot be made at this time.

## Product Liability and Other Legal Proceedings

We are also involved in product liability claims and other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

## 21. Commitments and Contingencies

## Leases

We rent laboratory and office space and certain equipment under non-cancelable operating leases. These lease agreements contain various clauses for renewal at our option and, in certain cases, escalation clauses typically linked to rates of inflation. Rental expense under these leases, net of amounts recognized in relation to exiting our Weston, Massachusetts facility, which terminate at various dates through 2028, amounted to \$68.6 million and \$62.4 million in 2015 and 2014, respectively. Rent expense was \$56.1 million in 2013. In addition to rent, the leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

As of December 31, 2015, minimum rental commitments under non-cancelable leases, net of income from subleases, for each of the next five years and total thereafter were as follows:

(In millions)	2016	2017	2018	2019	2020	Thereafter	Total
Minimum lease payments	\$75.9	\$75.7	\$67.9	\$66.7	\$63.2	\$382.7	\$732.1
(1) Less: income from subleases	(6.0 )	(6.0 )	(6.3 )	(6.3 )	(6.3 )	(28.9 )	(59.8 )
Net minimum lease payments	\$69.9	\$69.7	\$61.6	\$60.4	\$56.9	\$353.8	\$672.3

(1) As a result of our decision to relocate our corporate headquarters to Cambridge, Massachusetts, we vacated part of our Weston, Massachusetts facility in the fourth quarter of 2013. We incurred a charge of \$27.2 million in connection with this move. This charge represented our remaining lease obligation for the vacated portion of our Weston, Massachusetts facility, net of sublease income expected to be received. The term of our sublease to the vacated portion of our Weston, Massachusetts facility started in January 2014 and will continue through the remaining term of our lease agreement.

Under certain of our lease agreements, we are contractually obligated to return leased space to its original condition upon termination of the lease agreement. At the inception of a lease with such conditions, we record an asset retirement obligation liability and a corresponding capital asset in an amount equal to the estimated fair value of the obligation. In subsequent periods, for each such lease, we record interest expense to accrete the asset retirement obligation liability to full value and depreciate each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. Our asset retirement obligations were not significant as of December 31, 2015 or 2014.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Eisai Financing Arrangement

During 2015 we amended our existing lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. For additional information, please read Note 10, Property, Plant and Equipment to these consolidated financial statements. As of December 31, 2015, the net present value of the future minimum lease payments were as follows:

(In millions)	As of December 31, 2015
2016	\$2.0
2017	2.0
2018	16.7
2019	—
2020	—
Thereafter	—
Total	20.7
Less: interest	(0.9 )
Net present value of the future minimum lease payments	\$19.8

## 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, 2015, we have approximately \$45.4 million of net liabilities associated with uncertain tax positions.

## Other Funding Commitments

As of December 31, 2015, 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 \$25.0 million on our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2015. We have approximately \$559.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2015.

## Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2015, we could make potential future milestone payments to third parties of up to approximately \$2.8 billion as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2015, 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.

## Manufacturing Commitments

On December 1, 2015, we purchased land in Solothurn, Switzerland where we plan to build a biologics manufacturing facility over the next several years. As of December 31, 2015, we had contractual commitments of \$126.4 million for the construction of this facility.

## 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.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Contingent Consideration related to Business Combinations

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

As the acquisitions of Convergence, Stromedix and BIN, formerly Panima Pharmaceuticals AG, occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately \$1.3 billion in remaining milestones related to these acquisitions. For additional information related to our acquisition of Convergence please read Note 2, Acquisitions, to these consolidated financial statements.

## BIH

In connection with our acquisition of BIH, formerly Syntonix, in 2007, we agreed to pay up to an additional \$80.0 million if certain milestone events associated with the development of BIH's lead product, ALPROLIX are achieved. The first \$40.0 million contingent payment was achieved in 2010. We paid an additional \$20.0 million during the second quarter of 2014 as ALPROLIX was approved for the treatment of hemophilia B. A second \$20.0 million contingent payment will occur if, prior to the tenth anniversary of the closing date, a marketing authorization is granted by the EMA for ALPROLIX. This payment will be accounted for as an increase to intangible assets if achieved.

