

BIOGEN INC.  
Form 10-Q  
April 24, 2018

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-Q

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

For the quarterly period ended March 31, 2018  
OR

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

Commission File Number 0-19311

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware 33-0112644

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

225 Binney Street, Cambridge, MA 02142

(617) 679-2000

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

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

90 days: Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth 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  Accelerated filer

Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company) Emerging growth company

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

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

The number of shares of the issuer's Common Stock, \$0.0005 par value, outstanding as of April 20, 2018 was 211,007,945 shares.



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 For the Quarterly Period Ended March 31, 2018  
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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 of 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 limit 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;

adverse safety events involving our marketed products;

the anticipated timing to complete certain business development transactions;

the anticipated 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.

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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. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

**NOTE REGARDING COMPANY AND PRODUCT REFERENCES**

References in this report to:

“Biogen,” the “company,” “we,” “us” and “our” refer to Biogen Inc. and its consolidated subsidiaries;

“RITUXAN” refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan); 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**

AVONEX®, PLEGRIDY®, RITUXAN®, SPINRAZA®, TECFIDERA®, TYSABRI® and ZINBRYTA® are registered trademarks of Biogen. BENEPALI™, FLIXABI™, FUMADERM™ and IMRALDI™ are trademarks of Biogen. ALPROLIX®, ELOCTATE®, ENBREL®, FAMPYRA™, GAZYVA®, HUMIRA®, OCREVUS®, REMICADE® and other trademarks referenced in this report are the property of their respective owners.

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## PART I FINANCIAL INFORMATION

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

|                                                                             | For the Three<br>Months<br>Ended March 31, |           |
|-----------------------------------------------------------------------------|--------------------------------------------|-----------|
|                                                                             | 2018                                       | 2017      |
| Revenues:                                                                   |                                            |           |
| Product, net                                                                | \$2,523.5                                  | \$2,380.1 |
| Revenues from anti-CD20 therapeutic programs                                | 443.2                                      | 340.6     |
| Other                                                                       | 164.4                                      | 90.0      |
| Total revenues                                                              | 3,131.1                                    | 2,810.7   |
| Cost and expenses:                                                          |                                            |           |
| Cost of sales, excluding amortization of acquired intangible assets         | 446.0                                      | 384.6     |
| Research and development                                                    | 496.7                                      | 423.4     |
| Selling, general and administrative                                         | 501.3                                      | 498.7     |
| Amortization of acquired intangible assets                                  | 103.9                                      | 448.5     |
| Collaboration profit (loss) sharing                                         | 42.5                                       | 20.8      |
| Acquired in-process research and development                                | 10.0                                       | —         |
| (Gain) loss on fair value remeasurement of contingent consideration         | (5.6                                       | ) 10.0    |
| Restructuring charges                                                       | 1.6                                        | —         |
| Total cost and expenses                                                     | 1,596.4                                    | 1,786.0   |
| Income from operations                                                      | 1,534.7                                    | 1,024.7   |
| Other income (expense), net                                                 | (41.0                                      | ) (38.0   |
| Income before income tax expense and equity in loss of investee, net of tax | 1,493.7                                    | 986.7     |
| Income tax expense                                                          | 322.5                                      | 239.2     |
| Equity in loss of investee, net of tax                                      | —                                          | —         |
| Net income                                                                  | 1,171.2                                    | 747.5     |
| Net income (loss) attributable to noncontrolling interests, net of tax      | (1.7                                       | ) (0.1    |
| Net income attributable to Biogen Inc.                                      | \$1,172.9                                  | \$747.6   |
| Net income per share:                                                       |                                            |           |
| Basic earnings per share attributable to Biogen Inc.                        | \$5.55                                     | \$3.47    |
| Diluted earnings per share attributable to Biogen Inc.                      | \$5.54                                     | \$3.46    |
| Weighted-average shares used in calculating:                                |                                            |           |
| Basic earnings per share attributable to Biogen Inc.                        | 211.4                                      | 215.6     |
| Diluted earnings per share attributable to Biogen Inc.                      | 211.7                                      | 215.9     |

