BIOGEN INC.
Form 10-K
February 01, 2018

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number: 0-19311
BIOGEN INC.
(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $57,220,188,450.

As of January 26, 2018, the registrant had 211,562,686 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the "Safe Harbor" provisions of the Act. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will" and other words ar similar 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;
- our plans to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology;
- 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, filings 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 and the potential costs and expenses related to our current or future initiatives to streamline our operations and reallocate resources;
- 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 potential impact on our results of operations and liquidity of the United Kingdom's (U.K.) intent to voluntarily depart from the European Union (E.U.);
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs to constrain the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our 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;
- the anticipated benefits, costs and tax treatment of the spin-off of our hemophilia business; and
- the impact of new laws, including the Tax Cuts and Jobs Act of 2017, and accounting standards.

These forward-looking statements involve risks and uncertainties, including those that are described in Item 1A. Risk Factors included in 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

References in this report to:

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

NOTE REGARDING TRADEMARKS

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PART I

Item 1. Business

Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases, including in our core growth areas of multiple sclerosis (MS) and neuroimmunology, Alzheimer's disease (AD) and dementia, movement disorders and neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS). We also plan to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy in the previously mentioned areas. We also manufacture and commercialize biosimilars of advanced biologics.

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

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within our core and emerging growth areas. For nearly two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as the development of next generation therapies for MS, with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including AD, progressive supranuclear palsy (PSP), a rare condition that affects movement, speech, vision and cognitive function, Parkinson's disease and ALS.

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

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Key Developments

During 2017 we had a number of key developments affecting our business.

Corporate Matters

2017 Corporate Strategy

In July 2017 we announced an updated strategic framework to optimize the value of our MS business while investing for the future across our core growth areas of MS and neuroimmunology, AD and dementia, movement disorders and neuromuscular diseases, including SMA and ALS. We also plan to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology.

In order to deliver positive results in the near term while investing in the next stages of our growth, we will focus on the following strategic priorities:

- maximizing the resilience of our MS core business;
- accelerating efforts in SMA as a significant new growth opportunity;
- developing and expanding our neuroscience portfolio;
- focusing our capital allocation efforts to drive investment for future growth; and
- creating a leaner and simpler operating model to streamline our operations and reallocate resources towards prioritized research and development and commercial value creation opportunities.

In October 2017, in connection with creating a leaner and simpler operating model, we approved a corporate restructuring program intended to streamline our operations and reallocate resources. We expect to make total non-recurring operating and capital expenditures of up to $170.0 million, primarily in 2018, and our goal is to redirect resources of up to $400.0 million annually by 2020 to prioritized research and development and other value creation opportunities.

TECFIDERA Settlement and License Agreement

In January 2017 we entered into a settlement and license agreement with Forward Pharma A/S (Forward Pharma). Pursuant to this agreement, we obtained U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange, we paid Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016 we recognized a pre-tax charge of $454.8 million and in the first quarter of 2017 we recognized intangible assets of $795.2 million related to this agreement.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the E.U., concerning intellectual property related to TECFIDERA. In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma appealed to the U.S. Court of Appeals for the Federal Circuit and the appeal is pending. We evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded an impairment charge in the first quarter of 2017 to adjust the carrying value of the acquired U.S. asset to fair value reflecting the impact of the developments in the U.S. legal dispute. In January 2018 the European Patent Office (EPO) announced its decision revoking Forward Pharma's European Patent No. 2 801 355. Forward Pharma has stated that it expects to file an appeal to the Technical Board of Appeal of the EPO. Based upon our assessment of these rulings, we continue to amortize the remaining net book value of the U.S. and rest of world intangible assets in our consolidated statements of income utilizing an economic consumption model.

For additional information on our settlement and license agreement with Forward Pharma and related intangible assets, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report. For additional information on these disputes, please read Note 21, Litigation, to our consolidated financial statements included in this report.

Tax Reform

The Tax Cuts and Jobs Act of 2017 (the 2017 Tax Act), which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as

global intangible low-taxed income (GILTI). These changes are effective beginning in 2018.
The 2017 Tax Act also includes a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax).

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Changes in tax rates and tax laws are accounted for in the period of enactment. Therefore, during the year ended December 31, 2017, we recorded a charge totaling $1,173.6 million related to our current estimate of the provisions of the 2017 Tax Act, including a $989.6 million expense under the Transition Toll Tax. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

The 2017 Tax Act will provide us with flexibility in deploying our cash resources to advance our business interests. We expect that it will have a modest positive effect on our income tax rate in 2018 and a potential incremental benefit thereafter.

Hemophilia Spin-Off

On February 1, 2017, we completed the spin-off of our hemophilia business, Bioverativ Inc. (Bioverativ), as an independent, publicly traded company trading under the symbol "BIVV" on the Nasdaq Global Select Market. The spin-off was accomplished through the distribution of all the then outstanding shares of common stock of Bioverativ to Biogen shareholders, who received one share of Bioverativ common stock for every two shares of Biogen common stock they owned. The separation and distribution was structured to be tax-free for shareholders for federal income tax purposes. Bioverativ assumed all of our rights and obligations under our collaboration agreement with Swedish Orphan Biovitrum AB (Sobi) and our collaboration and license agreement with Sangamo Biosciences Inc. (Sangamo). Our consolidated results of operations and financial position included in this report reflect the financial results of our hemophilia business for all periods through January 31, 2017.

For additional information on the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in this report.

BIIB093 Acquisition

In May 2017 we completed an asset purchase of the Phase 3-ready candidate BIIB093 (intravenous glibencamide) (formerly known as CIRARA) from Remedy Pharmaceuticals Inc. (Remedy). The target indication for BIIB093 is large hemispheric infarction (LHI), a severe form of ischemic stroke where brain swelling (cerebral edema) often leads to a disproportionately large share of stroke-related morbidity and mortality. The U.S. Food and Drug Administration (FDA) recently granted BIIB093 Orphan Drug Designation for severe cerebral edema in patients with acute ischemic (AI) stroke. The FDA has also granted BIIB093 Fast Track designation.

Under this agreement, we are responsible for the future development and commercialization of BIIB093. Remedy will share in the cost of development for the target indication for BIIB093 in LHI stroke.

For additional information on our transaction with Remedy, please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

BIIB092 License Agreement

In June 2017 we completed an exclusive license agreement with Bristol-Myers Squibb Company (BMS) for BIIB092 (formerly known as BMS-986168), a Phase 2-ready experimental medicine with potential in AD and PSP. BIIB092 is an antibody targeting tau, the protein that forms the deposits, or tangles, in the brain associated with AD and other neurodegenerative tauopathies such as PSP.

Under this agreement, we received worldwide rights to BIIB092 and are responsible for the full development and global commercialization of BIIB092 in AD and PSP.

For additional information on our collaboration arrangement with BMS, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Eisai Collaboration Agreement

In October 2017 we entered into a new collaboration agreement with Eisai Co. Ltd. (Eisai) for the joint development and commercialization of aducanumab, our anti-amyloid beta antibody candidate for AD (Aducanumab Collaboration Agreement). Under the Aducanumab Collaboration Agreement, we will continue to lead the ongoing Phase 3 development of aducanumab and will remain responsible for 100% of development costs for aducanumab until April 2018. Eisai will then reimburse us for 15% of aducanumab development expenses for the period April 2018 through December 2018, and 45% thereafter. Upon commercialization, both companies will co-promote aducanumab with a region-based profit split.

In addition, we and Eisai will continue to jointly develop two product candidates for AD, BAN2401, a monoclonal antibody that targets amyloid beta aggregates, and E2609, a BACE inhibitor.

We and Eisai will co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai will distribute AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

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For additional information on our collaboration arrangement with Eisai, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Neurimmune Collaboration Agreement

In October 2017 we amended the terms of our collaboration and license agreement with Neurimmune Subone AG (Neurimmune). Under the amended agreement, we made a $150.0 million payment to Neurimmune, which is reflected as a charge to noncontrolling interests, in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab. Our royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab, will now range from the high single digits to low-teens.

Under the amended agreement, we also have an option that will expire in April 2018 to further reduce our royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab, by an additional 5% in exchange for a $50.0 million payment to Neurimmune.

For additional information on our collaboration arrangement with Neurimmune, please read Note 19, Investments in Variable Interest Entities, to our consolidated financial statements included in this report.

BIIB098 License Agreement

In November 2017 we entered into an exclusive license and collaboration agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), for BIIB098 (formerly known as ALKS 8700), an oral monomethyl fumarate (MMF) prodrug in Phase 3 development for the treatment of relapsing forms of MS.

Under this agreement, we received an exclusive, worldwide license to develop and commercialize BIIB098 and will pay Alkermes a royalty on potential worldwide net sales of BIIB098. Beginning in 2018 we are responsible for all development expenses related to BIIB098. Alkermes will maintain responsibility for regulatory interactions with the FDA through the potential approval of the New Drug Application (NDA) for BIIB098 for the treatment of MS.

For additional information on our collaboration arrangement with Alkermes, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Ionis Collaboration Agreement

In December 2017 we entered into a new collaboration agreement with Ionis Pharmaceuticals Inc. (Ionis) to identify new antisense oligonucleotide (ASO) drug candidates for the treatment of SMA. Under this agreement, we have the option to license therapies arising out of this collaboration and will be responsible for the development and commercialization of these therapies.

For additional information on our new collaboration arrangement with Ionis, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Management Changes

During 2017 we appointed several new executives, each of whom has significant experience in the biopharmaceutical industry and is a leader in his or her functional area. These appointments included:

- Michel Vounatsos, Chief Executive Officer;
- Jeffrey Capello, Executive Vice President and Chief Financial Officer;
- Ginger Gregory, Executive Vice President and Chief Human Resources Officer; and
- Chirfi Guindo, Executive Vice President and Head of Global Marketing, Market Access and Customer Innovation.

For additional information on these and our other executive officers, please read the subsection entitled “Our Executive Officers” included in this report.

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Product/Pipeline Developments

Core Growth Areas

Multiple Sclerosis and Neuroimmunology

TECFIDERA (dimethyl fumarate)

- In April 2017 we presented new real-world data evidence supporting TECFIDERA at the 69th annual meeting of the American Academy of Neurology (AAN) in Boston, MA.

We presented a comparison of real-world data that supported TECFIDERA's strong efficacy relative to other oral MS therapies, both in newly-treated MS patients and those previously treated with a prior disease modifying therapy (DMT). Subgroup analyses of the open-label studies PROTEC and RESPOND assessed TECFIDERA in early MS and early switch patients, respectively. Results showed that TECFIDERA significantly reduced the annualized relapse rate over one year in the early MS subgroups, including those who switched to TECFIDERA from a prior DMT. Additional data presented at the AAN meeting affirmed the well-characterized, long-term safety profile of TECFIDERA in patients treated for up to nine years.

TYSABRI (natalizumab)

- In February 2017 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion to update the TYSABRI E.U. label with pediatric information to remove the contraindication in pediatrics and to describe the results of the post-marketing meta-analysis of pediatric data. The label update entitles us to apply for a six-month extension to the E.U. patent Supplementary Protection Certificate.
- In April 2017 we presented new real-world data from the TYSABRI Observational Program that confirmed the efficacy of TYSABRI and demonstrated that early and continued treatment leads to better clinical outcomes. These data were presented at the 69th annual meeting of AAN in Boston, MA.

FAMPYRA (prolonged-release fampridine tablets)

- In May 2017 the European Commission (EC) granted a standard marketing authorization for FAMPYRA for walking improvement in people with MS.

ZINBRYTA (daclizumab)

- In July 2017 the EMA announced that it had provisionally restricted the use of ZINBRYTA to adult patients with highly active relapsing disease despite a full and adequate course of treatment with at least one DMT or with rapidly evolving severe relapsing MS who are unsuitable for treatment with other DMTs. These restrictions followed the initiation of an EMA review (referred to as an Article 20 Procedure) of ZINBRYTA following the report of a case of fatal fulminant liver failure, as well as four cases of serious liver injury.
- In October 2017, as part of the Article 20 Procedure of ZINBRYTA, the EMA Pharmacovigilance Risk Assessment Committee (PRAC) completed its assessment and recommended a further set of restrictions on the use of ZINBRYTA by MS patients.
- In November 2017 the CHMP adopted an opinion, confirming the PRAC's recommendations, for further restrictions to minimize the risk of serious liver injury with ZINBRYTA, including restriction of its use to adult patients with relapsing forms of MS who have had an inadequate response to at least two DMTs and for whom treatment with any other DMT is contraindicated or otherwise unsuitable. In January 2018 the EC adopted a final and legally-binding decision, which concluded the Article 20 Procedure, confirming the CHMP opinion. As a result of the CHMP's recommendation of these restrictions, we recorded net impairment charges related to intangible assets, inventory, property, plant and equipment and prepaid tax assets, totaling approximately $190.8 million. Offsetting these amounts was an unrecorded tax benefit related to certain ZINBRYTA related assets totaling approximately $93.8 million.

Opicinumab (anti-LINGO-1)

- In October 2017 we initiated the Phase 2b clinical trial AFFINITY, designed to evaluate opicinumab as an investigational add-on therapy in people with relapsing MS. The trial follows the comprehensive review of SYNERGY, a Phase 2 trial, which identified a specific population that may be more likely to respond to treatment.

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- In October 2017 we presented data supporting opicinumab as a potential therapy to repair damage to the central nervous system caused by MS. These data were presented at the seventh Joint Meeting of the European Committee for Treatment and Research in MS and Americas Committee for Treatment and Research in MS (ECTRIMS-ACTRIMS).

Neuromuscular Disorders

SPINRAZA (nusinersen)

- In January 2017 we presented new data from the Phase 3 ENDEAR study of SPINRAZA, which demonstrated a statistically significant reduction in the risk of death or permanent ventilation in SPINRAZA-treated infants with SMA compared to untreated infants. The data were presented at the British Pediatric Neurology Association annual conference in Cambridge, U.K.
- In April 2017 the CHMP of the EMA adopted a positive opinion recommending the granting of a marketing authorization in the E.U. for SPINRAZA to treat patients with SMA.
- In April 2017 we presented Phase 3 end of study SPINRAZA data from CHERISH, which demonstrated a highly statistically significant and clinically meaningful improvement in motor function in children with later-onset (most likely to develop Type 2 or Type 3) SMA compared to untreated children. The overall findings continued to support the efficacy and favorable safety profile of SPINRAZA across a broad range of individuals with SMA.

We also presented interim data from the Phase 2 NURTURE study evaluating SPINRAZA for the treatment of infants under six weeks old with genetically diagnosed SMA who were presymptomatic at treatment initiation. At the time of the interim analysis, infants (n=20) were enrolled for a median of 317.5 days, and all infants were alive and none required respiratory intervention (chronic non-invasive ventilation, invasive ventilation or tracheostomy). Further, most infants achieved motor milestone and growth parameter gains generally consistent with normal development, such as head control, independent sitting, standing and walking independently, as measured by validated scales. These data were presented at the 69th annual meeting of AAN in Boston, MA.

- In June 2017 the EC granted a marketing authorization for SPINRAZA for the treatment of 5q SMA in pediatric and adult patients in the E.U. SPINRAZA is the first approved treatment in the E.U. for SMA. SPINRAZA was reviewed under the EMA's accelerated assessment program.
- In June 2017 we presented robust efficacy and safety data from Phase 2 and Phase 3 SPINRAZA studies at the Cure SMA 2017 Annual SMA Conference in Orlando, FL. Data demonstrated motor function improvements in infants on permanent ventilation and no increase in the risk of adverse events in children with scoliosis.
- In July 2017 the Japanese Ministry of Health, Labor and Welfare approved the use of SPINRAZA for the treatment of infantile SMA.
- In September 2017 the Japanese Ministry of Health, Labor and Welfare approved the use of SPINRAZA for the treatment of pediatric and adult patients with SMA.
- In October 2017 we presented new data at the 22nd International Congress of the World Muscle Society demonstrating that earlier initiation of treatment with SPINRAZA may improve motor function outcomes in infants and children with SMA. Results demonstrated the favorable efficacy and safety profile of SPINRAZA.
- In October 2017 we and Ionis were awarded the 2017 Prix Galien USA Award for Best Biotechnology Product for SPINRAZA.
- In November 2017 the end of study results from ENDEAR, the Phase 3 study of SPINRAZA, were published in The New England Journal of Medicine.

Alzheimer's Disease and Dementia

Aducanumab (BIIB037)

- In March 2017 we presented data from research of aducanumab at the 13th International Conference on Alzheimer's and Parkinson's Diseases (AD/PD™) in Vienna, Austria.
- In April 2017 we presented data from a Phase 1b study of aducanumab at the 69th annual meeting of the AAN in Boston, MA. This data was previously presented at the Clinical Trials on Alzheimer's Disease (CTAD) meeting

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in December 2016 and included interim results from the titration cohort of the placebo-controlled period of the Phase 1b study as well as data from the first year of the long-term extension (LTE).