## Fumapharm AG

In 2006, we acquired Fumapharm AG. As part of this acquisition we acquired FUMADERM and TECFIDERA (together, Fumapharm Products). We paid \$220.0 million upon closing of the transaction and agreed to pay an additional \$15.0 million if a Fumapharm Product was approved for MS in the U.S. or E.U. In the second quarter of 2013, we paid this \$15.0 million contingent payment as TECFIDERA was approved in the U.S. for MS by the FDA. We are also required to make additional contingent payments to former shareholders of Fumapharm AG or holders of their rights based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior twelve month period, as defined in the acquisition agreement.

During 2015, we paid \$850.0 million in contingent payments as we reached the \$4.0 billion, \$5.0 billion and \$6.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2014, second quarter of 2015 and third quarter of 2015, respectively, and accrued \$300.0 million upon reaching \$7.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2015.

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. 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.

## 22. Guarantees

As of December 31, 2015 and 2014, we did not have significant liabilities recorded for guarantees.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is

minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2015 and 2014.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 23. Employee Benefit Plans

We sponsor various retirement and pension plans. Our estimates of liabilities and expenses for these plans incorporate a number of assumptions, including expected rates of return on plan assets and interest rates used to discount future benefits.

## 401(k) Savings Plan

We maintain a 401(k) Savings Plan which is available to substantially all regular employees in the U.S. over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. The 401(k) Savings Plan also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The expense related to our 401(k) Savings Plan primarily consists of our matching contributions.

Expense related to our 401(k) Savings Plan totaled \$51.8 million, \$49.3 million and \$39.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

## Deferred Compensation Plan

We maintain a non-qualified deferred compensation plan, known as the Supplemental Savings Plan (SSP), which allows a select group of management employees in the U.S. to defer a portion of their compensation. The SSP also provides certain credits to highly compensated U.S. employees, which are paid by the company. These credits are known as the Restoration Match. The deferred compensation amounts are accrued when earned. Such deferred compensation is distributable in cash in accordance with the rules of the SSP. Deferred compensation amounts under such plan as of December 31, 2015 and 2014 totaled approximately \$126.9 million and \$105.2 million, respectively, and are included in other long-term liabilities in our consolidated balance sheets. The SSP also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The Restoration Match and participant contributions vest immediately. Distributions to participants can be either in one lump sum payment or annual installments as elected by the participants.

## Pension Plans

Our retiree benefit plans include defined benefit plans for employees in our affiliates in Switzerland and Germany as well as other insignificant defined benefit plans in certain other countries in which we maintain an operating presence. Our Swiss plan is a government-mandated retirement fund that provides employees with a minimum investment return. The minimum investment return is determined annually by Swiss government and was 1.75% in 2015 and 2014 and 1.5% in 2013, respectively. Under the Swiss plan, both we and certain of our employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. Minimum employee contributions are based on the respective employee's age, salary, and gender. As of December 31, 2015 and 2014, the the Swiss plan had an unfunded net pension obligation of approximately \$42.4 million and \$31.9 million, respectively, and plan assets which totaled approximately \$63.9 million and \$43.9 million, respectively. In 2015, 2014 and 2013, we recognized expense totaling \$12.9 million, \$9.8 million and \$10.9 million, respectively, related to our Swiss plan.

The obligations under the German plans are unfunded and totaled \$27.6 million and \$24.8 million as of December 31, 2015 and 2014, respectively. Net periodic pension cost related to the German plans totaled \$4.0 million, \$3.5 million and \$3.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 24. Segment Information

We operate as one operating segment, which is discovering, developing, manufacturing and delivering therapies to patients for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders, and, therefore, our chief operating decision-maker manages the operations of our company as a single operating segment. Enterprise-wide disclosures about product revenues, other revenues and long-lived assets by geographic area and information relating to major customers are presented below. Revenues are primarily attributed to individual countries based on location of the customer or licensee.