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 (unaudited, in millions)

|                                                                                  | For the Three<br>Months<br>Ended March 31, |         |
|----------------------------------------------------------------------------------|--------------------------------------------|---------|
|                                                                                  | 2018                                       | 2017    |
| Net income attributable to Biogen Inc.                                           | \$1,172.9                                  | \$747.6 |
| Other comprehensive income:                                                      |                                            |         |
| Unrealized gains (losses) on securities available for sale, net of tax           | (2.2 )                                     | (1.6 )  |
| Unrealized gains (losses) on cash flow hedges, net of tax                        | (29.0 )                                    | (23.8 ) |
| Unrealized gains (losses) on pension benefit obligation, net of tax              | (0.5 )                                     | 0.1     |
| Currency translation adjustment                                                  | 44.7                                       | 20.0    |
| Total other comprehensive income (loss), net of tax                              | 13.0                                       | (5.3 )  |
| Comprehensive income attributable to Biogen Inc.                                 | 1,185.9                                    | 742.3   |
| Comprehensive income (loss) attributable to noncontrolling interests, net of tax | (1.7 )                                     | (0.1 )  |
| Comprehensive income                                                             | \$1,184.2                                  | \$742.2 |



See accompanying notes to these unaudited condensed consolidated financial statements.

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

|                                              | As of<br>March 31,<br>2018 | As of<br>December<br>31,<br>2017 |
|----------------------------------------------|----------------------------|----------------------------------|
| <b>ASSETS</b>                                |                            |                                  |
| Current assets:                              |                            |                                  |
| Cash and cash equivalents                    | \$4,108.0                  | \$1,573.8                        |
| Marketable securities                        | 1,808.0                    | 2,115.2                          |
| Accounts receivable, net                     | 1,939.2                    | 1,787.0                          |
| Due from anti-CD20 therapeutic programs      | 553.5                      | 532.6                            |
| Inventory                                    | 890.8                      | 902.7                            |
| Other current assets                         | 895.9                      | 962.0                            |
| Total current assets                         | 10,195.4                   | 7,873.3                          |
| Marketable securities                        | 1,200.2                    | 3,057.3                          |
| Property, plant and equipment, net           | 3,334.7                    | 3,182.4                          |
| Intangible assets, net                       | 3,794.5                    | 3,879.6                          |
| Goodwill                                     | 4,907.8                    | 4,632.5                          |
| Deferred tax assets                          | 2,277.4                    | 595.9                            |
| Investments and other assets                 | 380.1                      | 431.6                            |
| Total assets                                 | \$26,090.1                 | \$23,652.6                       |
| <b>LIABILITIES AND EQUITY</b>                |                            |                                  |
| Current liabilities:                         |                            |                                  |
| Current portion of notes payable             | \$3.3                      | \$3.2                            |
| Taxes payable                                | 231.9                      | 68.2                             |
| Accounts payable                             | 345.8                      | 395.5                            |
| Accrued expenses and other                   | 2,571.1                    | 2,901.3                          |
| Total current liabilities                    | 3,152.1                    | 3,368.2                          |
| Notes payable                                | 5,929.4                    | 5,935.0                          |
| Deferred tax liabilities                     | 1,331.1                    | 122.6                            |
| Other long-term liabilities                  | 1,640.0                    | 1,628.7                          |
| Total liabilities                            | 12,052.6                   | 11,054.5                         |
| Commitments and contingencies                |                            |                                  |
| Equity:                                      |                            |                                  |
| Biogen Inc. shareholders' equity:            |                            |                                  |
| Preferred stock, par value \$0.001 per share | —                          | —                                |
| Common stock, par value \$0.0005 per share   | 0.1                        | 0.1                              |
| Additional paid-in capital                   | —                          | 97.8                             |
| Accumulated other comprehensive loss         | (303.9 )                   | (318.4 )                         |
| Retained earnings                            | 17,334.6                   | 15,810.4                         |
| Treasury stock, at cost                      | (2,977.1 )                 | (2,977.1 )                       |
| Total Biogen Inc. shareholders' equity       | 14,053.7                   | 12,612.8                         |
| Noncontrolling interests                     | (16.2 )                    | (14.7 )                          |
| Total equity                                 | 14,037.5                   | 12,598.1                         |
| Total liabilities and equity                 | \$26,090.1                 | \$23,652.6                       |