- In May 2017 we announced that we had amended the protocol of the Phase 3 trials of aducanumab. ApoE4 carriers that previously would be on a high dose of 6 mg/kg may now be titrated up to 10 mg/kg. This amendment is being reviewed by regulatory bodies and clinical study ethic independent review boards globally and may be implemented on a country by country basis. The change has already been incorporated in the U.S.
- In July 2017 we presented a new post-hoc analysis of the Phase 1b PRIME study of aducanumab at the Alzheimer's Association International Conference in London, U.K. Data presented included changes in the cognitive and functional subscores of the clinical dementia rating score. Aducanumab slowed decline on both the cognitive and functional assessments compared to placebo, and the results of all subgroups studied were consistent with the overall study population.
- In August 2017 we announced results from a recently conducted analysis of the LTE of our ongoing Phase 1b study of aducanumab. The updated analyses include data from the placebo-controlled period and the LTE for patients treated with aducanumab up to 24 months in the titration cohort and up to 36 months in the fixed-dose cohorts. The results are consistent with previously reported analyses from this ongoing Phase 1b study and support the design of the ongoing Phase 3 studies of aducanumab for early AD.
- In November 2017 we presented new data from the LTE of our ongoing Phase 1b study of aducanumab at the CTAD meeting in Boston, MA. The data included results from patients in the Phase 1b study who were treated with a gradually increased dose of aducanumab for up to 24 months and those who were treated with a fixed dose of 3, 6 or 10 mg/kg aducanumab for up to 36 months. The results are consistent with previously reported analyses from the Phase 1b study and support the design of the ongoing Phase 3 studies of aducanumab for early AD.

BAN2401 (A mAb)

- In December 2017 we announced that an Independent Data Monitoring Committee determined that BAN2401 did not meet the criteria for success based on a Bayesian analysis at 12 months as the primary endpoint in an 856-patient Phase 2 clinical study. Following the predefined study protocol, the blinded study will continue and a comprehensive final analysis will be conducted at 18 months seeking to demonstrate clinically significant results. The results of the final analysis are expected to be obtained during the second half of 2018.

BIIB076

- In January 2017 we initiated a Phase 1 trial of BIIB076, an anti-tau monoclonal antibody, in healthy volunteers and participants with AD.

BIIB092

- In June 2017 we dosed our first patient in our Phase 2 study of BIIB092 for PSP.

BIIB080 (also known as Ionis-MAPT$_{Rx}$)

- In October 2017 our collaboration partner Ionis announced the initiation of a Phase 1/2a clinical study of IONIS-MAPT$_{Rx}$ in patients with mild AD. IONIS-MAPT$_{Rx}$ is an antisense drug designed to selectively reduce the production of microtubule-associated protein tau (MAPT), or tau protein, in the brain. We have an option to develop and commercialize IONIS-MAPT$_{Rx}$.

Movement Disorders

BIIB054 (anti-alpha-synuclein antibody)

- In March 2017 we presented data from research of BIIB054, our investigational treatment for Parkinson's disease, at the 13th International Conference on Alzheimer's and Parkinson's Diseases (AD/PD™) in Vienna, Austria.
- In July 2017 we completed enrollment in the Phase 1 study of BIIB054 in both healthy volunteers and patients with early onset Parkinson's disease.
- In January 2018 we dosed our first patient in our Phase 2 SPARK study of BIIB054 in Parkinson's disease.

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Emerging Growth Areas

Acute Neurology

Natalizumab (4-integrin inhibitor) - Acute Ischemic Stroke

- In August 2017 we completed enrollment in the Phase 2b ACTION2 study evaluating the effects of natalizumab versus placebo on clinical measures of functional independence and activities of daily living in acute ischemic stroke patients.

Natalizumab - Epilepsy

- In October 2017 we initiated the Phase 2 OPUS study evaluating the efficacy, safety and tolerability of natalizumab in drug-resistant focal epilepsy.

Biosimilars

Samsung Bioepis - Biogen's Joint Venture with Samsung Biologics

BENEPALI (Etanercept)

- In June 2017 we presented real-world evidence from investigator-initiated studies supported by us demonstrating sustained efficacy and safety of, and high acceptance and adherence in patients initiating treatment with, BENEPALI. These data were presented at the Annual European Congress of Rheumatology (EULAR) in Madrid.

IMRALDI (Adalimumab)

- In June 2017 the CHMP of the EMA issued a positive opinion for IMRALDI, an adalimumab biosimilar candidate referencing HUMIRA.
- In August 2017 the EC granted a marketing authorization for IMRALDI.

Genentech Relationship

Anti-CD20 Therapies

OCREVUS (ocrelizumab)

- In March 2017 the FDA approved OCREVUS, a humanized anti-CD20 monoclonal antibody, for the treatment of relapsing MS (RMS) and primary progressive MS (PPMS).
- In July 2017 OCREVUS was approved in Australia for the treatment of RMS and PPMS.
- In September 2017 OCREVUS was approved in Switzerland for the treatment of RMS and PPMS.
- In January 2018 the EC granted a marketing authorization for OCREVUS for the treatment of RMS and PPMS.

RITUXAN (rituximab)

- In March 2017 Roche announced that the FDA’s Oncologic Drugs Advisory Committee voted unanimously that the benefit-risk of rituximab/hyaluronidase for subcutaneous (under the skin) injection was favorable for the treatment of certain blood cancers. This new co-formulation includes the same monoclonal antibody as intravenous RITUXAN and hyaluronidase, a molecule that helps to deliver medicine under the skin.
- In June 2017 the FDA approved RITUXAN HYCELA (rituximab and hyaluronidase human) for subcutaneous injection for the treatment of adults with previously untreated and relapsed or refractory follicular lymphoma, previously untreated diffuse large B-cell lymphoma and CLL. This new treatment includes the same monoclonal antibody as intravenous RITUXAN in combination with hyaluronidase human, an enzyme that helps to deliver rituximab under the skin.

GAZYVA

- In November 2017 the FDA approved GAZYVA in combination with chemotherapy, followed by GAZYVA alone in those who responded, for people with previously untreated advanced follicular lymphoma. The approval is based on results from the Phase 3 GALLIUM study, which showed superior progression-free survival for patients who received this GAZYVA-based regimen compared with those who received a RITUXAN-based regimen as an initial therapy.

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Other

Idiopathic Pulmonary Fibrosis

BG00011 (STX-100)

- In October 2017 we reported that BG00011 (STX-100) achieved proof of biology in a Phase 2a study in patients with idiopathic pulmonary fibrosis (IPF), a chronic irreversible and ultimately fatal disease characterized by a progressive decline in lung function. We plan to initiate a Phase 2b study for BG00011 in 2018.

Marketed Products

The following graphs show our revenues by product and revenues from anti-CD20 therapeutic programs and geography as a percentage of revenues for the years ended December 31, 2017, 2016 and 2015.

(1) Interferon includes AVONEX and PLEGRIDY

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

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Product sales for TECFIDERA, AVONEX and TYSABRI and anti-CD20 therapeutic programs for RITUXAN each accounted for more than 10% of our total revenues for the years ended December 31, 2017, 2016 and 2015. For additional financial information about our product and other revenues and geographic areas where we operate, please read Note 25, 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 Item 1A. Risk Factors included in this report.

Multiple Sclerosis and Neuroimmunology

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 RMS experience an uneven pattern of disease progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient returns to a new baseline of functioning.

Our MS products and major markets include:

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

Germany

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Neuromuscular Diseases

SMA is characterized by loss of motor neurons in the spinal cord and lower brain stem, resulting in severe and progressive muscular atrophy and weakness. Ultimately, individuals with the most severe type of SMA can become paralyzed and have difficulty performing the basic functions of life, like breathing and swallowing. Due to a loss of, or defect in, the SMN1 gene, people with SMA do not produce enough survival motor neuron (SMN) protein, which is critical for the maintenance of motor neurons. The severity of SMA correlates with the amount of SMN protein. People with Type 1 SMA, the most severe life-threatening form, produce very little SMN protein and do not achieve the ability to sit without support or live beyond two years without respiratory support. People with Type 2 and Type 3 SMA produce greater amounts of SMN protein and have less severe, but still life-altering, forms of SMA.

In December 2016 the FDA approved SPINRAZA for the treatment of SMA in pediatric and adult patients. In June 2017 the EC approved SPINRAZA for the treatment of SMA in pediatric and adult patients in the E.U. The Japanese Ministry of Health, Labor and Welfare approved SPINRAZA for the treatment of infantile SMA in July 2017 and for the treatment of pediatric and adult patients with SMA in September 2017.

Our products for SMA and major markets include:

Product	Indication	Collaborator	Major Markets
SMA	SMA	Ionis	U.S. France Germany Japan Turkey

Biosimilars

Biosimilars are a group of biologic medicines that are similar to currently available biologic therapies known as originators. Under our agreement with Samsung Bioepis, we manufacture and commercialize two anti-TNF biosimilars in certain countries in the E.U.: BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE. In August 2017 the EC granted a marketing authorization for IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U.

Product	Indication	Major Markets
FLIXABI	Moderate to severe rheumatoid arthritis Progressive psoriatic arthritis Axial spondyloarthritis Moderate to severe plaque psoriasis	Germany Norway Sweden U.K.
BENEPALI	Rheumatoid arthritis Moderate to severe Crohn's disease Severe ulcerative colitis Severe ankylosing spondylitis Psoriatic arthritis Moderate to severe plaque psoriasis	Germany

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Genentech Relationships

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

Product	Indication	Major Markets
	Non-Hodgkin's lymphoma CLL Rheumatoid arthritis Two forms of ANCA-associated vasculitis	U.S. Canada
	In combination with chlorambucil for previously untreated CLL Follicular lymphoma	U.S.
	RMS PPMS	U.S. Australia Switzerland

For information about our anti-CD20 therapeutic programs and related agreements with Genentech, please read Note 1, Summary of Significant Accounting Policies, and Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Other

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

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Patient Support and Access

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

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

Marketing and Distribution

Sales Force and Marketing

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

We co-promote ZINBRYTA with AbbVie in the U.S., E.U. and Canadian territories and BENEPALI and FLIXABI with Samsung Bioepis in certain countries in the E.U.

We and Eisai co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings.

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

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

Distribution Arrangements

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

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

We distribute BENEPALI and FLIXABI in certain countries in the E.U.

Eisai distributes AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

RITUXAN, GAZYVA and OCREVUS are 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, 2017, 2016 and 2015, and on a combined basis, accounted for approximately 56%, 57% and 60% of our gross product revenues for the years ended December 31, 2017, 2016 and 2015, respectively. For additional information, please read Note 25, Segment Information, to our consolidated financial statements included in this report.

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

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extension (for up to 5 years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. The duration and extension of the term of foreign patents varies, in accordance with local law. For example, supplementary protection certificates (SPCs) on some of our products have been granted in a number of European countries, compensating in part for delays in obtaining marketing approval.

Regulatory exclusivity, which may consist of regulatory data protection and market protection, also can provide meaningful protection for our products. Regulatory data protection provides to the holder of a drug or biologic marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it created at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. After the applicable set period of time, third parties are then permitted to rely upon our data to file for approval of their abbreviated applications for, and to market (subject to any applicable market protection), their generic drugs and biosimilars referencing our data. Market protection provides to the holder of a drug or biologic marketing authorization the exclusive right to commercialize its product for a set period of time, thereby preventing the commercialization of another product containing the same active ingredient(s) during that period. Although the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory exclusivity to innovative pharmaceutical products, implementation and enforcement varies widely from country to country.

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

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

Our Patent Portfolio

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

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Product	Territory	Patent No.	General Subject Matter	Patent Expiration[1]
TECFIDERA	U.S.	7,619,001	Methods of treatment	2018
	U.S.	7,803,840	Methods of treatment	2018
	U.S.	8,399,514	Methods of treatment	2028
	U.S.	8,524,773	Methods of treatment	2018
	U.S.	6,509,376	Formulations of dialkyl fumarates for use in the treatment of autoimmune diseases	2019
	U.S.	8,759,393	Formulations	2019
	U.S.	7,320,999	Methods of treatment	2018
	Europe	1131065	Formulations of dialkyl fumarates and their use for treating autoimmune diseases	2019[2]
	Europe	2137537	Methods of use	2028[3]
AVONEX and PLEGRIDY	U.S.	7,588,755	Use of recombinant beta interferon for immunomodulation	2026
PLEGRIDY	U.S.	7,446,173	Polymer conjugates of interferon beta-1a	2022
	U.S.	8,524,660	Methods of treatment	2023
	U.S.	8,017,733	Polymer conjugates of interferon beta-1a	2027
	Europe	1656952	Polymer conjugates of interferon-beta-1a and uses thereof	2019
	Europe	1476181	Polymer conjugates of interferon-beta-1a and uses thereof	2023[4]
TYSABRI	U.S.	6,602,503	Humanized recombinant antibodies; nucleic acids and host cells; processes for production; therapeutic compositions; methods of use	2020
	U.S.	7,807,167	Methods of treatment	2023
	U.S.	9,493,567	Methods of treatment	2027
	Europe	0804237	Humanized immunoglobulins; nucleic acids; pharmaceutical compositions; medical uses	2020[5]
	Europe	1485127	Methods of use	2023
FAMPYRA	Europe	1732548	Sustained-release aminopyridine compositions for increasing walking speed in patients with MS	2025[6]
	Europe	23775536	Sustained-release aminopyridine compositions for treating MS	2025[7]
ZINBRYTA	U.S.	8,454,965	Methods of treatment	2024
	U.S.	7,258,859	Methods of treatment	2024
	U.S.	9,340,619	Daclizumab HYP compositions	2032
	Europe	1539200	Anti-IL-2-receptor antibody for use in a method of treating a subject with MS	2023
SPINRAZA	U.S.	6,166,197	Oligomeric Compounds Having Pyrimidine Nucleotide(s)	2017
	U.S.	6,210,892	Alteration of Cellular Behavior By Antisense Modulation of MRNA Processing	2018
	U.S.	7,101,993	Oligonucleotides Containing 2’-O-Modified Purines	2023
	U.S.	7,838,657	SMA Treatment Via Targeting of SMN2 Splice Site Inhibitory Sequences	2027
	U.S.	8,110,560	SMA Treatment Via Targeting of SMN2 Splice Site Inhibitory Sequences	2025
	U.S.	8,361,977	Compositions And Methods For Modulation of SMN2 Splicing	2030
	U.S.	8,980,853	Compositions And Methods For Modulation of SMN2 Splicing	2030
	U.S.	9,717,750	Compositions and Methods For Modulation of SMN2 Splicing	2030

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

Footnotes follow on next page.

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

Product	Territory	Expected Expiration
TECFIDERA	U.S.	2018
	E.U.	2024
PLEGRIDY	U.S.	2026
	E.U.	2024
FAMPYRA	E.U.	2021
ZINBRYTA	U.S.	2028
	E.U.	*
SPINRAZA	U.S.	2023
	E.U.	2027**

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

**SPINRAZA may be eligible for an additional two years exclusivity in Europe based on the orphan pediatric indication.

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

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

(4) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2028.

(5) Reflects SPCs granted in most European countries and pediatric extension in some countries.

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

(7) 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 Item 1A. Risk Factors included in this report, and a discussion of legal proceedings related to certain patents described above is set forth in Note 21, 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 or have commercialized products similar to those we market or are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Certain of these companies have substantially greater financial, marketing and research and development resources than we do.

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

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

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

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

Multiple Sclerosis

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

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

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

Competition in the MS market is intense. Along with us, a number of companies are working to develop additional treatments for MS that may in the future compete with our MS products. One such product that was approved in the

U.S. in 2017 and in the E.U. in 2018 is OCREVUS, a treatment for RMS and PPMS that was developed by Genentech. While we have a financial interest in OCREVUS, future sales of our MS products may be adversely affected if OCREVUS continues to gain market share, or if other MS products that we or our competitors are developing are commercialized. Future sales may also be negatively impacted by the introduction of generics, prodrugs of existing therapeutics or biosimilars of existing products and other technologies.

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Spinal Muscular Atrophy

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

Psoriasis

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

Biosimilars

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

Genentech Relationships in Other Indications

RITUXAN and GAZYVA in Oncology

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

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

RITUXAN in Rheumatoid Arthritis

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

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

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.

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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 Item 1A. Risk Factors included in this report.

Core Growth Areas	MS and Neuroimmunology	BIIB098 (monomethly fumarate prodrug)* - MS	Phase 3
		Opicinumab (anti-LINGO-1) - MS	Phase 2
	Alzheimer's Disease and Dementia	Aducanumab (A mAb)* - Alzheimer's	Phase 3
		Elenbecestat (E2609)* - Alzheimer's	Phase 3
		BAN2401 (A mAb)* - Alzheimer's	Phase 2
		BIIB092 (anti-tau mAb) - Alzheimer's	Phase 1
		BIIB076 (anti-tau mAb)* - Alzheimer's	Phase 1
		BIIB080 (IONIS-MAPT$_{Rx}$)* - Alzheimer's	Phase 1
	Parkinson's Disease and Movement Disorders	BIIB092 (anti-tau mAb) - PSP	Phase 2
		BIIB054 (anti-alpha-synuclein mAb) - Parkinson's	Phase 2
	Neuromuscular Disease Including SMA and ALS	BIIB067 (IONIS-SOD1$_{Rx}$)* - ALS	Phase 1
	Pain	BIIB074 (Vixotrigine) - Trigeminal Neuralgia	Phase 2
		BIIB074 (Nav1.7) - PLSR[#]	Phase 2
Emerging Growth Areas	Ophthalmology	BIIB087 (gene therapy)* - XLRS^	Phase 1/2
		BIIB093 (glibenclamide IV) - LHI Stroke	Phase 2
	Acute Neurology	Natalizumab - AI Stroke	Phase 2
		Natalizumab - Epilepsy	Phase 2
		Dapirolzumab pegol (anti-CD40L)* - SLE[@]	Phase 2
	Other		

BG00011 (STX-100) - IPF	Phase 2
BIIB059 (anti-BDCA2) - SLE@	Phase 2

* Collaboration programs
# Painful Lumbosacral Radiculophath (PLSR)
^ X-linked Retinoschisis (XLRS)
@ Systemic Lupus Erythematosus (SLE)

For information about certain of our agreements with collaborators and other third parties, please read the subsection entitled “Business Relationships” below and Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

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 additional information on certain of these relationships, including their ongoing financial and accounting impact on our business, please read Note 19, Investments in Variable Interest Entities, and Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

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AbbVie, Inc.
We have a collaboration agreement with AbbVie for the development and commercialization of ZINBRYTA in MS. Under this agreement, we and AbbVie conduct ZINBRYTA co-promotion activities in the U.S., E.U. and Canadian territories, and we are responsible for all manufacturing and research and development activities.
For information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.
Acorda Therapeutics, Inc.
We have a collaboration and license agreement with Acorda to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S. We are responsible for all regulatory activities and the future clinical development of related products in those markets.
Alkermes
We have an exclusive license and collaboration agreement with Alkermes to develop and commercialize BIIB098, an oral MMF prodrug in Phase 3 development for the treatment of relapsing forms of MS.
Applied Genetic Technologies Corporation
We have a collaboration agreement with Applied Genetic Technologies Corporation (AGTC) to develop gene-based therapies for multiple ophthalmic diseases. This collaboration is focused 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. This agreement also provides us with options to early stage discovery programs in two ophthalmic diseases and one non-ophthalmic condition.
Bristol-Myers Squibb Company
We have an exclusive license agreement with BMS for the development and commercialization of BIIB092. Under this agreement, we received worldwide rights to BIIB092 and are responsible for the full development and global commercialization of BIIB092 in AD and PSP.