Revenue by product is summarized as follows:

(In millions)	For the Years Ended December 31,			2014			2013		
	2015 United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	\$2,908.2	\$730.2	\$3,638.4	\$2,426.6	\$482.6	\$2,909.2	\$864.4	\$11.7	\$876.1
AVONEX	1,790.2	840.0	2,630.2	1,956.7	1,056.4	3,013.1	1,902.4	1,103.1	3,005.5
PLEGRIDY	227.1	111.4	338.5	27.8	16.7	44.5	—	—	—
TYSABRI	1,103.1	783.0	1,886.1	1,025.1	934.4	1,959.5	814.2	712.3	1,526.5
FAMPYRA	—	89.7	89.7	—	80.2	80.2	—	74.0	74.0
Hemophilia:									
ELOCTATE	308.3	11.4	319.7	58.4	—	58.4	—	—	—
ALPROLIX	208.9	25.6	234.5	72.1	3.9	76.0	—	—	—
Other product revenues:									
FUMADERM	—	51.4	51.4	—	62.5	62.5	—	60.2	60.2
Total product revenues	\$6,545.8	\$2,642.7	\$9,188.5	\$5,566.7	\$2,636.7	\$8,203.4	\$3,581.0	\$1,961.3	\$5,542.3

## Geographic Information

The following tables contain certain financial information by geographic area:

December 31, 2015 (In millions)	U.S.	Europe <sup>(1)</sup>	Germany	Asia	Other	Total
Product revenues from external customers	\$6,545.8	\$1,497.6	\$668.1	\$143.7	\$333.3	\$9,188.5
Unconsolidated joint business revenues	\$1,269.8	\$3.5	\$—	\$—	\$65.9	\$1,339.2
Other revenues from external customers	\$142.0	\$29.6	\$1.6	\$62.9	\$—	\$236.1
Long-lived assets	\$1,296.5	\$879.4	\$2.3	\$7.7	\$1.7	\$2,187.6
December 31, 2014 (In millions)	U.S.	Europe <sup>(1)</sup>	Germany	Asia	Other	Total
Product revenues from external customers	\$5,566.7	\$1,383.9	\$811.8	\$112.8	\$328.2	\$8,203.4
Unconsolidated joint business revenues	\$1,117.1	\$7.7	\$—	\$—	\$70.6	\$1,195.4
Other revenues from external customers	\$212.6	\$31.6	\$1.8	\$58.5	\$—	\$304.5
Long-lived assets	\$1,055.5	\$701.9	\$2.5	\$2.6	\$3.2	\$1,765.7

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December 31, 2013 (In millions)	U.S.	Europe <sup>(1)</sup>	Germany	Asia	Other	Total
Product revenues from external customers	\$3,581.0	\$1,170.2	\$417.7	\$93.2	\$280.2	\$5,542.3
Unconsolidated joint business revenues	\$1,087.3	\$1.6	\$—	\$3.2	\$33.9	\$1,126.0
Other revenues from external customers	\$193.5	\$26.1	\$1.2	\$43.1	\$—	\$263.9
Long-lived assets	\$984.4	\$758.3	\$2.5	\$2.1	\$3.3	\$1,750.7

(1) Represents amounts related to Europe less those attributable to Germany.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Revenues from Unconsolidated Joint Business

Approximately 12%, 12% and 16% of our total revenues in 2015, 2014 and 2013, respectively, are derived from our joint business arrangement with Genentech. For additional information related to our collaboration with Genentech, please read Note 19, Collaborative and Other Relationships to these consolidated financial statements.

## Significant Customers

We recorded revenue from two wholesalers accounting for 34% and 26% of gross product revenues in 2015, 33% and 27% of gross product revenues in 2014, and 32% and 24% of gross product revenues in 2013, respectively.

## Other

As of December 31, 2015, 2014 and 2013, approximately \$684.9 million, \$676.0 million and \$731.1 million, respectively, of our long-lived assets were related to our manufacturing facilities in Denmark.