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
 (unaudited, in millions)

|                                                                                      | For the Three<br>Months<br>Ended March 31, |            |
|--------------------------------------------------------------------------------------|--------------------------------------------|------------|
|                                                                                      | 2018                                       | 2017       |
| Cash flows from operating activities:                                                |                                            |            |
| Net income                                                                           | \$1,171.2                                  | \$747.5    |
| Adjustments to reconcile net income to net cash flows from operating activities:     |                                            |            |
| Depreciation and amortization                                                        | 168.9                                      | 512.0      |
| Acquired in-process research and development                                         | 10.0                                       | —          |
| Share-based compensation                                                             | 43.4                                       | 37.0       |
| Deferred income taxes                                                                | 53.1                                       | 76.1       |
| Other                                                                                | 26.1                                       | 18.1       |
| Changes in operating assets and liabilities, net:                                    |                                            |            |
| Accounts receivable                                                                  | (134.0 )                                   | (195.7 )   |
| Inventory                                                                            | 2.6                                        | (46.2 )    |
| Accrued expenses and other current liabilities                                       | (121.8 )                                   | (684.2 )   |
| Income tax assets and liabilities                                                    | 257.6                                      | (195.1 )   |
| Other changes in operating assets and liabilities, net                               | (20.0 )                                    | (34.3 )    |
| Net cash flows provided by operating activities                                      | 1,457.1                                    | 235.2      |
| Cash flows from investing activities:                                                |                                            |            |
| Proceeds from sales and maturities of marketable securities                          | 4,068.9                                    | 1,884.3    |
| Purchases of marketable securities                                                   | (1,919.2 )                                 | (1,256.7 ) |
| Contingent consideration paid related to Fumapharm AG acquisition                    | (600.0 )                                   | (300.0 )   |
| Purchases of property, plant and equipment                                           | (194.7 )                                   | (210.0 )   |
| Acquired in-process research and development                                         | (10.0 )                                    | —          |
| Acquisitions of intangible assets                                                    | —                                          | (855.2 )   |
| Other                                                                                | 1.6                                        | (6.6 )     |
| Net cash flows provided by (used in) investing activities                            | 1,346.6                                    | (744.2 )   |
| Cash flows from financing activities:                                                |                                            |            |
| Purchases of treasury stock                                                          | (250.0 )                                   | (583.6 )   |
| Payments related to issuance of stock for share-based compensation arrangements, net | (21.2 )                                    | (25.5 )    |
| Net cash contribution to Bioverativ Inc.                                             | —                                          | (302.7 )   |
| Other                                                                                | 2.6                                        | 10.4       |
| Net cash flows used in financing activities                                          | (268.6 )                                   | (901.4 )   |
| Net (decrease) increase in cash and cash equivalents                                 | 2,535.1                                    | (1,410.4 ) |
| Effect of exchange rate changes on cash and cash equivalents                         | (0.9 )                                     | 7.9        |
| Cash and cash equivalents, beginning of the period                                   | 1,573.8                                    | 2,326.5    |
| Cash and cash equivalents, end of the period                                         | \$4,108.0                                  | \$924.0    |

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Summary of Significant Accounting Policies

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 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. In March 2018 we and AbbVie Inc. (AbbVie) announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing MS. For additional information on our voluntary withdrawal of ZINBRYTA, please read Note 18, Collaborative and Other Relationships, to these condensed consolidated financial statements.

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, 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 European Union (E.U.).

Basis of Presentation

In the opinion of management, our accompanying unaudited condensed consolidated financial statements (condensed consolidated financial statements) include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The information included in this quarterly report on Form 10-Q should be read in conjunction with our consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2017 (2017 Form 10-K). Our accounting policies are described in the "Notes to Consolidated Financial Statements" in our 2017 Form 10-K and updated, as necessary, in this Form 10-Q. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2018, are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

We operate as one operating segment, focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Consolidation

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

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

Use of Estimates

The preparation of our condensed consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe 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.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed below, we do not believe that the adoption of recently issued standards have or may have a material impact on our condensed consolidated financial statements and disclosures.