Eisai Co., Ltd.
We have a collaboration agreement with Eisai to jointly develop and commercialize E2609 and BAN2401, two Eisai product candidates for the treatment of AD. Eisai serves as the global operational and regulatory lead for both 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.
We also have the Aducanumab Collaboration Agreement with Eisai for the joint development and commercialization of aducanumab. Under the Aducanumab Collaboration Agreement, the two companies will co-promote aducanumab with a region-based profit split and we will continue to lead the ongoing Phase 3 development of aducanumab.
We and Eisai will co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai will distribute AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.
Genentech (Roche Group)
We have a collaboration agreement with Genentech which entitles us to certain financial and other rights with respect to RITUXAN, GAZYVA, OCREVUS and other anti-CD20 product candidates.
Ionis Pharmaceuticals, Inc.
We have an exclusive, worldwide option and collaboration agreement with Ionis relating to the development and commercialization of up to three gene targets, and an exclusive, worldwide option and collaboration agreement with Ionis under which both companies are responsible for the development and commercialization of SPINRAZA for the treatment of SMA.
We also have research collaboration agreements with Ionis, under which both companies perform discovery level research and will develop and commercialize new ASO drug candidates for the treatment of SMA and additional antisense and other therapeutics for the treatment of neurological disorders.
Neurimmune

We have a collaboration and license agreement with Neurimmune for the development and commercialization of antibodies for the treatment of AD, including aducanumab. Under this agreement, we are responsible for the development, manufacturing and commercialization of all licensed products.

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Samsung Bioepis

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

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

University of Pennsylvania

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

Regulatory

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

Regulation of Pharmaceuticals

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

APPROVAL PROCESS

Before new pharmaceutical products may be sold in the U.S., preclinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. With limited exceptions, the FDA requires companies to register both pre-approval and post-approval clinical trials and disclose clinical trial results in public databases. Failure to register a trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties. Clinical trial programs must establish efficacy, determine an appropriate dose and dosing regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. The results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a Biologics License Application (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.

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

- Accelerated Approval: The FDA may grant “accelerated approval” status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. Under the FDA'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 30 days prior to initial dissemination. The FDA may withdraw approval under accelerated approval after a hearing if, for instance, post-marketing studies fail to verify any clinical benefit, it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use, or if a sponsor fails to comply with the conditions of the accelerated approval.
- Fast Track Status: The FDA may grant "fast track" status to products that treat a serious condition and have data demonstrating the potential to address an unmet medical need or a drug that has been designated as a qualified infectious disease product.
- Breakthrough Therapy: The FDA may grant “breakthrough therapy” status to drugs designed to treat, alone or in combination with another drug or drugs, a serious or life-threatening disease or condition and for which preliminary clinical evidence suggests a substantial improvement over existing therapies. Such drugs need not address an unmet need, but are nevertheless eligible for expedited review if they offer the potential for an improvement. Breakthrough therapy status entitles the sponsor to earlier and more frequent meetings with the FDA regarding the development of nonclinical and clinical data and permits the FDA to offer product development or regulatory advice for the purpose of shortening the time to product approval. Breakthrough therapy status does not guarantee that a product will be developed or reviewed more quickly and does not ensure FDA approval.
- Priority Review: Priority Review only applies to applications (original or efficacy supplement) for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications. Priority Review may also be granted for any supplement that proposes a labeling change due to studies completed in response to a written request from the FDA for pediatric studies, for an application for a drug that has been designated as a qualified infectious disease product, or any application or supplement for a drug submitted with a priority review voucher.

In December 2016, the FDA issued us a rare pediatric disease priority review voucher in connection with the approval of SPINRAZA.

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

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can delay, impede or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials), or suspend or withdraw approval of the product. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

APPROVAL OF CHANGES TO AN APPROVED PRODUCT

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

REGULATION OF PRODUCT ADVERTISING AND PROMOTION

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

Regulation of Combination Products

Combination products are defined by the FDA to include products comprising two or more regulated components (e.g., a biologic and a device). Biologics and devices each have their own regulatory requirements, and combination products may have additional requirements. Some of our marketed

products meet this definition and are regulated under this framework and similar regulations outside the U.S., and we expect that some of our pipeline product candidates may be evaluated for regulatory approval under this framework as well.

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

We market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, for example, where a substantial part of our ex-U.S. efforts are focused, there are several tracks for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing authorization application is similar to the NDA or BLA in the U.S. and is evaluated by the CHMP, the expert scientific committee of the EMA responsible for human medicines. If the CHMP determines that the marketing authorization application fulfills the requirements for quality, safety and efficacy and that the medicine has a positive benefit risk balance, it will adopt a positive opinion recommending grant of the marketing authorization by 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 of the E.U. 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 national procedure, which requires an application to the competent authority of an E.U. country (if an application is to be made in more than one E.U. country, following approval in the first country, the applicant must submit applications in the other countries using the mutual recognition procedure);
- a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval, if the medicine has not yet been authorized in any E.U. country; and

- a mutual recognition procedure, where applicants that have a medicine authorized in one E.U. country can apply for mutual recognition of this authorization in other E.U. countries.

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In the E.U., there is detailed legislation on pharmacovigilance and extensive guidance on good pharmacovigilance practices.

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. The EMA's PRAC is responsible for assessing and monitoring the safety of human medicines and makes recommendations on product safety issues.

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

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected (commonly referred to as current Good Clinical Practices (cGCP)). Regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites, contract research organizations (CROs) and institutional review boards. If our studies fail to comply with applicable cGCP guidelines, 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.

In April 2014, the EC adopted a new Clinical Trial Regulation, which was effective in June 2014 but is not expected to apply until the second half of 2019. The regulation harmonizes the procedures for assessment and governance of clinical trials throughout the E.U. and will require that information on the authorization, conduct and results of each clinical trial conducted in the E.U. be publicly available.

Approval of Biosimilars

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

A biosimilars approval pathway has been in place in the E.U. since 2003. The EMA has issued a number of scientific and product specific biosimilar guidelines, including requirements for approving biosimilars containing monoclonal antibodies. In the E.U., biosimilars are generally approved under the centralized procedure. The approval pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on reliance on the clinical trial data of an innovator product to which the biosimilar has been demonstrated, through comprehensive comparability studies, to be “similar”. In many cases, this allows biosimilars to be brought to market without conducting the full complement of clinical trials typically required for novel biologic drugs.

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Orphan Drug Act

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

Regulation Pertaining to Pricing and Reimbursement

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

Within the U.S.

Medicaid: Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate is established by law and is adjusted upward if average manufacture price (AMP) increases more than inflation (measured by the Consumer Price Index - Urban).

- The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services (CMS). The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

Medicare: Medicare is a federal program that is administered by the federal government. The program 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. Medicare Part B

- pays for such drugs under a payment methodology based on the average sales price (ASP) of the drugs. Manufacturers, including us, are required to provide ASP information to the CMS on a quarterly basis. The manufacturer-submitted information is used to calculate Medicare payment rates. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S.

- government. 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 pharmacies, and may condition formulary placement on the availability of manufacturer

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

- Federal Agency Discounted Pricing: Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration (VA), Department of Defense, Coast Guard and Public Health Service (PHS). Coverage under Medicaid, Medicare and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the VA, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties.
- 340B Discounted Pricing: To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend significant discounts to certain covered entities that purchase products under Section 340B of the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics 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., 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 and 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 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 anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). In the U.S., federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these

laws, our business could be harmed.

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

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay 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 U.K. generally will be subject to the Bribery Act. Penalties under the Bribery Act include significant 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 Research Triangle Park (RTP), NC 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.

The European Parliament and the Council of the European Union adopted a comprehensive general data privacy regulation (GDPR) in 2016 to replace the current E.U. Data Protection Directive and related country-specific legislation. The GDPR will take effect in May 2018 and governs the collection and use of personal data in the E.U. The GDPR, which is wide-ranging in scope, will impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with

the processing of the personal data. The GDPR will also impose strict rules on the transfer of personal data out of the E.U. to the U.S., will provide an enforcement authority and will impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater.

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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.

Manufacturing

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

Manufacturing Facilities

Our drug substance manufacturing facilities include:

Facility	Drug Substance Manufactured
RTP, North Carolina	ALPROLIX AVONEX ELOCTATE PLEGRIDY TYSABRI ZINBRYTA Other*
Hillerød, Denmark	TYSABRI Biosimilars

* Other includes products manufactured for contract manufacturing partners

In addition to our drug substance manufacturing facilities, we have a drug product manufacturing facility and supporting infrastructure in RTP, NC including a parenteral facility and an oral solid dose products manufacturing facility.

The parenteral facility adds capabilities and capacity for filling biologics into vials and is principally used for filling product candidates. The oral solid dose products facility supplements our outsourced small molecule manufacturing capabilities, including the manufacture of TECFIDERA.

We also have a new oligonucleotide synthesis manufacturing (OSM) facility in RTP, NC. This facility gives us the capability to manufacture ASO drugs like SPINRAZA as well as our other ASO candidates currently in our clinical pipeline.

During the first quarter of 2016 we purchased land in Solothurn, Switzerland and are building a large-scale biologics manufacturing facility at this site. We expect this facility to be operational by the end of the decade.

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

Third-Party Suppliers and Manufacturers

We principally use third parties to manufacture the API and 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, to a lesser extent, 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 Hillerød facility. Raw materials, delivery devices, such as syringes and auto-injectors, and other supplies required for the production of our products and product candidates are procured from various third-party suppliers and manufacturers in quantities adequate to meet our needs. Continuity of supply of such raw materials, devices and supplies is assured using a strategy of dual sourcing where possible or by a risk-based inventory strategy. Our third-party service providers, suppliers and manufacturers may be subject to routine cGMP inspections by the FDA or comparable agencies in other jurisdictions and undergo assessment and certification by our quality management group.

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Our Employees

As of December 31, 2017, we had approximately 7,300 employees worldwide.

Our Executive Officers (as of February 1, 2018)

Officer	Current Position	Age	Year Joined Biogen
Michel Vounatsos	Chief Executive Officer	56	2016
Susan H. Alexander	Executive Vice President, Chief Legal, Corporate Services and Secretary	61	2006
Jeffrey D. Capello	Executive Vice President and Chief Financial Officer	53	2017
Gregory F. Covino	Vice President, Finance and Chief Accounting Officer	52	2012
Michael D. Ehlers, M.D., Ph.D.	Executive Vice President, Research and Development	49	2016
Ginger Gregory, Ph.D.	Executive Vice President and Chief Human Resources Officer	50	2017
Chirfi Guindo	Executive Vice President and Head of Global Marketing, Market Access and Customer Innovation	52	2017
Paul McKenzie, Ph.D.	Executive Vice President, Pharmaceutical Operations and Technology	52	2016
Alfred W. Sandrock, Jr., M.D., Ph.D.	Executive Vice President and Chief Medical Officer	60	1998

Michel Vounatsos

Experience

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

Education

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

Susan H. Alexander

Experience

Ms. Alexander has served as our Executive Vice President, Chief Legal, Corporate Services and Secretary since March 2017. Prior to that, from December 2011 to March 2017, Ms. Alexander served as our Executive Vice President, Chief Legal Officer and Secretary and from 2006 to December 2011, as our Executive Vice President, General Counsel and Corporate Secretary. From 2003 to January 2006, Ms. Alexander served as the Senior Vice President, General Counsel and Corporate Secretary of PAREXEL International Corporation, a biopharmaceutical services company. From 2001 to 2003, Ms. Alexander served as General Counsel of IONA Technologies, a software company. From 1995 to 2001, Ms. Alexander served as Counsel at Cabot Corporation, a specialty chemicals and performance materials company. Prior to that, Ms. Alexander was a partner at the law firms of Hinckley, Allen & Snyder and Fine & Ambrogne.

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

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

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Jeffrey D. Capello

Experience

Mr. Capello has served as our Executive Vice President and Chief Financial Officer since December 2017. Prior to that, Mr. Capello served as the Chief Financial Officer of Beacon Health Options, Inc., a behavioral health company, with responsibility for finance, human resources, information technology, real estate and procurement, from October 2016 until November 2017. From July 2015 until September 2016, Mr. Capello was the founder and Chief Executive Officer of Monomoy Advisors which focuses on helping companies drive shareholder value. From July 2014 until June 2015, Mr. Capello served as the Executive Vice President and Chief Financial Officer of Ortho-Clinical Diagnostics, an in vitro diagnostics company that was acquired by the Carlyle Group from Johnson & Johnson, with responsibility for global finance and business development. Prior to his role at Ortho-Clinical Diagnostics, Mr. Capello served as Chief Financial Officer and Executive Vice President of Boston Scientific Corporation, a medical device company, from March 2010 to December 2013. At Boston Scientific, Mr. Capello was responsible for the worldwide management of Boston Scientific's finance, information systems, business development and corporate strategy functions. Mr. Capello joined Boston Scientific in June 2008 and served as Senior Vice President and Chief Accounting Officer until March 2010. Prior to joining Boston Scientific, he was the Senior Vice President and Chief Financial Officer with responsibilities for global finance and business development at PerkinElmer, Inc., a life sciences tool company, from 2006 to 2008. Previously, he served as PerkinElmer's Vice President of Finance, Corporate Controller, Treasurer and Chief Accounting Officer from 2001 to 2006. Prior to his tenure at PerkinElmer, Mr. Capello was a Partner at PricewaterhouseCoopers LLP, both in the United States and in the Netherlands.

Public Company Boards

- OvaScience, Inc., a biotechnology company
- Flex Pharma, Inc., a biotechnology company

Education

- University of Vermont, B.S. in Business Administration
- Harvard Business School, M.B.A.

Gregory F. Covino

Experience

Mr. Covino has served as our Vice President and Chief Accounting Officer since April 2012. From

June 2017 to December 2017, Mr. Covino also served as our interim Principal Financial Officer. From March 2010 to April 2012, Mr. Covino served at Boston Scientific Corporation, a medical device company, as Vice President, Corporate Analysis and Control, having responsibility for the company's internal audit function, and as Vice President, Finance, International from February 2008 to March 2010, having responsibility for the financial activities of the company's international division. Prior to that, Mr. Covino held several finance positions at Hubbell Incorporated, an electrical products company, including Vice President, Chief Accounting Officer and Controller from 2002 to January 2008, Interim Chief Financial Officer from 2004 to 2005, and Director, Corporate Accounting from 1999 to 2002.

Education

- Bryant University, B.S. in Business Administration

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Michael D. Ehlers, M.D., Ph.D.

Experience

Dr. Ehlers has served as our Executive Vice President, Head of Research and Development since May 2016. Prior to joining Biogen, from August 2010 to April 2016, Dr. Ehlers served in leadership positions at Pfizer, Inc., a biopharmaceutical company, including Senior Vice President & Head BioTherapeutics R&D and Chief Scientific Officer, Neuroscience & Pain. Prior to that, Dr. Ehlers was the George Barth Geller Professor of Neurobiology and an Investigator of the Howard Hughes Medical Institute at Duke University Medical Center. He is the recipient of numerous awards including the Eppendorf & Science Prize in Neurobiology, the John J. Abel Award in Pharmacology, the Society for Neuroscience Young Investigator Award, a National Institute of Mental Health MERIT Award, the National Alliance for Schizophrenia and Depression Distinguished Investigator Award and the Massachusetts Medical Society Honored Business Leader Award. In 2013, Dr. Ehlers became the 11th recipient of the Thudichum Medal of the Biochemical Society of the United Kingdom. Past recipients include two Nobel laureates. Dr. Ehlers has authored over 100 scientific papers, has served on the Editorial Boards of Annual Reviews in Medicine, Annual Reviews in Pharmacology and Toxicology, the Journal of Neuroscience, the Journal of Biological Chemistry, the Journal of Molecular and Cellular Neuroscience and has sat on advisory committees of the National Institutes of Health.

Outside Affiliations

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

Education

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

Ginger Gregory, Ph.D.