## 25. Quarterly Financial Data (Unaudited)

(In millions, except per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
2015			(a) (b)	(c) (d)	
Product revenues, net	\$2,172.3	\$2,198.6	\$2,391.7	\$2,425.9	\$9,188.5
Unconsolidated joint business revenues	\$330.6	\$337.5	\$337.2	\$333.9	\$1,339.2
Other revenues	\$52.0	\$55.6	\$49.0	\$79.5	\$236.1
Total revenues	\$2,555.0	\$2,591.6	\$2,777.9	\$2,839.3	\$10,763.8
Gross profit (1)	\$2,242.6	\$2,305.5	\$2,467.9	\$2,507.5	\$9,523.4
Net income	\$820.2	\$924.8	\$1,019.5	\$828.7	\$3,593.2
Net income attributable to Biogen Inc.	\$822.5	\$927.3	\$965.6	\$831.6	\$3,547.0
Net income per share:					
Basic earnings per share attributable to Biogen Inc.	\$3.50	\$3.94	\$4.16	\$3.77	\$15.38
Diluted earnings per share attributable to Biogen Inc.	\$3.49	\$3.93	\$4.15	\$3.77	\$15.34
Weighted-average shares used in calculating:					
Basic earnings per share attributable to Biogen Inc.	235.0	235.3	232.2	220.4	230.7
Diluted earnings per share attributable to Biogen Inc.	235.6	235.7	232.6	220.8	231.2

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(In millions, except per share amounts)	First Quarter (e)	Second Quarter (f) (g)	Third Quarter (f)	Fourth Quarter (f)	Total Year
2014					
Product revenues, net	\$1,742.8	\$2,056.3	\$2,117.3	\$2,287.0	\$8,203.4
Unconsolidated joint business revenues	\$296.9	\$303.3	\$290.7	\$304.5	\$1,195.4
Other revenues	\$90.1	\$61.9	\$103.4	\$49.2	\$304.5
Total revenues	\$2,129.8	\$2,421.5	\$2,511.4	\$2,640.7	\$9,703.3
Gross profit (1)	\$1,850.5	\$2,129.6	\$2,208.8	\$2,343.4	\$8,532.3
Net income	\$479.7	\$723.1	\$856.1	\$882.6	\$2,941.6
Net income attributable to Biogen Inc.	\$480.0	\$714.5	\$856.9	\$883.5	\$2,934.8
Net income per share:					
Basic earnings per share attributable to Biogen Inc.	\$2.03	\$3.02	\$3.63	\$3.75	\$12.42
Diluted earnings per share attributable to Biogen Inc.	\$2.02	\$3.01	\$3.62	\$3.74	\$12.37
Weighted-average shares used in calculating:					
Basic earnings per share attributable to Biogen Inc.	236.8	236.7	236.2	235.5	236.4
Diluted earnings per share attributable to Biogen Inc.	237.8	237.4	237.0	236.3	237.2

(1) Gross profit is calculated as total revenues less cost of sales, excluding amortization of acquired intangible assets.

Net income and net income attributable to Biogen Inc., for the third quarter of 2015, include a pre-tax charge to (a) research and development expense of \$48.1 million recorded upon entering into the collaboration agreement with AGTC.

Net income attributable to Biogen Inc., for the third quarter of 2015, reflects the attribution of a \$60.0 million (b) charge to noncontrolling interests, net of tax, related to a milestone payment due Neurimmune upon the enrollment of the first patient in a Phase 3 trial for aducanumab.

Net income and net income attributable to Biogen Inc., for the fourth quarter of 2015, include a pre-tax charge to (c) research and development expense of \$60.0 million recorded upon entering into the collaboration agreement with MTPC.

(d) Net income and net income attributable to Biogen Inc., for the fourth quarter of 2015, include pre-tax restructuring charges totaling \$93.4 million.

Net income and net income attributable to Biogen Inc., for the first quarter of 2014, include pre-tax charges to (e) research and development expense of \$117.7 million recorded upon entering into the collaboration agreement with Eisai.