Revenue Recognition

In May 2014 the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry specific guidance. This new standard requires a company to recognize revenues when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB subsequently issued the following amendments to ASU No. 2014-09 that have the same effective date and transition date: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. We adopted these amendments with ASU 2014-09 (collectively, the new revenue standards).

The new revenue standards became effective for us on January 1, 2018, and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018, did not change our revenue recognition as the majority of our revenues continue to be recognized when the customer takes control of our product. As we did not identify any accounting changes that impacted the amount of reported revenues with respect to our product revenues, revenues from anti-CD20 therapeutic programs or other revenues, no adjustment to retained earnings was required upon adoption. However, the adoption of the new revenue standards may result in a change in the timing of revenue recognition related to certain of our contract manufacturing activities based upon the terms of



the underlying agreements.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

**Product Revenues**

In the U.S. we sell our products primarily to wholesale distributors and specialty pharmacy providers. In other countries, we sell our products primarily to wholesale distributors, hospitals, pharmacies and other third-party distribution partners. These customers subsequently resell our products to health care providers and patients. In addition, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and allowances related to our products.

Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

**Reserves for Discounts and Allowances**

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Our process for estimating reserves established for these variable consideration components do not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns.

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 of reserves established for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. 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 discounts, rebates and product returns, 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 revenues. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expenses.

For additional information on our revenues, please read Note 4, Revenues, to these condensed consolidated financial statements.

**Revenues from Anti-CD20 Therapeutic Programs**

Our collaboration with Genentech is within the scope of Accounting Standards Codification (ASC) 808, Collaborative Agreements, which provides guidance on the presentation and disclosure of collaborative arrangements. Our share of the pre-tax co-promotion profits on RITUXAN and GAZYVA and royalty revenues on the sale of OCREVUS resulted from an exchange of a license. As we do not have any future performance obligations under the license or

collaboration agreement, revenues are recognized as the underlying sales occur.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Revenues from anti-CD20 therapeutic programs consist of:

- (i) our share of pre-tax profits and losses in the U.S. for RITUXAN and GAZYVA;
- (ii) reimbursement of our selling and development expenses in the U.S. for RITUXAN; and
- (iii) other revenues from anti-CD20 therapeutic programs, which primarily consist of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenues on sales of OCREVUS.

For additional information on our collaboration with Genentech, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

**Collaborative and Other Relationships**

Our development and commercialization arrangements with AbbVie and Samsung Bioepis also represent collaborative arrangements as each party is an active participant and exposed to significant risks and rewards of the arrangements. These arrangements resulted from an exchange of a license and utilize the sales and usage based royalty exception. Therefore, revenues are recognized as the underlying sales occur. Where we are the principal on sales transactions with third parties, we recognize revenues, cost of sales and operating expenses on a gross basis in their respective lines in our condensed consolidated statements of income. Where we are not the principal on sales transactions with third parties, we record our share of the revenues, cost of sales and operating expenses on a net basis in collaborative and other relationships included in other revenues in our condensed consolidated statements of income.

For additional information on our collaborations with AbbVie and Samsung Bioepis, please read Note 18, Collaborative and Other Relationships, to these condensed consolidated financial statements.

**Royalty Revenues**

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

**Other Corporate Revenues**

We record other corporate revenues primarily from amounts earned under contract manufacturing agreements. Revenues under contract manufacturing agreements are recognized when the customer obtains control of our product, which may occur at a point in time or over time depending on the terms and conditions of the agreement.

**Accounts Receivable**

The majority of our accounts receivable arise from product sales and primarily represent amounts due from our wholesale and other third-party distributors, public hospitals, pharmacies and other government entities.

We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale.

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

We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve.



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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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The adoption of the new revenue standards did not change our historical accounting methods for our accounts receivable.

Financial Instruments

In January 2016 the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. This new standard amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values are to be measured at fair value with any changes in fair value recognized in a company's results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those investments that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets.