Experience

Dr. Gregory has served as our Executive Vice President and Chief Human Resources Officer since July 2017. Prior to joining Biogen, Dr. Gregory served as Executive Vice President and Chief Human Resources Officer at Shire PLC, a global specialty biopharmaceutical company, from February 2014 to April 2017. Prior to that, Dr. Gregory held executive-level human resources positions for several multinational companies across a variety of industries, including Dunkin' Brands, where she served as Chief Human Resource Officer; Novartis, AG, where she was the division head of Human Resources for Novartis Vaccines and Diagnostics, Novartis Consumer Health and Novartis Institutes of BioMedical Research from 2005 to 2012; and Novo Nordisk, where she served as Senior Vice President,

Corporate People & Organization at the company's headquarters in Copenhagen, Denmark. Earlier in her career, she held a variety of human resources generalist and specialist positions at Bristol-Myers Squibb and served as a consultant with Booz Allen & Hamilton in the area of organization change and effectiveness.

Education

- University of Massachusetts B.A., in Psychology
- The George Washington University, Ph.D. Psychology

Chirfi Guindo

Experience

Mr. Guindo has served as our Executive Vice President and Head of Global Marketing, Market Access and Customer Innovation since November 2017. Prior to joining Biogen, Mr. Guindo spent 27 years in the global pharmaceutical industry and has held several leadership positions at Merck in Canada, the U.S., France, Africa and the Netherlands. He worked in several disciplines including Finance, Sales & Marketing, General Management and Global Strategy/Product Development in specialty, acute and hospital care. Most recently Mr. Guindo was Vice President and Managing Director and President and Managing Director of Merck Canada from October 2014 to November 2017. From January 2011 to October 2014, he was Vice President and General Manager, Global HIV Franchise at Merck & Co.

Education

- Ecole Central de Paris (France), Engineering
- Stern School of Business, New York University, M.B.A. in Finance/Economics

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Paul McKenzie, Ph.D.

Experience

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

Education

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

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

Experience

Dr. Sandrock has served as our Executive Vice President and Chief Medical Officer since October 2017. Prior to that, Dr. Sandrock served as our Executive Vice President, Chief Medical Officer Neurology and Neurodegeneration from October 2015 to October 2017, as our Chief Medical Officer and Group Senior Vice President from April 2013 to October 2015 and as our Chief Medical Officer and Senior Vice President of Development Sciences from February 2012 to April 2013. Prior to that, Dr. Sandrock held several senior executive positions since joining us in 1998, including Senior Vice President of Neurology Research and Development and Vice President of Clinical Development, Neurology.

Public Company Boards

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

Education

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

Available Information

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

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Item 1A. Risk Factors

We are substantially dependent on revenues from our principal products.

Our current revenues depend upon continued sales of our principal products, and, unless we develop or acquire rights to new products and technologies, we will be substantially dependent on sales from our principal products for many years. Further, following the completion of the spin-off of our hemophilia business, our revenues are further reliant and concentrated on sales of our MS products in an increasingly competitive market, and revenues from sales of our product for SMA. 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, including lower-priced competing products;
- constraints and additional pressures on product pricing or price increases, including those resulting from governmental or regulatory requirements, increased competition or changes in, or implementation of, reimbursement policies and practices of payors and other third parties; or
- adverse legal, administrative, regulatory or legislative developments.

SPINRAZA has been approved by, among others, the FDA, the EC and the Japanese Ministry of Health, Labor and Welfare, and is in the early stages of commercial launch in these and other markets. In addition to risks associated with new product launches and the other factors described in these “Risk Factors,” our ability to successfully commercialize SPINRAZA may be adversely affected due to:

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

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

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

Our products are also susceptible to increasing 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, as well as lower-priced competing products, likely would significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may have an adverse impact on our results of operations.

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

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

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

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

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

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

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs;
- 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; and
- our value-based contracting pilot program pursuant to which we aim to tie the pricing of our products to their clinical values by either aligning price to patient outcomes or adjusting price for patients who discontinue therapy for any reason, including efficacy or tolerability concerns.

Our ability to set the price for our products varies 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 favorable prices in a particular country may not only limit the revenues from our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third-party cross-border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

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

Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. In addition, competition from current and future competitors may negatively impact our ability to maintain pricing and our market share. New products or treatments brought to market by our competitors could cause revenues for our products to decrease due to potential price reductions and lower sales volumes. 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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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, patient and/or investor confidence in our products and our reputation. Any of these could result in liabilities, loss of revenues, 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, a serious brain infection, or liver injury in the label for certain of our products, may significantly reduce expected revenues for those products and require significant expense and management time.

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

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

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

the covered products and services.

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

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

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.

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

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, 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. For example, provisions of the PPACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D

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and the expansion of the number of hospitals eligible for discounts under Section 340B of the PHSA. These changes have had and are expected to continue to have a significant impact on our business.

We may face uncertainties as a result of federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

The administration has also indicated an intent to address prescription drug pricing and recent Congressional hearings have brought increased public attention to the costs of prescription drugs. These actions and the uncertainty about the future of the PPACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

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

In the E.U. and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures to reduce health care costs to limit 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. These measures have negatively impacted our revenues, and may continue to adversely affect our revenues and results of operations in the future.

Manufacturing issues could substantially increase our costs, limit supply of our products and/or 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.
- 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 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.

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- Global Bulk Supply Risks. We rely on our principal manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- Risks Relating to Compliance with cGMP. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

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

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

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

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

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

- we may be unable to control the resources our collaborators or third parties devote to our programs or products;
- disputes may arise under the agreement, including with respect to the achievement and payment of milestones or ownership of rights to technology developed with our collaborators or other third parties, and the underlying contract

with our collaborators or other third parties may fail to provide significant protection or may fail to be effectively enforced if the collaborators or third parties fail to perform;

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- the interests of our collaborators or third parties may not always be aligned with our interests, and such parties may not pursue regulatory approvals or market a product in the same manner or to the same extent that we would, which could adversely affect our revenues;
- third-party relationships and collaborations often require the parties to cooperate, and failure to do so effectively could adversely affect product sales, or the clinical development or regulatory approvals of products under joint control or could result in termination of the research, development or commercialization of product candidates or result in litigation or arbitration; and
- any failure on the part of our collaborators or other third parties to comply with applicable laws and regulatory requirements in the marketing, sale and maintenance of the marketing authorization of our products or to fulfill any responsibilities our collaborators or other third parties may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings.

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

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

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

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

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

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

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

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

While we believe we currently have sufficient large scale manufacturing capacity to meet our near-term manufacturing requirements, it is probable that we would need additional large scale manufacturing capacity to support future clinical and commercial manufacturing requirements for product candidates in our pipeline, if such candidates are successful and approved. We are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. Due to the long lead times necessary for the expansion of manufacturing capacity, we expect to make significant investments to build 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.

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 significant restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies such as ours have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third party charities that provide such assistance. If we, or our vendors or donation recipients, are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

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 judicial 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;
- the hiring freeze implemented by the federal government in 2017, including at the FDA, could impact the review and potential approval of new products, which may adversely affect our business and financial condition;
- 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
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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.

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

Our effective tax rate fluctuates, 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, including the 2017 Tax Act. 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.

The 2017 Tax Act has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as GILTI. These changes are effective beginning in 2018.

The 2017 Tax Act also includes the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

Our preliminary estimate of the Transition Toll Tax and the remeasurement of our deferred tax assets and liabilities is subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the 2017 Tax Act, changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries and the filing of our tax returns. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the 2017 Tax Act may require further adjustments and changes in our estimates, which could have a material adverse effect on our business, results of operations or financial conditions. The final determination of the Transition Toll Tax and the remeasurement of our deferred tax assets and liabilities will be completed as additional information becomes available, but no later than one year from the enactment of the 2017 Tax Act.

In addition, 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 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;
- uncertainties regarding the collectability of accounts receivable;
- fluctuations in foreign currency exchange rates that may adversely impact our revenues and net income;

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- 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 Bribery Act, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- the effects of the implementation of the U.K.’s decision to voluntarily depart from the E.U., known as Brexit;
- 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 FCPA prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay 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. 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 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 or other initiatives to streamline our operations and reallocate resources;
- 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.

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Our revenues are also subject to foreign currency 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 other 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.

Our investment in Samsung Bioepis, and our success in commercializing biosimilars developed by Samsung Bioepis, is 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, is 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/or payors do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- Ability to Provide Adequate Supply. Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet higher than anticipated demand; and
- Competitive Challenges. Biosimilar products face significant competition, including from innovator products and from biosimilar products offered by other companies. In some jurisdictions, local tendering processes may restrict biosimilar products from being marketed and sold in those jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective matter are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area.

Our investments in properties may not be fully realized.

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

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

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

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

From time to time our Board of Directors authorizes stock repurchase programs, including most recently a program to repurchase up to $5.0 billion of our common stock, which was authorized by our Board of Directors in July 2016 (2016 Share Repurchase Program). 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 shareholders 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, our results of operations, our 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.

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 and credit 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 in the past, 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 or credit 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 indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

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

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

Our 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.

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

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

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

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

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

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

We may incur operational difficulties or be exposed to claims and liabilities as a result of the spin-off of our hemophilia business.

On February 1, 2017, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen shareholders in connection with the spin-off of our hemophilia business. In connection with the distribution, we entered into a separation and distribution agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between us and Bioverativ going forward, including with respect to potential tax-related losses associated with the separation and distribution. They also provide for the performance of services by each company for the benefit of the other for a period of time (including under the manufacturing and supply agreement pursuant to which we will manufacture and supply certain products and materials to Bioverativ).

The spin-off of our hemophilia business as an independent public company is intended to qualify for tax-free treatment to Biogen and its shareholders under the Internal Revenue Code. Completion of the spin-off was conditioned upon, among other things, our receipt of a favorable opinion from our tax advisors with respect to the tax-free nature of the transaction. The opinion is not binding on the U.S. Internal Revenue Service (IRS) or the courts, and there can be no assurance that the IRS or the courts will not challenge the qualification of the spin-off as a tax-free transaction or that any such challenge would not prevail. If the spin-off is determined to be taxable, the full financial benefits expected to result from the separation may not be achieved and/or Biogen and its shareholders could incur significant tax liabilities, which could adversely affect our business, financial condition or results of operations and the value of our stock could be adversely impacted.

Bioverativ has agreed to indemnify us for certain potential liabilities that may arise, but we cannot guarantee that Bioverativ will be able to satisfy its indemnification obligations. The separation and distribution agreement provides for indemnification obligations designed to make Bioverativ financially responsible for many liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation. It is possible that a court would disregard the allocation agreed to between us and Bioverativ and

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require us to assume responsibility for obligations allocated to Bioverativ. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation and distribution agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Bioverativ may be significant. These risks could negatively affect our business, financial condition or results of operations.

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

We may not achieve some or all of the anticipated benefits of the spin-off of our hemophilia business, which may adversely affect our business.

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Below is a summary of our owned and leased properties as of December 31, 2017.

Massachusetts

In Cambridge, MA, 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 totaling approximately 245,000 square feet.

In addition, we lease a total of approximately 1,157,000 square feet in Massachusetts, which is summarized as follows:

- 800,000 square feet in Cambridge, MA, which is comprised of offices for our corporate headquarters, and other administrative and development functions and laboratories, of which 242,000 square feet is subleased by multiple companies for general office space, laboratories and manufacturing facilities; and
- 357,000 square feet of office space in Weston, MA, of which 174,000 square feet has been subleased through the remaining term of our lease agreement.

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

North Carolina

In RTP, NC, we own approximately 1,022,000 square feet of real estate space, which is summarized as follows:

- 357,000 square feet of laboratory and office space;
- 188,000 square feet related to an oral solid dose manufacturing facility;
- 175,000 square feet related to a large-scale biologics manufacturing facility;
- 105,000 square feet related to a small-scale biologics manufacturing facility;
- 84,000 square feet of warehouse space and utilities;
- 70,000 square feet related to a parenteral fill-finish facility; and

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- 43,000 square feet related to a large-scale purification facility.

In addition, we own approximately 40,000 square feet of warehouse space in Durham, NC.

Denmark

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

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

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

Switzerland

In December 2015 we purchased land in Solothurn, Switzerland and are building a large-scale biologics manufacturing facility at this site. We expect this facility to be operational by the end of the decade. Upon completion, the facility will include 393,000 square feet related to a large-scale biologics manufacturing facility, 290,000 square feet of warehouse, utilities and support space and 51,000 square feet of administrative space.

Other International

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

Item 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2017, please read Note 21, 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, 2017 and 2016:

	Common Stock Price			
	2017		2016	
	High	Low	High	Low
First Quarter	$298.00	$254.15	$301.02	$242.07
Second Quarter	$291.90	$244.28	$292.69	$223.02
Third Quarter	$330.00	$269.50	$333.65	$240.07
Fourth Quarter	$348.84	$301.81	$329.83	$268.00

The sales prices in the first quarter of 2017 in the tables above have been adjusted for the impact of the spin-off of our hemophilia business. For additional information on the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in this report.

As of January 26, 2018, there were approximately 665 shareholders of record of our common stock.

Dividends

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

Issuer Purchases of Equity Securities

In July 2016 our Board of Directors authorized our 2016 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. This authorization does not have an expiration date. All share repurchases under this authorization will be retired.

During the year ended December 31, 2017, we repurchased and retired approximately 3.7 million shares of common stock at a cost of $1.0 billion under our 2016 Share Repurchase Program. As of December 31, 2017, approximately $3.0 billion remains available for share repurchases under our 2016 Share Repurchase Program.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of our common stock (2011 Share Repurchase Program). Shares repurchased under this authorization were principally used to offset common stock issuances under our share-based compensation programs.

During the year ended December 31, 2017, we repurchased approximately 1.2 million shares of common stock at a cost of $365.4 million under our 2011 Share Repurchase Program. Our 2011 Share Repurchase Program was completed as of March 31, 2017.

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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, 2012 with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance. The table below reflects the stock prices as adjusted for the spin-off of our hemophilia business, which was effected on February 1, 2017. For additional information on the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in this report.

	2012	2013	2014	2015	2016	2017
Biogen Inc.	100.00	191.00	231.91	209.30	193.74	235.96
Nasdaq Pharmaceutical	100.00	135.68	165.29	174.27	172.37	205.33
S&P 500 Index	100.00	132.39	150.51	152.59	170.84	208.14
Nasdaq Biotechnology	100.00	166.02	223.13	249.39	196.15	238.64

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Item 6. Selected Financial Data

BIOGEN INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

Our results of operations are summarized as follows:

	For the Years Ended December 31,				
(In millions, except per share amounts)	2017 (a) (b) (c) (d) (e)	2016 (c) (e)	2015 (e) (f)	2014	2013 (g)
Results of Operations (1)					
Product revenues, net (2)	$10,354.7	$9,817.9	$9,188.5	$8,203.4	$5,542.3
Revenues from anti-CD20 therapeutic programs	1,559.2	1,314.5	1,339.2	1,195.4	1,126.0
Other revenues	360.0	316.4	236.1	304.5	263.9
Total revenues	12,273.9	11,448.8	10,763.8	9,703.3	6,932.2
Total cost and expenses	6,929.7	6,298.4	5,872.8	5,747.7	4,441.6
Gain on sale of rights	—	—	—	16.8	24.9
Income from operations	5,344.2	5,150.4	4,891.0	3,972.4	2,515.5
Other income (expense), net	(215.4)	(217.4)	(123.7)	(25.8)	(34.9)
Income before income tax expense and equity in loss of investee, net of tax	5,128.8	4,933.0	4,767.3	3,946.6	2,480.6
Income tax expense	2,458.7	1,237.3	1,161.6	989.9	601.0
Equity in loss of investee, net of tax	—	—	12.5	15.1	17.2
Net income	2,670.1	3,695.7	3,593.2	2,941.6	1,862.3
Net income (loss) attributable to noncontrolling interests, net of tax	131.0	(7.1)	46.2	6.8	—
Net income attributable to Biogen Inc.	$2,539.1	$3,702.8	$3,547.0	$2,934.8	$1,862.3
Diluted Earnings Per Share					
Diluted earnings per share attributable to Biogen Inc.	$11.92	$16.93	$15.34	$12.37	$7.81
Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Inc.	213.0	218.8	231.2	237.2	238.3

Our financial condition is summarized as follows:

	As of December 31,				
	2017	2016	2015	2014	2013
(In millions)					
Financial Condition (1)					
Cash, cash equivalents and marketable securities	$6,746.3	$7,724.5	$6,188.9	$3,316.0	$1,848.5
Total assets	$23,652.6	$22,876.8	$19,504.8	$14,314.7	$11,863.3
Notes payable and other financing arrangements, less current portion (3)	$5,935.0	$6,512.7	$6,521.5	$580.3	$592.4
Total Biogen Inc. shareholders' equity (4)	$12,612.8	$12,140.1	$9,372.8	$10,809.0	$8,620.2

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 Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations included in this report and our previously filed Annual Reports on Form 10-K.

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(1) On February 1, 2017, we completed the spin-off of our hemophilia business, Bioverativ, as an independent, publicly traded company. Our consolidated results of operations and financial position reflect the financial results of our hemophilia business for all periods through January 31, 2017. For additional information on the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in this report.

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

- Commercial sales of SPINRAZA in the U.S. began in the fourth quarter of 2016 and in rest of world markets in the first quarter of 2017.
- Under our collaboration agreement with AbbVie, we began to recognize revenues on sales of ZINBRYTA to third parties in the E.U. in the third quarter of 2016.
- Under our commercial agreement with Samsung Bioepis, we began to recognize revenues on sales of BENEPALI and FLIXABI to third parties in the E.U. in the first quarter of 2016 and third quarter of 2016, respectively.
- Commercial sales of ALPROLIX commenced in the second quarter of 2014 and commercial sales of ELOCTATE and PLEGRIDY commenced in the third quarter of 2014.
- Commercial sales of TECFIDERA began in April 2013.