Product revenues, net and total revenues for the second, third and fourth quarters of 2014 include net revenues related to ALPROLIX as commercial sales of ALPROLIX commenced in the second quarter of 2014. Product (f) revenues, net and total revenues for the third and fourth quarters of 2014 include net revenues related to ELOCTATE and PLEGRIDY as commercial sales of ELOCTATE and PLEGRIDY commenced in the third quarter of 2014.

(g) Product revenues, net and total revenues for the second quarter of 2014 include the recognition of \$53.5 million of revenue previously deferred in Italy relating to the pricing agreement with AIFA.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Biogen Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, comprehensive income, equity and cash flows present fairly, in all material respects, the financial position of Biogen Inc. and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting under item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 16 to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes in 2015 and 2014 due to the adoption of Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

February 3, 2016

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EXHIBIT INDEX

Exhibit No.	Description
2.1†	Asset Purchase Agreement among Biogen Idec International Holding Ltd., Elan Pharma International Limited and Elan Pharmaceuticals, Inc., dated as of February 5, 2013. Filed as Exhibit 2.1 to our Current Report on Form 8-K/A filed on February 12, 2013.
3.1	Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
3.2	Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015.
3.3	Third Amended and Restated Bylaws. Filed as Exhibit 3.2 to our Current Report on Form 8-K filed on March 27, 2015.
4.1	Reference is made to Exhibit 3.1 for a description of the rights, preferences and privileges of our Series A Preferred Stock and Series X Junior Participating Preferred Stock.
4.2	Indenture between Biogen Idec and The Bank of New York Trust Company, N.A. dated as of February 26, 2008. Filed as Exhibit 4.1 to our Registration Statement on Form S-3 (File No. 333-149379).
4.3	First Supplemental Indenture between Biogen Idec and The Bank of New York Trust Company, N.A. dated as of March 4, 2008. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on March 4, 2008.
4.4	Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015.
4.5	First Supplemental Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015.
10.1	Credit Agreement, dated August 28, 2015, between Biogen Inc., Bank of America, N.A., as administrative agent, swing line lender and an L/C issuer, and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015.
10.2†	Expression Technology Agreement between Biogen Idec and Genentech, Inc. dated March 16, 1995. Filed as an exhibit to Biogen Idec's Quarterly Report on Form 10-Q for the quarter ended March 31, 1995.
10.3	Letter Agreement between Biogen Idec and Genentech, Inc. dated May 21, 1996. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 6, 1996.
10.4†	Second Amended and Restated Collaboration Agreement between Biogen Idec and Genentech, Inc. dated as of October 18, 2010. Filed as Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2010.
10.5†	Letter agreement regarding GA101 financial terms between Biogen Idec and Genentech, Inc. dated October 18, 2010. Filed as Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 31, 2010.
10.6*	Biogen Idec Inc. 2008 Amended and Restated Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
10.7*	Form of performance unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
10.8*	Form of market stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
10.9*	

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Form of restricted stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on August 1, 2008.

10.10\*

Form of nonqualified stock option award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K filed on August 1, 2008.

10.11\*

Form of cash-settled performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.