We adopted this new standard on January 1, 2018, using the modified retrospective method, as of that date, and recognized a \$1.3 million net adjustment to retained earnings reflecting the cumulative impact for the accounting changes made upon adoption. The adoption of the new standard resulted in the reclassification of where we recognize changes in fair value related to certain equity security investments. Prior to adoption of ASU 2016-01, we recognized changes in fair value in accumulated other comprehensive income (loss), net. Upon adoption of ASU 2016-01, we recognize changes in fair value in other income (expense), net.

Leasing

In February 2016 the FASB issued ASU No. 2016-02, Leases (Topic 842). This new standard establishes a right-of-use (ROU) model that requires all lessees to recognize ROU assets and liabilities on their balance sheet that arise from leases with terms longer than 12 months as well as provide disclosures with respect to certain qualitative and quantitative information related to their leasing arrangements. This new standard will become effective for us on January 1, 2019. A modified retrospective transition approach is required to leases existing as of, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. While we are currently evaluating the impact that this new standard may have on our consolidated results of operations, financial position and disclosures, we expect that the adoption of this new standard may materially affect the reported amount of total assets and total liabilities within our condensed consolidated balance sheet with no material impact to our condensed consolidated statement of income. We are unable to quantify the impact at this time as the ultimate impact of adopting this new standard will depend on the total amount of our lease commitments as of the adoption date.

Income Taxes

In October 2016 the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory. This new standard eliminates the deferral of the tax effects of intra-entity asset transfers other than inventory. As a result, the income tax consequences from the intra-entity transfer of an asset other than inventory and associated changes to deferred taxes will be recognized when the transfer occurs.

We adopted this new standard on January 1, 2018, using the modified retrospective method, through a cumulative-effect adjustment to retained earnings as of that date. Upon adoption, we recognized additional net deferred tax assets of approximately \$0.5 billion offset by a corresponding net increase to retained earnings of approximately \$0.5 billion. We will recognize incremental deferred income tax expense thereafter as these net deferred tax assets are utilized.

For additional information, please read Note 15, Income Taxes, to these condensed consolidated financial statements.



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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Net Periodic Pension Cost

In March 2017 the FASB issued ASU No. 2017-07, Compensation - Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost. This new standard requires that an employer disaggregate the service cost component from the other components of net benefit cost. This new standard also provides explicit guidance on how to present the service cost component and the other components of net benefit cost in the income statement and allows only the service cost component of net benefit cost to be eligible for capitalization. The other components of the net periodic benefit cost must be presented separately from the line items that include service cost and outside of any subtotal of operating income on our condensed consolidated statements of income. We adopted this new standard on January 1, 2018, using the retrospective method.

As a result of this new standard, the other components of the net periodic benefit cost, which we previously presented as a component of operating income, are now classified in other income (expense), net in our condensed consolidated income statements. For the three months ended March 31, 2017, \$0.4 million was reclassified from operating income to other income (expense), net in our condensed consolidated income statement to conform to our current year presentation.

Debt Securities

In March 2017 the FASB issued ASU No. 2017-08, Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities. This new standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. This new standard will be effective for us on January 1, 2019. We are currently evaluating the potential impact that this new standard may have on our financial position and results of operations.

Derivative Instruments and Hedging Activities

In August 2017 the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. This new standard provides guidance to better align an entity's risk management activities and financial reporting for hedging relationships through changes to both the designation and measurement guidance for qualifying hedging relationships and the presentation of hedge results. This new standard expands and refines hedge accounting for both non-financial and financial risk components and aligns the recognition and presentation of the effects of the hedging instrument and the hedged item in the financial statements.

We adopted this new standard on January 1, 2018, using the modified retrospective method, which did not have an impact on our financial position or results of operations; however, the adoption of this new standard resulted in additional disclosures. Prior to the adoption of ASU 2017-12, to the extent ineffective, hedge transaction gains and losses were reported in other income (expense), net. Upon the adoption of ASU 2017-12, we recognize all fair value changes of derivatives in earnings in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.

For additional information on our derivative instruments and hedging activities, please read Note 9, Derivative Instruments, to these condensed consolidated financial statements.

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

We assess at inception and on an on-going basis, whether the derivative instruments that are used in hedging transactions are highly effective in offsetting the changes in cash flows or fair values of the hedged items. We exclude the forward points portion of the derivative instrument used in a hedging transaction from the effectiveness test and record the fair value gain or loss related to this portion each period in the same line item as the underlying hedged item. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge



accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

2. Acquisitions

Karyopharm Therapeutics Inc.