(3) Notes payable and other financing arrangements reflects:

- Our 2017 repayment of our 6.875% notes that were issued in 2008 with an aggregate principal amount of $550.0 million, and
- The issuance of our senior unsecured notes for an aggregate principal amount of $6.0 billion in September 2015.

(4) Total Biogen Inc. shareholders' equity reflects the repurchase of approximately 29.9 million shares of our common stock at a cost of approximately $8.7 billion between 2013 and 2017:

- During 2017 we repurchased and retired approximately 3.7 million shares of our common stock at a cost of $1.0 billion under our 2016 Share Repurchase Program.
- During 2017 we repurchased approximately 1.2 million shares of our common stock at a cost of $365.4 million under our 2011 Share Repurchase Program.
- During 2016 we repurchased and retired approximately 3.3 million shares of our common stock at a cost of $1.0 billion under our 2016 Share Repurchase Program.
- During 2015 we repurchased and retired approximately 16.8 million shares of our common stock at a cost of $5.0 billion under a program authorized by our Board of Directors in May 2015 for the repurchase of up to $5.0 billion of our common stock (2015 Share Repurchase Program).
- During 2014 and 2013 we repurchased approximately 2.9 million and 2.0 million shares, respectively, of our common stock at a cost of approximately $1.3 billion under our 2011 Share Repurchase Program.

(a) Total cost and expenses for the year ended December 31, 2017, includes a pre-tax charge to acquired in-process research and development of $120.0 million for an upfront payment made to Remedy upon closing of our asset purchase transaction for BIIB093.

(b) Net income (loss) attributable to noncontrolling interests, net of tax for the year ended December 31, 2017, includes a pre-tax charge of $150.0 million for a payment to Neurimmune in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab.

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

Total cost and expenses for the year ended December 31, 2017, includes $444.2 million of amortization and impairment charges related to our U.S. and rest of world licenses to Forward Pharma’s intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. For additional information on our

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settlement and license agreement with Forward Pharma and related intangible assets, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report.

(d) Income tax expense for the year ended December 31, 2017, includes $1,173.6 million related to our current estimate of the provisions of the 2017 Tax Act, including a $989.6 million expense under the Transition Toll Tax. For additional information on the 2017 Tax Act, please read Note 17, Income Taxes, to our consolidated financial statements included in this report.

(e) Total cost and expenses for the years ended December 31, 2017, 2016 and 2015, include restructuring charges of $0.9 million, $33.1 million and $93.4 million, respectively. In addition, total cost and expenses for the year ended December 31, 2016, also include charges to cost of sales totaling $52.4 million of expenses incurred as a result of our determination to cease manufacturing and vacate our small-scale biologics facility in Cambridge, MA as well as close and vacate our warehouse in Somerville, MA. Total cost and expenses for the years ended December 31, 2017 and 2016, also includes $19.2 million and $18.1 million, respectively, of costs incurred directly related to the spin-off of our hemophilia business into an independent, publicly traded company.

(f) Net income attributable to Biogen Inc. for the year ended December 31, 2015, includes a pre-tax charge to noncontrolling interest of $60.0 million for a milestone payment due to Neurimmune upon the enrollment of the first patient in a Phase 3 trial for aducanumab.

(g) 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 closing of this transaction, our collaboration agreement was terminated.

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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 and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases, including in our core growth areas of MS and neuroimmunology, AD and dementia, movement disorders and neuromuscular disorders, including SMA and ALS. We also plan to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy in the previously mentioned areas. We also manufacture and commercialize biosimilars of advanced biologics.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for the treatment of MS, SPINRAZA for the treatment of SMA and FUMADERM for the treatment of severe plaque psoriasis. We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, CLL and other conditions, GAZYVA for the treatment of CLL and follicular lymphoma, OCREVUS for the treatment of PPMS and RMS, and other potential anti-CD20 therapies under a collaboration agreement with Genentech.

Our current revenues depend upon continued sales of our principal products and, unless we develop, acquire rights to and/or commercialize new products and technologies, we may be substantially dependent on sales from our principal products for many years.

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

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

2017 Corporate Strategy

In July 2017 we announced an updated strategic framework to optimize the value of our MS business while investing for the future across our core growth areas of MS and neuroimmunology, AD and dementia, movement disorders, and neuromuscular diseases, including SMA and ALS. We also plan to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry, and acute neurology.

We expect the continued performance of our commercial assets and the expiration of the contingent payments related to TECFIDERA, discussed further in the "Contractual Obligations and Off-Balance Sheet Arrangements" section of this report, to enable us to invest in and build an industry leading neuroscience pipeline. We view investment in growth as our top priority, but also recognize the value of opportunistically returning excess capital to shareholders through share repurchases.

In order to deliver positive results in the near term while investing in the next stages of our growth, we will focus on the following strategic priorities:

- maximizing the resilience of our MS core business;
- accelerating efforts in SMA as a significant new growth opportunity;
- developing and expanding our neuroscience portfolio;
- focusing our capital allocation efforts to drive investment for future growth; and
-

creating a leaner and simpler operating model to streamline our operations and reallocate resources towards prioritized research and development and commercial value creation opportunities.

In October 2017, in connection with creating a leaner and simpler operating model, we approved a corporate restructuring program intended to streamline our operations and reallocate resources. We expect to make total non-recurring operating and

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capital expenditures of up to $170.0 million, primarily in 2018, and our goal is to redirect resources of up to $400.0 million annually by 2020 to prioritized research and development and other value creation opportunities.

Tax Reform

The 2017 Tax Act has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as GILTI. These changes are effective beginning in 2018.

The 2017 Tax Act also includes the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings.

Changes in tax rates and tax laws are accounted for in the period of enactment. Therefore, during the year ended December 31, 2017, we recorded a charge totaling $1,173.6 million related to our current estimate of the provisions of the 2017 Tax Act, including a $989.6 million expense under the Transition Toll Tax. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

The 2017 Tax Act will provide us with flexibility in deploying our cash resources to advance our business interests. We expect that it will have a modest positive effect on our income tax rate in 2018 and a potential incremental benefit thereafter.

Hemophilia Spin-Off

On February 1, 2017, we completed the spin-off of our hemophilia business, Bioverativ, as an independent, publicly traded company trading under the symbol "BIVV" on the Nasdaq Global Select Market. The spin-off was accomplished through the distribution of all the then outstanding shares of common stock of Bioverativ to Biogen shareholders, who received one share of Bioverativ common stock for every two shares of Biogen common stock they owned. The separation and distribution was structured to be tax-free for shareholders for federal income tax purposes. Bioverativ assumed all of our rights and obligations under our collaboration agreement with Sobi and our collaboration and license agreement with Sangamo.

Our consolidated results of operations and financial position included in this report reflect the financial results of our hemophilia business for all periods through January 31, 2017.

For additional information on the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in this report.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were $11.92 for 2017, representing a decrease of 29.6% versus the same period in 2016.

As described below under “Results of Operations,” our income from operations for the year ended December 31, 2017 reflects the following:

- Total revenues were $12,273.9 million for 2017, representing an increase of 7.2% over the same period in 2016. Product revenues, net totaled $10,354.7 million for 2017, representing an increase of 5.5% over the same period in 2016. This increase was primarily driven by revenues from SPINRAZA, TECFIDERA and BENEPALI, partially offset by the elimination of worldwide ALPROLIX and ELOCTATE revenues resulting from the spin-off of our hemophilia business on February 1, 2017 and a net decrease in total Interferon sales.

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- Revenues from anti-CD20 therapeutic programs totaled $1,559.2 million for 2017, representing an increase of 18.6% over the same period in 2016. This increase was primarily driven by royalty revenues on sales of OCREVUS and Biogen's share of pre-tax profits on RITUXAN.
- Other revenues totaled $360.0 million for 2017, representing an increase of 13.8% from the same period in 2016. This increase was primarily driven by an increase in other royalty and corporate revenues.
- Total cost and expenses totaled $6,929.7 million for 2017, representing an increase of 10.0%, compared to the same period in 2016. This increase was primarily driven by $444.2 million of amortization and impairment charges related to our U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, a 14.2% increase in research and development primarily related to higher milestone and upfront expenses, a 10.2% increase in cost of goods sold, a $120.0 million pre-tax charge to acquired in-process research and development for an upfront payment made to Remedy upon the closing of the asset purchase transaction for BIIB093 and an increase in collaboration profit sharing. These increases were partially offset by a $454.8 million litigation settlement charge in the prior year.

As described below under "Financial Condition, Liquidity and Capital Resources":

- We generated $4,551.0 million of net cash flows from operations for 2017, which were primarily driven by earnings.
- Cash, cash equivalents and marketable securities totaled approximately $6,746.3 million as of December 31, 2017.
- We repurchased approximately 4.9 million shares of common stock at a cost of $1.4 billion during 2017 under our share repurchase programs.

Acquisitions

BIIB093 Acquisition

In May 2017 we completed an asset purchase of the Phase 3-ready candidate BIIB093 (intravenous glibencamide) (formerly known as CIRARA) from Remedy. The target indication for BIIB093 is LHI, a severe form of ischemic stroke where cerebral edema often leads to a disproportionately large share of stroke-related morbidity and mortality. The FDA recently granted BIIB093 Orphan Drug Designation for

severe cerebral edema in patients with acute ischemic stroke. The FDA has also granted BIIB093 Fast Track designation.

Under this agreement, we are responsible for the future development and commercialization of BIIB093. Remedy will share in the cost of development for the target indication for BIIB093 in LHI stroke.

For additional information on our transaction with Remedy, please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

Collaborative and Other Relationships

BIIB092 License Agreement

In June 2017 we completed an exclusive license agreement with BMS for BIIB092 (formerly known as BMS-986168), a Phase 2-ready experimental medicine with potential in AD and PSP. BIIB092 is an antibody targeting tau, the protein that forms the deposits, or tangles, in the brain associated with AD and other neurodegenerative tauopathies such as PSP.

Under this agreement, we received worldwide rights to BIIB092 and are responsible for the full development and global commercialization of BIIB092 in AD and PSP.

For additional information on our collaboration arrangement with BMS, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Eisai Collaboration Agreement

In October 2017 we entered into a new collaboration agreement with Eisai for the joint development and commercialization of aducanumab (the Aducanumab Collaboration Agreement). Under the Aducanumab Collaboration Agreement, we will continue to lead the ongoing Phase 3 development of aducanumab and will remain responsible for 100% of development costs for aducanumab until April 2018. Eisai will then reimburse us for 15% of aducanumab development expenses for the period April 2018 through December 2018, and 45% thereafter. Upon commercialization, both companies will co-promote aducanumab with a region-based profit split.

In addition, we and Eisai will continue to jointly develop BAN2401 and E2609.

We and Eisai will co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai will distribute AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

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For additional information on our collaboration arrangement with Eisai, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Neurimmune Collaboration Agreement

In October 2017 we amended the terms of our collaboration and license agreement with Neurimmune. Under the amended agreement, we made a $150.0 million payment to Neurimmune, which is reflected as a charge to noncontrolling interests, in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab. Our royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab, will now range from the high single digits to low-teens.

Under the amended agreement, we also have an option that will expire in April 2018 to further reduce our royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab, by an additional 5% in exchange for a $50.0 million payment to Neurimmune.

For additional information on our collaboration arrangement with Neurimmune, please read Note 19, Investments in Variable Interest Entities, to our consolidated financial statements included in this report.

BIIB098 License Agreement

In November 2017 we entered into an exclusive license and collaboration agreement with Alkermes for BIIB098 (formerly known as ALKS 8700), an oral MMF prodrug in Phase 3 development for the treatment of relapsing forms of MS.

Under this agreement, we received an exclusive, worldwide license to develop and commercialize BIIB098 and will pay Alkermes a royalty on potential worldwide net sales of BIIB098. Beginning in 2018 we are responsible for all development expenses related to BIIB098. Alkermes will maintain responsibility for regulatory interactions with the FDA through the potential approval of the NDA for BIIB098 for the treatment of MS.

For additional information on our collaboration arrangement with Alkermes, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Ionis Collaboration Agreement

In December 2017 we entered into a new collaboration agreement with Ionis to identify new ASO drug candidates for the treatment of SMA. Under this agreement, we have the option to license therapies arising out of this collaboration and will be responsible for the development and commercialization of these therapies.

For additional information on our new collaboration arrangement with Ionis, please read Note 20, 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 and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. 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 therapies or biosimilars of existing products and other technologies.

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

In addition, our sales and operations are subject to the risks of doing business internationally. For example, the effects of the implementation of the U.K.’s decision to voluntarily depart from the E.U., known as Brexit, remain unclear; compliance with any resulting regulatory mandates may prove challenging and the macroeconomic impact on our sales and consolidated results of operations from these developments remains unknown.

For additional information on our competition and pricing risks that could negatively impact our product sales, please read Item 1A. Risk Factors and Item 7A. Quantitative and Qualitative Disclosures About Market Risk included in 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, 2017	2016	2015	% Change 2017 compared to 2016	2016 compared to 2015
Product Revenues:					
United States	$7,017.1	$7,050.4	$6,545.8	(0.5)%	7.7 %
Rest of world	3,337.6	2,767.5	2,642.7	20.6 %	4.7 %
Total product revenues	10,354.7	9,817.9	9,188.5	5.5 %	6.8 %
Revenues from anti-CD20 therapeutic programs	1,559.2	1,314.5	1,339.2	18.6 %	(1.8)%
Other revenues	360.0	316.4	236.1	13.8 %	34.0 %
Total revenues	$12,273.9	$11,448.8	$10,763.8	7.2 %	6.4 %

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2017	2016	2015	% Change 2017 compared to 2016	2016 compared to 2015
Multiple Sclerosis:					
TECFIDERA	$4,214.0	$3,968.1	$3,638.4	6.2 %	9.1 %
Interferon*	2,645.8	2,795.2	2,968.7	(5.3)%	(5.8)%
TYSABRI	1,973.1	1,963.8	1,886.1	0.5 %	4.1 %
FAMPYRA	91.6	84.9	89.7	7.9 %	(5.4)%
ZINBRYTA	52.7	7.8	—	**	**
Spinal Muscular Atrophy:					
SPINRAZA	883.7	4.6	—	**	**
Hemophilia:					
ELOCTATE	48.4	513.2	319.7	(90.6)%	60.5 %
ALPROLIX	26.0	333.7	234.5	(92.2)%	42.3 %
Other product revenues:					
FUMADERM	39.6	45.9	51.4	(13.7)%	(10.7)%
BENEPALI	370.8	100.6	—	**	**
FLIXABI	9.0	0.1	—	**	**
Total product revenues	$10,354.7	$9,817.9	$9,188.5	5.5 %	6.8 %

* Interferon includes AVONEX and PLEGRIDY.

** Percentage not meaningful.

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Multiple Sclerosis (MS)

TECFIDERA

For 2017 compared to 2016, the increase in U.S. TECFIDERA revenues was primarily due to price increases, partially offset by higher discounts and allowances and a decrease in unit sales volume of 3%.

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

For 2017 compared to 2016, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume of 19% primarily in the E.U., partially offset by pricing reductions in certain European countries.

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

We anticipate a modest increase in TECFIDERA demand on a global basis in 2018, compared to 2017, with expected volume growth in our international markets partially offset by declines in the U.S., due to increased competition from additional treatments for MS, including OCREVUS.

Interferon

AVONEX and PLEGRIDY

For 2017 compared to 2016, the decrease in U.S. Interferon revenues was primarily due to an overall decrease in Interferon unit sales volumes of 12%, which was primarily attributable to patients transitioning to other MS therapies, partially offset by price increases.

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

For 2017 compared to 2016, the decrease in rest of world Interferon revenues was primarily due to an overall decrease in AVONEX unit sales volume of 14% primarily due to patients transitioning to other MS therapies in the E.U.

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

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We expect that overall Interferon revenues will continue to decline compared to prior year periods as a result of increasing competition from our other products as well as other treatments for MS, including biosimilars.

AVONEX

For 2017, 2016 and 2015, U.S. AVONEX revenues totaled $1,593.6 million, $1,675.3 million and $1,790.2 million, respectively.

For 2017, 2016 and 2015 rest of world AVONEX revenues totaled $557.9 million, $638.2 million and $840.0 million, respectively.

PLEGRIDY

For 2017, 2016 and 2015, U.S. PLEGRIDY revenues totaled $295.5 million, $305.0 million and $227.1 million, respectively.

For 2017, 2016 and 2015, rest of world PLEGRIDY revenues totaled $198.8 million, $176.7 million and $111.4 million, respectively.

TYSABRI

For 2017 compared to 2016, the decrease in U.S. TYSABRI revenues was primarily due to higher discounts and allowances and a decrease in unit sales volume of 4%, partially offset by price increases.

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

For 2017 compared to 2016, the increase in rest of world TYSABRI revenues was primarily due to the recognition of approximately $45.0 million of previously deferred revenue in Italy relating to the pricing agreement with AIFA and a 12% increase in unit sales volume primarily in our international partner markets, partially offset by a prior year favorable adjustment of approximately $20.0 million to previous reserves estimates related to a government price reimbursement program included in our discounts and allowances. For information on our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 18, Other Consolidated Financial Statement Detail, to our consolidated financial statements included in this report.

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

We anticipate a decline in TYSABRI demand on a global basis in 2018, compared to 2017, with expected volume declines in the U.S., due to increased competition from additional treatments for MS, including OCREVUS, offsetting volume growth in our international markets.