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Exhibit No.	Description
10.12*	Form of performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.12 to our Annual Report on Form 10-K for the year ended December 31, 2013.
10.13*	Form of market stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
10.14*	Biogen Inc. 2006 Non-Employee Directors Equity Plan, as amended. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015.
10.15*	Biogen Idec Inc. 2005 Omnibus Equity Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 15, 2005.
10.16*	Amendment No. 1 to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated April 4, 2006. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
10.17*	Amendment No. 2 to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated February 12, 2007. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
10.18*	Amendment to the Biogen Idec Inc. 2005 Omnibus Equity Plan dated April 18, 2008. Filed as Exhibit 10.7 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.19*	Amendment to Biogen Idec Inc. 2005 Omnibus Equity Plan dated October 13, 2008. Filed as Exhibit 10.30 to our Annual Report on Form 10-K for the year ended December 31, 2008.
10.20*	Biogen Inc. 2015 Employee Stock Purchase Plan. Filed as Appendix A to Biogen's Definitive Proxy Statement on Schedule 14A filed on April 30, 2015.
10.21*	Biogen Idec Inc. 2008 Performance-Based Management Incentive Plan. Filed as Appendix B to Biogen Idec's Definitive Proxy Statement on Schedule 14A filed on May 8, 2008.
10.22*	Voluntary Executive Supplemental Savings Plan, as amended and restated effective January 1, 2004. Filed as Exhibit 10.13 to our Annual Report on Form 10-K for the year ended December 31, 2003.
10.23*+	Supplemental Savings Plan, as amended.
10.24*+	Voluntary Board of Directors Savings Plan, as amended.
10.25*	Biogen Idec Inc. Executive Severance Policy — U.S. Executive Vice President, as amended effective January 1, 2014. Filed as Exhibit 10.39 to our Annual Report on Form 10-K for the year ended December 31, 2013.
10.26*	Biogen Idec Inc. Executive Severance Policy — International Executive Vice President, as amended effective January 1, 2014. Filed as Exhibit 10.40 Annual Report on Form 10-K for the year ended December 31, 2013.
10.27*	Biogen Idec Inc. Executive Severance Policy — U.S. Senior Vice President, as amended effective October 13, 2008. Filed as Exhibit 10.53 to our Annual Report on Form 10-K for the year ended December 31, 2008.
10.28*	Biogen Idec Inc. Executive Severance Policy — International Senior Vice President, as amended effective October 13, 2008. Filed as Exhibit 10.54 to our Annual Report on Form 10-K for the year ended December 31, 2008.
10.29*	Annual Retainer Summary for Board of Directors. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.
10.30*	Form of indemnification agreement for directors and executive officers. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 7, 2011.
10.31*	

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Employment Agreement between Biogen Idec and George A. Scangos amended as of August 23, 2013. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on August 26, 2013.

10.32\* Letter regarding employment arrangement of Paul J. Clancy dated August 17, 2007. Filed as Exhibit 10.49 to our Annual Report on Form 10-K for the year ended December 31, 2007.

10.33\* Letter regarding employment arrangement of Douglas E. Williams dated December 7, 2010. Filed as Exhibit 10.57 to our Annual Report on Form 10-K for the year ended December 31, 2011.

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Exhibit No.	Description
10.34*	Letter regarding employment arrangement of Steven H. Holtzman dated November 19, 2010. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2011.
10.35*	Letter regarding employment arrangement of Kenneth DiPietro dated December 12, 2011. Filed as Exhibit 10.49 to our Annual Report on Form 10-K for the year ended December 31, 2012.
10.36*	Letter regarding employment arrangement of Alfred Sandrock dated May 7, 2013. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.
10.37*+	Letter regarding employment arrangement of Alfred Sandrock dated October 19, 2015.
10.38*	Letter regarding employment arrangement of Adam Koppel dated January 10, 2014. Filed as Exhibit 10.43 to our Annual Report on Form 10-K for the year ended December 31, 2014.
10.39*	Letter regarding employment arrangement of Susan Alexander dated December 13, 2005. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2009.
10.40*	Letter regarding employment arrangement of Adriana Karaboutis dated August 7, 2014. Filed as Exhibit 10.44 to our Annual Report on Form 10-K for the year ended December 31, 2014.
10.41*+	Letter regarding employment arrangement of John Cox dated September 7, 2010.
10.42*+	Letter regarding separation arrangement of Tony Kingsley dated November 12, 2015.
21+	Subsidiaries.
23+	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm.
31.1+	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Equity and (vi) Notes to Consolidated Financial Statements.

^ References to "our" filings mean filings made by Biogen Inc. (formerly Biogen Idec Inc.) and filings made by IDEC Pharmaceuticals Corporation prior to the merger with Biogen, Inc. Unless otherwise indicated, exhibits were previously filed with the Securities and Exchange Commission under Commission File Number 0-19311 and are incorporated herein by reference.

\* Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit.

+ Filed herewith.

+ + Furnished herewith.