ZINBRYTA

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

For 2017 compared to 2016, the increase in ZINBRYTA revenues was primarily due to an increase in unit sales volume.

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We expect that the future sales growth of ZINBRYTA will be negatively impacted as a result of the EC approved restrictions on the use of ZINBRYTA.

For additional information on our relationship with AbbVie, including information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Spinal Muscular Atrophy (SMA)

SPINRAZA

We began to recognize revenues on sales of SPINRAZA in the U.S. in the fourth quarter of 2016 and the rest of world in the first quarter of 2017.

We expect that the rate at which SPINRAZA revenues will grow will moderate over time due to the loading dynamics as patients transition to dosing once every four months.

For additional information on our relationship with Ionis, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Biosimilars

BENEPALI and FLIXABI

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

For 2017 compared to 2016, the increase in biosimilar revenues was primarily due to an increase in BENEPALI unit sales volume in new and existing markets.

For additional information on our relationship with Samsung Bioepis, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

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Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN and GAZYVA collaboration operating profits in the U.S. and other revenues on anti-CD20 therapeutic programs are summarized as follows:

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

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

	For the Years Ended December 31,		
(In millions)	2017	2016	2015
Product revenues, net	$4,206.9	$3,941.8	$3,847.9
Cost and expenses	755.2	744.5	673.7
Pre-tax profits in the U.S.	$3,451.7	$3,197.3	$3,174.2
Biogen's share of pre-tax profits	$1,316.4	$1,249.5	$1,269.8

Our share of RITUXAN annual pre-tax co-promotion profits in the U.S. in excess of $50.0 million decreased to 39% from 40% in February 2016 when GAZYVA was approved by the FDA as a new treatment for follicular lymphoma and further decreased to 37.5% in the third quarter of 2017 as gross sales of GAZYVA in the U.S. for the preceding 12-month period exceeded $150.0 million.

In November 2017 the FDA approved GAZYVA in combination with chemotherapy, followed by GAZYVA alone, for people with previously untreated advanced follicular lymphoma.

In June 2017 the FDA approved RITUXAN HYCELA for subcutaneous injection for the treatment of adults with previously untreated and relapsed or refractory follicular lymphoma, previously untreated diffuse large B-cell lymphoma and CLL. This new treatment includes the same monoclonal antibody as intravenous RITUXAN in combination with hyaluronidase human, an enzyme that helps to deliver rituximab under the skin.

For 2017 compared to 2016, the increase in U.S. product revenues was primarily due to selling price increases and an increase in RITUXAN and GAZYA unit sales volume of 2% and 6%, respectively, partially offset by higher discounts and allowances.

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

Collaboration costs and expenses for 2017, as depicted in the table above, excludes certain expenses charged to the collaboration by Genentech that we believe remain the responsibility of Genentech and that we are not obligated to pay under the terms of the collaboration agreement. Accordingly, we did not recognize the effect of those expenses in the determination of our share of pre-tax collaboration profits and Genentech has withheld approximately $120 million from amounts due to us in relation to collaboration activity for 2017, representing Genentech's estimate of our share of these expenses. We remain in discussions with Genentech about a resolution relating to these amounts.

Excluding amounts under dispute, collaboration costs and expenses for 2017 compared to 2016 increased primarily due to higher branded pharmaceutical drug fees and an increase in RITUXAN selling and marketing costs, partially offset by a decrease in GAZYVA research and development costs.

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

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Other Revenues from Anti-CD20 Therapeutic Programs

Other revenues from anti-CD20 therapeutic programs primarily consist of royalty revenues on sales of OCREVUS and our share of pre-tax co-promotion profits on RITUXAN in Canada.

For 2017 compared to 2016, other revenues from anti-CD20 therapeutic programs increased primarily due to the launch of OCREVUS in the second quarter of 2017.

For 2016 compared to 2015, other revenues from anti-CD20 therapeutic programs decreased as a result of lower pre-tax co-promotion profits on RITUXAN in Canada.

OCREVUS

In March 2017 the FDA approved OCREVUS, a humanized anti-CD20 monoclonal antibody, for the treatment of RMS and PPMS. Under our agreement with Genentech, we will receive a tiered royalty on U.S. net sales from 13.5% and increasing up to 24% if annual net sales exceed $900.0 million. There will be a 50% reduction to these royalties if a biosimilar to OCREVUS is approved in the U.S.

In addition, we will receive a 3% royalty on net sales of OCREVUS outside the U.S., with the royalty period lasting 11 years from the first commercial sale of OCREVUS on a country-by-country basis. OCREVUS was approved for treatment of RMS and PPMS in Australia, Switzerland and the E.U. in July 2017, September 2017 and January 2018, respectively. Marketing applications for OCREVUS are currently under review in numerous markets worldwide, including in Latin America and the Middle East.

The commercialization of OCREVUS does not impact the percentage of the co-promotion profits we receive for RITUXAN or GAZYVA. Genentech is solely responsible for development and commercialization of OCREVUS and funding future costs. OCREVUS royalty revenues were based on our estimates from third party and market research data of OCREVUS sales occurring during the corresponding period. Differences between actual and estimated royalty revenues will be adjusted for in the period in which they become known, which is expected to be the following quarter.

For additional information on our collaboration with Genentech, including information regarding the pre-tax profit sharing formula and its impact on future revenues from anti-CD20 therapeutic programs, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Other Revenues

Other revenues are summarized as follows:

	For The Years Ended December 31,			% Change	
(In millions, except percentages)	2017	2016	2015	2017 compared to 2016	2016 compared to 2015
Revenues from collaborative and other relationships	$36.5	$39.3	$69.1	(7.1)%	(43.1)%
Other royalty and corporate revenues	323.5	277.1	167.0	16.7 %	65.9 %
Total other revenues	$360.0	$316.4	$236.1	13.8 %	34.0 %

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Revenues from Collaborative and Other Relationships

Other revenues from collaborative and other relationships include revenues earned under our 50% share of the co-promotion profits or losses of ZINBRYTA in the U.S. with AbbVie and revenues from our technical development and manufacturing services agreements with Samsung Bioepis. Prior to the spin-off of our hemophilia business, other revenues from collaborative and other relationships also included revenues earned under our manufacturing services agreement with Sobi on shipments of ELOCTA and ALPROLIX to Sobi and royalties from Sobi on sales of ELOCTA and ALPROLIX in their territory, which included substantially all of Europe, Russia and certain markets in Northern Africa and the Middle East. Bioverativ assumed all of our rights and obligations under our agreement with Sobi on February 1, 2017.

For 2017 compared to 2016, the decrease in other revenues from collaborative and other relationships was primarily due to the impact of the spin-off of our hemophilia business on February 1, 2017, partially offset by higher revenues earned under our manufacturing services agreement with Samsung Bioepis.

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

For additional information on our collaborative and other relationships, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Other Royalty and Corporate Revenues

We receive royalties from net sales on products related to patents that we have out-licensed and we record other corporate revenues primarily from amounts earned under contract manufacturing agreements.

For 2017 compared to 2016, the increase in royalty and other corporate revenues was primarily due to an increase in sales of the underlying products from which we receive royalties and higher contract manufacturing revenues related to the volume of shipments of drug substance production provided to our strategic partners, including Bioverativ.

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

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Reserves for Discounts and Allowances

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

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

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

For the years ended December 31, 2017, 2016 and 2015, reserves for discounts and allowances as a percentage of gross product revenues were 22.0%, 21.3% and 19.3%, respectively.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For 2017 compared to 2016, the decrease in discounts was primarily driven by the impact from the spin-off of our hemophilia business on February 1, 2017, partially offset by an increase in rest of world product revenues, due in part to an increase in biosimilar revenues, as well as an increase in gross selling prices.

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

Contractual Adjustments

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

For 2017 compared to 2016, the increase in contractual adjustments was primarily due to higher managed care rebates and Medicaid and other governmental rebates and allowances in the U.S., due in part to an increase in gross selling prices and the launch of SPINRAZA in the U.S. in the fourth quarter of 2016, partially offset by the impact from the spin-off of our hemophilia business on February 1, 2017.

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

Returns

Product return reserves are established for returns made by wholesalers. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to product expiration. Provisions for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales.

For 2017 compared to 2016, return provisions were relatively consistent.

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

For additional information on our reserves, please read Note 5, Reserves for Discounts and Allowances, to our consolidated financial statements included in this report.

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Cost and Expenses

A summary of total cost and expenses is as follows:

(In millions, except percentages)	For the Years Ended December 31, 2017	2016	2015	% Change 2017 compared to 2016	2016 compared to 2015
Cost of sales, excluding amortization of acquired intangible assets	$1,630.0	$1,478.7	$1,240.4	10.2 %	19.2 %
Research and development	2,253.6	1,973.3	2,012.8	14.2 %	(2.0)%
Selling, general and administrative	1,935.5	1,947.9	2,113.1	(0.6)%	(7.8)%
Amortization of acquired intangible assets	814.7	385.6	382.6	111.3 %	0.8 %
Acquired in-process research and development	120.0	—	—	**	**
Collaboration profit sharing	112.3	10.2	—	**	**
Loss (gain) on fair value remeasurement of contingent consideration	62.7	14.8	30.5	323.6 %	(51.5)%
Restructuring charges	0.9	33.1	93.4	(97.3)%	(64.6)%
TECFIDERA litigation settlement charge	—	454.8	—	(100.0)%	**
Total cost and expenses	$6,929.7	$6,298.4	$5,872.8	10.0 %	7.2 %

** Percentage not meaningful.

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

Product Cost of Sales

For 2017 compared to 2016, the increase in product cost of sales was primarily driven by higher unit sales volume related to our biosimilar product shipments, higher contract manufacturing shipments of drug substance production provided to our strategic partners, including Bioverativ, and an increase in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons. These increases were partially offset by the impact from the spin-off of our hemophilia business on February 1, 2017, and the accelerated depreciation recorded in the second, third and fourth quarters of 2016 as a result of our decision to cease manufacturing in Cambridge, MA.

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

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

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Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons totaled $76.9 million, $48.2 million and $41.9 million for the years ended December 31, 2017, 2016 and 2015, respectively. Amounts written down during the year ended December 31, 2017, includes the impairment of $14.4 million related to the EC approved restrictions on the use of ZINBRYTA.

For additional information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Royalty Cost of Sales

For 2017 compared to 2016, the increase in royalty cost of sales was primarily driven by the recognition of royalties payable to Ionis on sales of SPINRAZA and higher royalties on sales of AVONEX and PLEGRIDY in the U.S., as described below. These increases were partially offset by the elimination of royalties payable on sales of hemophilia product resulting from the spin-off of our hemophilia business on February 1, 2017 and lower royalties on sales of TYSABRI resulting from the expiration of certain third-party royalties.

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

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

Research and Development

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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 our core and emerging growth areas.

A significant amount of our 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, information technology and facility-based expenses. These costs are considered other research and development costs in the table above and are not allocated to a specific program or stage.

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. 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 2017 compared to 2016, the increase in research and development expense was primarily related to milestone and upfront expenses and costs incurred in connection with our early stage and late stage programs, partially offset by decreased costs incurred in connection with our marketed products.

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

We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where a drug candidate has the potential to be highly differentiated.

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Milestone and Upfront Expenses included in Research and Development Expense

Research and development expense for 2017 includes:

- $300.0 million upfront payment made to BMS upon entering into our agreement to exclusively license BIIB092;
- $60.0 million developmental milestone payment due to the former shareholders of iPierian, Inc. (iPierian), which became payable upon dosing of the first patient in the Phase 2 PSP study for BIIB092;
- $28.0 million upfront payment made to Alkermes upon entering into our agreement to exclusively license BIIB098, representing our share of BIIB098 development costs already incurred in 2017;
- $50.0 million accrual based upon the expected continuation of our agreement with Alkermes to develop and exclusively license BIIB098; and
- $25.0 million upfront payment recognized upon entering into a new collaboration agreement with Ionis to identify new ASO drug candidates for the treatment of SMA.

Research and development expense for 2016 includes:

- $75.0 million license fee paid to Ionis as we exercised our option to develop and commercialize SPINRAZA from Ionis;
- $50.0 million milestone payment to Eisai related to the initiation of a Phase 3 trial for E2609; and
- $20.0 million upfront payment recognized upon entering into a collaboration and alliance agreement with UPenn.

Research and development expense for 2015 includes:

- $60.0 million recognized upon entering into our collaboration with Mitsubishi Tanabe Pharma Corporation;
- $48.1 million recognized upon entering into our collaboration with AGTC;
- $30.0 million in milestones recognized 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 2015.

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

For additional information about these collaborations, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Early Stage Programs

The increase in spending associated with our early stage programs for 2017 compared to 2016 was primarily related to spending associated with the development of BIIB092 in AD and PSP pursuant to our license agreement with BMS, BIIB074 in trigeminal neuralgia (TGN) and BIIB076 in AD. These increases were partially offset by a reduction in costs resulting from our discontinuance of development of amiselimod in the third quarter of 2016.

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

Late Stage Programs

The increase in spending associated with our late stage programs for 2017 compared to 2016 was primarily related the increased costs associated with the development of aducanumab in AD and costs incurred associated with the development of E2609, a BACE inhibitor that was advanced to a late stage program in the fourth quarter of 2016. These increases were partially offset by advancement of SPINRAZA to marketed products following its approval in the U.S. in the fourth quarter of 2016.

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

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Marketed Products

The decrease in spending associated with our marketed products for 2017 compared to 2016 was primarily due to a reduction in spending resulting from the spin-off of our hemophilia business on February 1, 2017 and a reduction in spending related to TECFIDERA. These decreases were partially offset by increased spending related to SPINRAZA following its approval in the U.S. in the fourth quarter of 2016.

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

Selling, General and Administrative

For 2017 compared to 2016, the decrease in selling, general and administrative expenses was primarily due to a reduction in operational spending resulting from the spin-off of our hemophilia business on February 1, 2017, the execution of targeted cost reduction initiatives and a reduction in costs resulting from the discontinuance of our TECFIDERA television advertising campaign in the second quarter of 2016. These decreases were offset by an increase in SPINRAZA commercialization costs and an increase in corporate giving.

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

Amortization of Acquired Intangible Assets

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

Our most recent long-range planning cycle was completed in the third quarter of 2017. The results of our TECFIDERA, AVONEX and TYSABRI analyses were impacted by changes in the estimated timing of the impact of other alternative MS formulations, including OCREVUS, which may compete with TYSABRI, TECFIDERA and AVONEX. The outcome of this most recent analysis did not result in a significant net change in our expected rate of amortization for acquired intangible assets.

Based upon this most recent analysis, the estimated future amortization of acquired intangible assets for the next five years is expected to be as follows:

(In millions)	As of December 31, 2017
2018	$ 423.5
2019	401.8
2020	381.6
2021	254.3
2022	242.3

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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 products. 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 2017 compared to 2016, the increase in amortization of acquired intangible assets was primarily due to $444.2 million of amortization and impairment charges associated with our U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, acquired in the first quarter of 2017, as discussed further below. Amortization of acquired intangible assets for 2017 also reflects the $31.2 million impairment of our acquired and in-licensed rights and patents intangible asset related to the Article 20 Procedure of ZINBRYTA.

For additional information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

For 2016 compared to 2015, amortization of acquired intangible assets was relatively consistent as our most recent analysis completed during the third quarter of 2016 resulted in no significant net change in our expected rate of amortization for acquired intangible assets. Amortization of acquired intangible assets for 2016 also reflects impairment charges recognized upon the termination of our collaboration agreements with Rodin Therapeutics, Inc. and Ataxion Inc., which resulted in impairment losses of $8.7 million and $3.5 million, respectively, related to the IPR&D assets recorded upon entering into the collaboration agreements.

Impairment charges related to intangible assets during 2015 were insignificant.

TECFIDERA License Rights

In January 2017 we entered into a settlement and license agreement with Forward Pharma. Pursuant to this agreement, we obtained U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange, we paid Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016, we recognized a pre-tax charge of $454.8 million and in the first quarter of 2017 we recognized an intangible asset of $795.2 million related to this agreement. The pre-tax charge recognized in the fourth quarter of 2016 represented the fair value of our licenses to Forward Pharma’s intellectual property for the period April 2014, when we started selling TECFIDERA, through December 31, 2016. The intangible asset represented the fair value of the U.S. and rest of world licenses to Forward Pharma’s intellectual property related to TECFIDERA revenues for the period January 2017, the month in which we entered into this agreement, through December 2020, the last month before royalty payments could first commence pursuant to this agreement.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the E.U., concerning intellectual property related to TECFIDERA. In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma appealed to the U.S. Court of Appeals for the Federal Circuit and the appeal is pending. We evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded an impairment charge in the first quarter of 2017 to adjust the carrying value of the acquired U.S. asset to fair value reflecting the impact of the developments in the U.S. legal dispute. In January 2018 the EPO announced its decision revoking Forward Pharma’s European Patent No. 2 801 355. Forward Pharma has stated that it expects to file an appeal to the Technical Board of Appeal of the EPO. Based upon our assessment of these rulings, we continue to amortize the remaining net book value of the U.S. and rest of world intangible assets in our consolidated statements of income utilizing an economic consumption model.

For additional information on our settlement and license agreement with Forward Pharma and related intangible assets, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report. For additional information on these disputes, please read Note 21, Litigation, to our consolidated financial statements included in this report.

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In Process Research & Development (IPR&D) related to Business Combinations

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.

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 to us that the carrying value of the assets might not be recoverable. Our most recent impairment assessment as of October 31, 2017, resulted in no impairments. Changes to clinical development plans, regulatory feedback received, life cycle management strategies and changes in program economics, including foreign currency exchange rates, are evaluated regularly. The field of developing treatments for forms of neuropathic pain, such as TGN, is highly competitive and can be affected by changes to expected market candidates and changes in timing and the clinical development of our product candidates. There can be no assurance that we will be able to successfully develop BIIB074 for the treatment of TGN or other indications, including our ability to confirm safety and efficacy based on data from clinical trials, or that a successfully developed therapy will be able to secure sufficient pricing in a competitive market. Changes in events and circumstances for these programs may have a material impact on the value of our related IPR&D.

For additional information on the impairment and amortization of acquired intangible assets, including our TECFIDERA settlement and license agreement, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report.

Acquired In-Process Research and Development

In May 2017 we completed an asset purchase of the Phase 3-ready candidate, BIIB093, from Remedy. In connection with the closing of this transaction, we made an upfront $120.0 million payment to Remedy, which was recorded as acquired in-process research and development in our consolidated statements of income as BIIB093 had not yet reached technological feasibility. For additional information on our transaction with Remedy, please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

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Collaboration Profit (Loss) Sharing

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

We began to recognize revenues on sales of biosimilars in the first quarter of 2016. For 2017 we shared collaboration profits and therefore recognized net expense of $111.0 million as compared to net expense of $15.1 million in the prior year comparative period. The increase in profit sharing expense for the comparative period was primarily due to increased collaboration profits resulting from increased biosimilar product sales.

We began to recognize revenues on sales of ZINBRYTA in the E.U. in the third quarter of 2016. For 2017 we recognized net expense of $1.3 million to reflect AbbVie's 50% sharing of the net collaboration profits in the E.U. and Canada as compared to net income recognized of $4.9 million in the prior year comparative period, to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada. The increase in profit sharing expense for the comparative period was primarily due to increased collaboration profits resulting from increased ZINBRYTA product sales.

We expect that the future sales growth of ZINBRYTA will be negatively impacted as a result of the EC approved restrictions on the use of ZINBRYTA. For additional information on our relationship with AbbVie, including information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Loss (Gain) on Fair Value Remeasurement of Contingent Consideration

Consideration payable for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular event or events. 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 2017 was primarily due to the increase in the probability of achieving certain developmental milestones based upon the progression of the underlying clinical programs.

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

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

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Restructuring, Business Transformation and Other Cost Saving Initiatives

2017 Corporate Strategy

In July 2017 we announced an updated strategic framework to optimize the value of our MS business while investing for the future across our core growth areas of MS and neuroimmunology, AD and dementia, Parkinson's disease and movement disorders and neuromuscular diseases including SMA and ALS. We also plan to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology.

We expect the continued performance of our commercial assets and the expiration of the contingent payments related to TECFIDERA, discussed further in the "Contractual Obligations and Off-Balance Sheet Arrangements" section of this report, to enable us to invest in and build an industry leading neuroscience pipeline. We view investment in growth as our top priority, but also recognize the value of opportunistically returning excess capital to shareholders through share repurchases.

In order to deliver positive results in the near term while investing in the next stages of our growth, we will focus on the following strategic priorities:

- maximizing the resilience of our MS core business;
- accelerating efforts in SMA as a significant new growth opportunity;
- developing and expanding our neuroscience portfolio;
- focusing our capital allocation efforts to drive investment for future growth; and
- creating a leaner and simpler operating model to streamline our operations and reallocate resources towards prioritized research and development and commercial value creation opportunities.

In October 2017, in connection with creating a leaner and simpler operating model, we approved a corporate restructuring program intended to streamline our operations and reallocate resources. We expect to make total non-recurring operating and capital expenditures of up to $170.0 million, primarily in 2018, and our goal is to redirect resources of up to $400.0 million annually by 2020 to prioritized research and development and other value creation opportunities.

For the year ended December 31, 2017, we recognized charges in our consolidated statements of income totaling $19.4 million related to this effort, of which $18.5 million is included in selling, general and administrative expense and $0.9 million is reflected as restructuring charges. These restructuring charges, which were substantially incurred and paid in 2017, were primarily related to severance.

2016 Organizational Changes and Cost Saving Initiatives

2016 Restructuring Charges

During the third quarter of 2016 we initiated cost saving measures primarily intended to realign our organizational structure due to the changes in roles and workforce resulting from our decision to spin-off our hemophilia business, and to achieve further targeted cost reductions. For the year ended December 31, 2016, we recognized charges totaling $17.7 million related to this effort, which are in addition to, and separate from, the 2015 restructuring charges described below. These amounts, which were substantially incurred and paid by the end of 2016, were primarily related to severance and are reflected in restructuring charges in our consolidated statements of income.

Cambridge, MA Manufacturing Facility

In June 2016 following an evaluation of our current and future manufacturing capabilities and capacity needs, we determined that we intended to cease manufacturing and vacate our 67,000 square foot small-scale biologics manufacturing facility in Cambridge, MA and close and vacate our 46,000 square foot warehouse space in Somerville, MA.

In December 2016 we subleased our rights to the Cambridge, MA manufacturing facility to Brammer Bio MA, LLC (Brammer). Brammer also purchased from us certain manufacturing equipment, leasehold improvements and other assets in exchange for shares of Brammer common LLC interests and assumed manufacturing operations effective January 1, 2017. In December 2016 we closed and vacated our warehouse space in Somerville, MA.

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

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

2015 Cost Saving Initiatives

2015 Restructuring Charges

In October 2015 we announced a corporate restructuring, which included the termination of certain pipeline programs and an 11% reduction in workforce. Under this restructuring, cash payments were estimated to total approximately $120.0 million, of which $15.9 million were related to previously accrued 2015 incentive compensation, resulting in net restructuring charges totaling approximately $102.0 million. These amounts were substantially paid by the end of 2016.

During the years ended December 31, 2016 and 2015, we recognized $8.0 million and $93.4 million, respectively, of restructuring charges related to our 2015 restructuring program in our consolidated statements of income. Our restructuring reserve is included in accrued expenses and other in our consolidated balance sheets.

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

(In millions)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2015	$ 33.7	$ 3.6	$37.3
Expense	4.9	5.4	10.3
Payment	(31.2)	(9.0)	(40.2)
Adjustments to previous estimates, net	(5.2)	2.9	(2.3)
Restructuring reserve as of December 31, 2016	$ 2.2	$ 2.9	$5.1
Payment	(1.7)	(2.9)	(4.6)
Restructuring reserve as of December 31, 2017	$ 0.5	$ —	$0.5

TECFIDERA Litigation Settlement Charge

As described above under "Amortization of Acquired Intangible Assets - TECFIDERA License Rights," in January 2017 we entered into a settlement and license agreement with Forward Pharma pursuant to which we obtained U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange, we paid Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016, we recognized a pre-tax charge of $454.8 million and in the first quarter of 2017 we recognized an intangible asset of $795.2 million related to this agreement. The pre-tax charge recognized in the fourth quarter of 2016 represented the fair value of our licenses to Forward Pharma’s intellectual property for the period April 2014, when we started selling TECFIDERA, through December 31, 2016.

For additional information on our TECFIDERA settlement and license agreement, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report.

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Other Income (Expense), Net

For 2017 compared to 2016, the change in other income (expense), net was primarily due to an increase in foreign currency exchange gains, an increase in interest income and a decrease in interest expense, partially offset by other than temporary impairments recorded on strategic investments and marketable debt securities during the year.

Interest expense for the year ended December 31, 2017, includes a net $5.2 million debt extinguishment charge recognized in November 2017 upon redemption of our 6.875% Senior Notes due March 1, 2018.

For additional information on this redemption and our outstanding indebtedness, please read Note 12, Indebtedness, to our consolidated financial statements included in this report.

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

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 changes in tax laws, variability in the allocation of our taxable earnings among multiple jurisdictions, 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 2017 compared to 2016 increased primarily due to the effect of the 2017 Tax Act and the impairment of prepaid tax assets related to our ZINBRYTA program.

On December 22, 2017, the 2017 Tax Act was signed into law and has resulted in significant changes to the U.S. corporate income tax system. The 2017 Tax Act includes a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits, the Transition Toll Tax and other changes to taxation of foreign subsidiaries.

Changes in tax rates and tax laws are accounted for in the period of enactment. Therefore, during the year ended December 31, 2017, we recorded a charge totaling $1,173.6 million related to our current estimate of the provisions of the 2017 Tax Act, including a $989.6 million expense under the Transition Toll Tax. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

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The 2017 Tax Act will provide us with flexibility in deploying our cash resources to advance our business interests. We expect that it will have a modest positive effect on our income tax rate in 2018 and a potential incremental benefit thereafter.

Article 20 Procedure of ZINBRYTA

As a result of the CHMP's recommendation of restrictions on the use of ZINBRYTA, we impaired prepaid tax balances totaling $142.6 million. Offsetting these amounts was an unrecorded tax benefit related to certain ZINBRYTA related assets totaling approximately $93.8 million. For additional information on the Article 20 Procedure of ZINBRYTA and resulting impairment of ZINBRYTA related assets, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

Excluding the effect of the 2017 Tax Act and the ZINBRTYA impairments, our income tax rate would have decreased due to a lower percentage of our earnings being recognized in the U.S., a higher tax jurisdiction. The geographic split of our earnings was affected by milestone and upfront payments in the current year and the spin-off of our hemophilia business, partially offset by growth from the U.S. launch of SPINRAZA and increases in our revenues from anti-CD20 therapeutic programs in the U.S. In addition, in 2017 we earned a lower benefit from the orphan drug credit due to the FDA's approval of SPINRAZA.

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

Accounting for Uncertainty in Income Taxes

For additional information on our uncertain tax positions and income tax rate reconciliation for 2017, 2016 and 2015, please read Note 17, Income Taxes, to our consolidated financial statements included in this report.

Equity in Loss of Investee, Net of Tax

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

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

For additional information on this transaction, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in this report.

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Noncontrolling Interest

For 2017 compared to 2016, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily related to a $150.0 million pre-tax upfront payment made to Neurimmune in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab.

Under the amended agreement, we also have an option that will expire in April 2018 to further reduce our royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab, by an additional 5% in exchange for a $50.0 million payment to Neurimmune.

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

For additional information on our collaboration arrangement with Neurimmune, please read Note 19, Investments in Variable Interest Entities, to our consolidated financial statements included in this report.

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

	As of December 31,		% Change 2017
(In millions, except percentages)	2017	2016	compared to 2016
Financial assets:			
Cash and cash equivalents	$1,573.8	$2,326.5	(32.4)%
Marketable securities — current	2,115.2	2,568.6	(17.7)%
Marketable securities — non-current	3,057.3	2,829.4	8.1 %
Total cash, cash equivalents and marketable securities	$6,746.3	$7,724.5	(12.7)%
Borrowings:			
Current portion of notes payable and other financing arrangements	$3.2	$4.7	(31.9)%
Notes payable and other financing arrangements	5,935.0	6,512.7	(8.9)%
Total borrowings	$5,938.2	$6,517.4	(8.9)%
Working Capital:			
Current assets	$7,873.3	$8,732.2	(9.8)%
Current liabilities	(3,368.2)	(3,419.9)	(1.5)%
Total working capital	$4,505.1	$5,312.3	(15.2)%

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For the year ended December 31, 2017, certain significant cash flows were as follows:

- $4.6 billion in net cash flows provided by operating activities, net of:
  - $1.1 billion in total net payments for income taxes;
  - $463.0 million in upfront and milestone payments to BMS, iPierian, Eisai, Alkermes and Ionis; and
  - $454.8 million payment made to Forward Pharma for the litigation settlement charge that was accrued as of December 31, 2016;
- $1.4 billion used for share repurchases;
- $1.2 billion in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $867.4 million used for purchases of property, plant and equipment;
- $795.2 million payment made to Forward Pharma to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA;
- $557.7 million payment made for the redemption of our 6.875% Senior Notes due March 1, 2018 prior to their maturity;
- $302.7 million net cash contribution made in connection with the spin-off of our hemophilia business;
- $295.0 million in upfront and milestone payments made to Remedy, Ionis and Samsung Bioepis; and
- $132.4 million payment, net of tax, made to Neurimmune in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab.

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

- $4.6 billion in net cash flows provided by operating activities, net of:
  - $1.6 billion in total net payments for income taxes;
  - $75.0 million license fee payment made to Ionis; and
  - $20.0 million upfront payment to UPenn;
- $1.2 billion in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $1.0 billion used for share repurchases;
- $616.1 million used for purchases of property, plant and equipment; and
- $82.0 million in milestone payments made to Samsung Bioepis and AbbVie.

Overview

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

Tax Reform

On December 22, 2017, the 2017 Tax Act was signed into law and has resulted in significant changes to the U.S. corporate income tax system.

The 2017 Tax Act eliminates the deferral of U.S. income tax on the historical unrepatriated earnings by imposing the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on undistributed foreign earnings. The Transition Toll Tax is assessed on the U.S. shareholder's share of the foreign corporation's accumulated foreign earnings that have not previously been taxed. Earnings in the form of cash and cash equivalents will be taxed at a rate of 15.5% and all other earnings will be taxed at a rate of 8.0%. As of December 31, 2017, we have accrued income tax liabilities of $989.6 million under the Transition Toll Tax, of which $78.3 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest. Of the total cash, cash equivalents and marketable securities at December 31, 2017, approximately $4.0 billion was generated in foreign

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jurisdictions and may now be deployed with greater flexibility to advance our business interests.

For additional information on certain risks that could negatively impact our consolidated financial position or future results of operations, please read Item 1A. Risk Factors and Item 7A. Quantitative and Qualitative Disclosures About Market Risk included in this report.

Share Repurchase Programs

In July 2016 our Board of Directors authorized our 2016 Share Repurchase Program to repurchase up to $5.0 billion of our common stock. This authorization does not have an expiration date. All share repurchases under this authorization will be retired. Under this authorization, we repurchased and retired 3.7 million and 3.3 million shares of our common stock during the years ended December 31, 2017 and 2016, respectively, at a cost of $1.0 billion for each year. As of December 31, 2017, approximately $3.0 billion remains available for share repurchases under this authorization.

In May 2015 our Board of Directors authorized our 2015 Share Repurchase Program to repurchase up to $5.0 billion of our common stock. All share repurchases under this authorization were retired. Our 2015 Share Repurchase Program was completed as of December 31, 2015. Under this authorization, we repurchased and retired 16.8 million shares of our common stock at a cost of $5.0 billion during the year ended December 31, 2015.

In February 2011 our Board of Directors authorized our 2011 Share Repurchase Program to repurchase up to 20.0 million shares of our common stock. Shares repurchased under this authorization have been principally used to offset common stock issuances under our share-based compensation plans. Our 2011 Share Repurchase Program was completed as of March 31, 2017. Under this authorization, we repurchased 1.2 million shares of our common stock at a cost of $365.4 million during the year ended December 31, 2017. We did not repurchase any shares of our common stock under this authorization during the years ended December 31, 2016 and 2015.

Cash, Cash Equivalents and Marketable Securities

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

portfolio that limits the amount of exposure as to institution, maturity and investment type.

The net decrease in cash, cash equivalents and marketable securities at December 31, 2017, from December 31, 2016, was primarily due to the payment made to Forward Pharma in connection with our January 2017 settlement and license agreement, the payment made for the redemption of our 6.875% Senior Notes due March 1, 2018 prior to their maturity in November 2017, cash used for share repurchases, the net cash contribution made in connection with the spin-off of our hemophilia business in February 2017, net purchases of property, plant and equipment, upfront and milestone payments made to Remedy, Ionis and Samsung Bioepis and the payment to Neurimmune in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab.

Borrowings

The following is a summary of our principal indebtedness as of December 31, 2017:

- $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;
- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;
- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and
- $1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

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

In November 2017 we redeemed our 6.875% Senior Notes due March 1, 2018, with an aggregate principal amount of $550.0 million. For additional information on this redemption please read Note 12, Indebtedness, to our consolidated financial statements included in this report.

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During the third quarter of 2015, we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of December 31, 2017, 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 that are payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica, payable in June 2018, had a carrying value of 3.1 million Swiss Francs ($3.2 million) and 6.2 million Swiss Francs ($6.0 million) as of December 31, 2017 and 2016, respectively.

For a summary of the fair values of our outstanding borrowings as of December 31, 2017 and 2016, please read Note 8, Fair Value Measurements, to our consolidated financial statements included in this report.

Working Capital

We define working capital as current assets less current liabilities. The change in working capital at December 31, 2017, from December 31, 2016, reflects a decrease in total current assets of $858.9 million, partially offset by a decrease in current liabilities of $51.7 million.

The decrease in total current assets was driven by a decrease in net cash, cash equivalents and marketable securities, as described above, partially offset by an increase in accounts receivable due to an increase in revenues and the timing of customer payments, including amounts due in connection with anti-CD20 therapeutic programs.

The decrease in total current liabilities primarily resulted from a reduction in taxes payable and accrued expenses primarily due to the payment of the $454.8 million charge that was accrued as of December 31, 2016, in relation to our settlement and license agreement with Forward Pharma, offset by an increase in the accrual of contingent payments related to FUMADERM and TECFIDERA (together, the Fumapharm Products) upon reaching $15.0 billion and $16.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2017.

Cash Flows

The following table summarizes our cash flow activity:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2017	2016	2015	2017 compared to 2016	2016 compared to 2015
Net cash flows provided by operating activities	$4,551.0	$4,587.2	$3,919.4	(0.8)%	17.0 %
Net cash flows used in by investing activities	$(2,963.1)	$(2,484.8)	$(4,553.6)	19.2 %	(45.4)%
Net cash flows (used in) provided by financing activities	$(2,380.0)	$(1,052.6)	$783.1	126.1 %	(234.4)%

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, acquired in-process research and development and share-based compensation;
- 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 2017 compared to 2016, net cash flows provided by operations were relatively consistent. Higher sales and lower income tax payments were offset by the $454.8 million payment related to our settlement and license agreement with Forward Pharma, which had been accrued as of December 31, 2016, and the timing of customer payments, including

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amounts due in connection with anti-CD20 therapeutic programs.

Net income was lower in 2017, primarily due to the Transition Toll Tax under the 2017 Tax Act and higher depreciation and amortization.

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

Investing Activities

For 2017 compared to 2016, the increase in net cash flows used in investing activities was primarily due to:

- the $795.2 million payment made to Forward Pharma to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA;
- an increase in purchases of property, plant and equipment primarily related to the construction of our Solothurn, Switzerland facility;
- $175.0 million in milestone payments made to Ionis and Samsung Bioepis; and
- the $120.0 million payment made to Remedy for the purchase of BIIB093.

These increases were partially offset by an increase in net proceeds of marketable securities.

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

Financing Activities

For 2017 compared to 2016, the increase in net cash flows used in financing activities was primarily due to an increase in cash used for share repurchases, the payment made for the redemption of our 6.875% Senior Notes due March 1, 2018 prior to their maturity, the $302.7 million net cash contribution made in connection with the spin-off of our hemophilia business on February 1, 2017, and the net distributions to noncontrolling interest, including the payment made to Neurimmune in exchange for a 15% reduction in royalty rates payable on products developed under the agreement, including on potential commercial sales of aducanumab.

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

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2017, excluding amounts related to uncertain tax positions, funding commitments, contingent development, regulatory and commercial milestone payments, TYSABRI contingent payments and contingent consideration related to our business combinations, as described below.

	Payments Due by Period				
(In millions)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Non-cancellable operating leases (1), (2)	$428.5	$ 48.3	$92.1	$88.3	$199.8
Long-term debt obligations (3)	9,430.0	244.8	1,983.3	1,396.3	5,805.6
Purchase and other obligations (4)	1,657.1	637.3	344.9	234.6	440.3
Defined benefit obligation	91.8	—	—	—	91.8
Total contractual obligations	$11,607.4	$ 930.4	$2,420.3	$1,719.2	$6,537.5

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(1) 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.

(2) Obligations are presented net of sublease income expected to be received for the vacated small-scale biologics manufacturing facility in Cambridge, MA, the vacated portion of our Weston, MA facility and other facilities throughout the world.

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

(4) Purchase and other obligations primarily includes our obligations to purchase direct materials, $989.6 million related to our current estimate of the impact of the 2017 Tax Act, $270.0 million in contractual commitments for the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland and $111.3 million related to the fair value of net liabilities on derivative contracts.

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 acquisition agreement, we are obligated to make contingent payments to Elan of 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013, and Perrigo subsequently sold its rights to these payments to a third party effective January 2017.

Contingent Consideration related to Business Combinations

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

As the acquisitions of Convergence, Stromedix and BIN occurred after January 1, 2009, we recorded the contingent consideration liabilities associated with these transactions at their fair value on the

acquisition date and revalue these obligations each reporting period. We may pay up to approximately $1.1 billion in remaining milestones related to these acquisitions. For additional information on our acquisition of Convergence please read Note 2, Acquisitions, to our consolidated financial statements included in this report.

Fumapharm AG

In 2006 we acquired Fumapharm AG. As part of this acquisition we acquired FUMADERM and TECFIDERA (together, Fumapharm Products). We are required to make contingent payments to the 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 12-month period, as defined in the acquisition agreement.

During 2017 we paid $1.2 billion in contingent payments as we reached the $11.0 billion, $12.0 billion, $13.0 billion and $14.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2016 and the first, second and third quarters of 2017, respectively, and accrued $600.0 million upon reaching $15.0 billion and $16.0 billion in total cumulative sales of Fumapharm Products in the fourth quarter of 2017.

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

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2017, we could make potential future milestone payments to third parties of up to approximately $4.2 billion, including approximately $0.7 billion in development milestones, approximately $1.5 billion in regulatory milestones and approximately $2.0 billion in commercial milestones

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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 was not considered probable as of December 31, 2017, 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.

Provided various development, regulatory or commercial milestones are achieved, we anticipate that we may pay approximately $110.0 million of milestone payments in 2018.

Other Funding Commitments

As of December 31, 2017, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $40.0 million in our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2017. We have approximately $460.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2017.

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, 2017, we have approximately $77.3 million of net liabilities associated with uncertain tax positions.

As of December 31, 2017, we have accrued income tax liabilities of $989.6 million under the Transition Toll Tax, of which $78.3 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

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, 2017, please read Note 21, 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 revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions. Other significant accounting policies are outlined in Note 1, Summary of Significant Accounting Policies, to our consolidated financial statements included in this report.

Revenue Recognition and Related Allowances

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

Product Revenues

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

distributor orders and shipments can cause variability in earnings.

Reserves for Discounts and Allowances

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

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

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

Concentrations of Credit Risk

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

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

To date, we have not experienced any significant losses with respect to the collection of our accounts receivable. If economic conditions worsen and/or the financial condition of our customers were to further

deteriorate, our risk of collectability may increase, which may result in additional allowances and/or significant bad debts.

For additional information on our concentration of credit risk associated with our accounts receivable balances, please read the subsection entitled “Credit Risk” in Item 7A. Quantitative and Qualitative Disclosures About Market Risk included in 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)
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 upon its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

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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.

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. No assurance can be given that the underlying assumptions used to estimate expected project sales, development costs or profitability, or the events associated with such projects, will transpire as estimated.

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

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

Long-lived Assets Other than Goodwill

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

When performing our impairment assessment, we calculate the fair value using the same methodology as described above under "Acquired Intangible Assets, including In-process Research and Development (IPR&D)". If the carrying value of our 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 treatments for forms of neuropathic pain, such as TGN. Such programs could become impaired if assumptions used in determining the fair value change.

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 relate to obtaining the fair value of the U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, and 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 TECFIDERA, TYSABRI and AVONEX using the economic consumption method based on revenues generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of TECFIDERA, 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 TECFIDERA, TYSABRI or AVONEX.

For additional information on the impairment charges related to our long-lived assets during 2017 and 2016, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in this report. Impairment charges related to our long-lived assets during 2015 were insignificant.

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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, we would record an impairment loss equal to the difference.

We completed our required annual impairment test in the fourth quarters of 2017, 2016 and 2015, 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.

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 8, Fair Value Measurements, to our consolidated financial statements included in this report, 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.

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Determining the appropriate valuation model and related assumptions requires judgment, and includes estimating the expected market price of our stock on vesting date and stock price volatility as well as the term of the expected awards. Determining the appropriate amount to expense based on the anticipated achievement of performance targets requires judgment, including forecasting the achievement of future financial targets. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made throughout the term as appropriate. The cumulative impact of any revision is reflected in the period of change.
We also estimate forfeitures over the requisite service period when recognizing share-based compensation expense based on historical rates and forward-looking factors. These estimates are adjusted to the extent that actual forfeitures differ, or are expected to materially differ, from our estimates.

Contingent Consideration

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

Restructuring Charges

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

Income Taxes

We prepare and file income tax returns based on our interpretation of each jurisdiction’s tax laws and regulations. In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our consolidated financial position and results of operations.
All tax effects associated with intercompany transfers of assets within our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through our consolidated statements of income when the asset transferred is sold to a third-party or otherwise recovered through amortization of the asset's remaining economic life. If the asset transferred becomes impaired, for example through the obsolescence of inventory or the discontinuation of a research program, we will expense any remaining deferred charge or prepaid tax.
As of December 31,

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2017, total deferred charges and prepaid taxes were $617.7 million. For additional information on the new accounting standard related to tax effects associated with intercompany transfers of assets within our consolidated group, please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements, to our consolidated financial statements included in this report.

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.

On December 22, 2017, the 2017 Tax Act was signed into law and has resulted in significant changes to the U.S. corporate income tax system.

The 2017 Tax Act eliminates the deferral of U.S. income tax on the historical unrepatriated earnings by imposing the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on undistributed foreign earnings. The Transition Toll Tax is assessed on the U.S. shareholder's share of the foreign corporation's accumulated foreign earnings that have not previously been taxed. Earnings in the form of cash and cash equivalents will be taxed at a rate of 15.5% and all other earnings will be taxed at a rate of 8.0%. As of December 31, 2017, we have accrued

income tax liabilities of $989.6 million under the Transition Toll Tax, of which $78.3 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight-year period, starting in 2018, and will not accrue interest.

New Accounting Standards

For a discussion of new accounting standards and their expected impact on our consolidated financial statements or disclosures, please read Note 1, Summary of Significant Accounting Policies, 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 that may affect our results of operations, cash flows and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements, pricing pressures worldwide and weak economic conditions in the foreign markets in which we operate. We manage the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. We do not enter into financial instruments for trading or speculative purposes. The counterparties to these contracts are major financial institutions, and there is no significant concentration of exposure with any one counterparty.

Foreign Currency Exchange Risk

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

dollar, Swiss franc, Danish krone and Japanese yen.

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While the financial results of our global activities are reported in U.S. dollars, the functional currency for most of our foreign subsidiaries is their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar strengthens versus other currencies, the value of the non-U.S. revenues 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. expenses, 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. revenues 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 currency exchange rates.

In June 2016 the U.K. voted in a referendum to voluntarily depart from the E.U., known as Brexit, and in March 2017, the U.K. formally started the process for the U.K. to leave the E.U. The macroeconomic impact on our results of operations from these developments remains unknown. To date, the foreign currency exchange impact has been insignificant since we hedged the balance sheet foreign currency exchange risk.

Revenue and Operating Expense Hedging Program

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues and operating expenses. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 21 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 10, 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 and liabilities 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 statements 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, 2017 and 2016, 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 $286.0 million and $172.0 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, 2017 and 2016, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $50.0 million 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, 2017 and 2016, a 100 basis-point adverse movement (increase in LIBOR) would increase

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annual interest expense by approximately $6.8 million.

Pricing Pressure

Governments in some international markets in which we operate have implemented measures aimed at reducing healthcare costs to limit the 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.

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

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

Our products are also susceptible to increasing 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, as well as lower-priced competing 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 consolidated results of operations.

There is also significant economic pressure on state budgets that results 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 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, 2017 and 2016. 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-78 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, 2017. 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, 2017, 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, 2017. 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, 2017, 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, 2017, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information concerning our executive officers is set forth under the heading “Our Executive Officers” in Item 1 of this report. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.biogen.com, under the “Governance” subsection of the “About Us” section of the site. We intend to make all required disclosures regarding any amendments to, or waivers from, provisions of our code of business conduct at the same location of our website.

The response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Proposal 1 - Election of Directors,” “Corporate Governance at Biogen,” “Stock Ownership - Section 16(a) Beneficial Ownership Reporting Compliance” and “Miscellaneous - Stockholder Proposals” contained in the proxy statement for our 2018 annual meeting of stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Executive Compensation Matters” and “Corporate Governance at Biogen” contained in the proxy statement for our 2018 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 2018 annual meeting of stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled “Certain Relationships and Related Person Transactions” and “Corporate Governance at Biogen” contained in the proxy statement for our 2018 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 2018 annual meeting of stockholders.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

a. (1) Consolidated Financial Statements:

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

Certain totals may not sum due to rounding.

(2) Exhibits

The exhibits listed on the Exhibit Index beginning on page 94, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

(3) 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.

Item 16. Form 10-K Summary

Not applicable.

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EXHIBIT INDEX

Exhibit No.	Description
2.1†	Asset Purchase Agreement among Biogen Idec International Holding Ltd., Elan Pharma International Limited and Elan Pharmaceuticals, Inc., dated as of February 5, 2013. Filed as Exhibit 2.1 to our Current Report on Form 8-K/A filed on February 12, 2013.
2.2	Separation Agreement between Biogen Inc. and Bioverativ Inc. dated as of January 31, 2017. Filed as Exhibit 2.1 to our Current Report on Form 8-K filed on February 2, 2017.
3.1	Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
3.2	Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015.
3.3	Fourth Amended and Restated Bylaws. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on June 9, 2017.
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 Inc. and U.S. Bank National Association, dated as of September 15, 2015. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015.
4.3	First Supplemental Indenture between Biogen Inc. and U.S. Bank National Association, dated September 15, 2015. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015.
10.1	Credit Agreement between Biogen Inc., Bank of America, N.A., Goldman Sachs Bank USA and other lenders party thereto, dated August 28, 2015. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015.
10.2†	Second Amended and Restated Collaboration Agreement between Biogen Idec Inc. 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.
10.3†	Letter Agreement regarding GA101 financial terms between Biogen Idec Inc. 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.
10.4	Settlement and License Agreement, dated January 17, 2017, between Biogen Swiss Manufacturing GmbH, Biogen International Holdings ltd., Forward Pharma A/S and other parties thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 1, 2017.
10.5*	Biogen Inc. 2017 Omnibus Equity Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2017.
10.6*	Form of restricted stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.7*	Form of market stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.8*	Form of performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.9*	Form of cash-settled performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.10*+	Form of performance stock units award agreement (cash-settled) under the Biogen Inc. 2017 Omnibus Equity Plan.
10.11*+	Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan.
10.12*	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.
10.13*	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.

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Exhibit No.	Description
10.14*	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.
10.15*	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.
10.16*	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.
10.17*	Form of cash-settled performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
10.18*	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.
10.19*	Biogen Inc. 2015 Employee Stock Purchase Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 30, 2015.
10.20*	Biogen Idec Inc. 2008 Performance-Based Management Incentive Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on May 8, 2008.
10.21*	Biogen Idec Inc. 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.
10.22*	Biogen Idec Inc. Supplemental Savings Plan, as amended. Filed as Exhibit 10.23 to our Annual Report on Form 10-K for the year ended December 31, 2015.
10.23*	Biogen Idec Inc. Voluntary Board of Directors Savings Plan, as amended. Filed as Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 31, 2015.
10.24*	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.
10.25*	Biogen Idec Inc. Executive Severance Policy - International Executive Vice President, as amended effective January 1, 2014. Filed as Exhibit 10.40 to our Annual Report on Form 10-K for the year ended December 31, 2013.
10.26*	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.
10.27*	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.
10.28*+	Annual Retainer Summary for Board of Directors.
10.29*	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.
10.30*	Employment Agreement between Biogen Inc. and Michel Vounatsos dated December 18, 2016. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on December 19, 2016.
10.31*+	Letter regarding employment arrangement of Jeffrey Capello dated November 14, 2017.
10.32*+	Letter regarding employment arrangement of Gregory Covino dated February 25, 2012.
10.33*+	Letter regarding employment arrangement of Michael Ehlers dated April 16, 2016.
10.34*	Letter regarding employment arrangement of Susan Alexander dated December 31, 2005. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2009.
10.35*	Employment Agreement between Biogen Idec. Inc. 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.

10.36*	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.
10.37*	Letter regarding employment arrangement of John Cox dated May 19, 2016. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

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Exhibit No.	Description
10.38*	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.
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, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Equity and (vi) Notes to Consolidated Financial Statements.

References to "our" filings mean filings made by Biogen Inc. and filings made by IDEC Pharmaceuticals Corporation
^ prior to the merger with Biogen, Inc. Unless otherwise indicated exhibits were previously filed with the Securities and Exchange Commission under Commission File Number 0-19311 and are incorporated herein by reference.

* Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit.

+ Filed herewith.

++ Furnished herewith.

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SIGNATURES

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

BIOGEN INC.

By: /S/ MICHEL VOUNATSOS
Michel Vounatsos
Chief Executive Officer
Date: February 1, 2018

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

Name	Capacity	Date
/S/ MICHEL VOUNATSOS Michel Vounatsos	Director and Chief Executive Officer (principal executive officer)	February 1, 2018
/S/ Jeffrey D. Capello Jeffrey D. Capello	Executive Vice President and Chief Financial Officer (principal financial officer)	February 1, 2018
/S/ GREGORY F. COVINO Gregory F. Covino	Vice President, Finance, Chief Accounting Officer (principal accounting officer)	February 1, 2018
/S/ STELIOS PAPADOPOULOS Stelios Papadopoulos	Director and Chairman of the Board of Directors	February 1, 2018
/S/ ALEXANDER J. DENNER Alexander J. Denner	Director	February 1, 2018
/S/ CAROLINE D. DORSA Caroline D. Dorsa	Director	February 1, 2018
/S/ NANCY L. LEAMING Nancy L. Leaming	Director	February 1, 2018
/S/ RICHARD C. MULLIGAN Richard C. Mulligan	Director	February 1, 2018
/S/ ROBERT W. PANGIA Robert W. Pangia	Director	February 1, 2018
/S/ BRIAN S. POSNER Brian S. Posner	Director	February 1, 2018
/S/ ERIC K. ROWINSKY Eric K. Rowinsky	Director	February 1, 2018
/S/ LYNN SCHENK Lynn Schenk	Director	February 1, 2018
/S/ STEPHEN A. SHERWIN Stephen A. Sherwin	Director	February 1, 2018

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BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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

	For the Years Ended December 31,		
	2017	2016	2015
Revenues:			
Product, net	$10,354.7	$9,817.9	$9,188.5
Revenues from anti-CD20 therapeutic programs	1,559.2	1,314.5	1,339.2
Other	360.0	316.4	236.1
Total revenues	12,273.9	11,448.8	10,763.8
Cost and expenses:			