In January 2018 we acquired the exclusive worldwide rights to develop and commercialize Karyopharm Therapeutics Inc.'s (Karyopharm) Phase 1 ready investigational oral compound BIIB100 (formerly known as KPT-350) for the treatment of certain neurological and neurodegenerative conditions, primarily in ALS. BIIB100 is a novel therapeutic candidate that works by inhibiting a protein known as XPO1, with the goal of reducing inflammation and neurotoxicity, along with increasing neuroprotective responses.

We accounted for this transaction as an asset acquisition as the value being acquired relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of \$10.0 million, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB100 has not yet reached technological feasibility. We have also agreed to pay Karyopharm up to \$207.0 million in additional milestone payments, as well as potential royalties.

3. Restructuring

2017 Corporate Strategy

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 recognized restructuring charges of \$0.9 million in our consolidated statements of income during the fourth quarter of 2017. These restructuring charges were substantially incurred and paid in 2017 and were primarily related to severance.

For the three months ended March 31, 2018, we recognized restructuring charges of \$1.6 million in our condensed consolidated statements of income. These restructuring charges, which will be substantially incurred and paid by mid-2018, are primarily related to severance.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 4. Revenues

## Product Revenues

Revenues by product are summarized as follows:

| (In millions)            | For the Three Months<br>Ended March 31, |               |           | 2017          |               |           |
|--------------------------|-----------------------------------------|---------------|-----------|---------------|---------------|-----------|
|                          | 2018                                    |               | Total     | 2017          |               | Total     |
|                          | United States                           | Rest of World |           | United States | Rest of World |           |
| Multiple Sclerosis:      |                                         |               |           |               |               |           |
| TECFIDERA                | \$728.9                                 | \$258.0       | \$986.9   | \$751.1       | \$207.1       | \$958.2   |
| Interferon*              | 371.4                                   | 178.9         | 550.3     | 464.8         | 183.5         | 648.3     |
| TYSABRI                  | 249.7                                   | 212.4         | 462.1     | 305.5         | 239.5         | 545.0     |
| FAMPYRA                  | —                                       | 24.4          | 24.4      | —             | 20.5          | 20.5      |
| ZINBRYTA                 | —                                       | 1.4           | 1.4       | —             | 10.7          | 10.7      |
| Spinal Muscular Atrophy: |                                         |               |           |               |               |           |
| SPINRAZA                 | 188.0                                   | 175.9         | 363.9     | 46.4          | 1.0           | 47.4      |
| Hemophilia:              |                                         |               |           |               |               |           |
| ELOCTATE                 | —                                       | —             | —         | 42.2          | 6.2           | 48.4      |
| ALPROLIX                 | —                                       | —             | —         | 21.0          | 5.0           | 26.0      |
| Other Product Revenues:  |                                         |               |           |               |               |           |
| FUMADERM                 | —                                       | 7.0           | 7.0       | —             | 9.7           | 9.7       |
| BENEPALI                 | —                                       | 120.9         | 120.9     | —             | 65.3          | 65.3      |
| FLIXABI                  | —                                       | 6.6           | 6.6       | —             | 0.6           | 0.6       |
| Total product revenues   | \$1,538.0                               | \$985.5       | \$2,523.5 | \$1,631.0     | \$749.1       | \$2,380.1 |

\*Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 34.0% and 15.9% of gross product revenues for the three months ended March 31, 2018, and 36.8% and 19.3% of gross product revenues for the three months ended March 31, 2017.

An analysis of the change in reserves for discounts and allowances is summarized as follows:

| (In millions)                                        | Discounts | Contractual Adjustments | Returns | Total    |
|------------------------------------------------------|-----------|-------------------------|---------|----------|
| Balance, as of December 31, 2017                     | \$ 109.6  | \$ 606.0                | \$ 46.0 | \$ 761.6 |
| Current provisions relating to sales in current year | 159.4     | 641.2                   | 5.8     | 806.4    |
| Adjustments relating to prior years                  | 1.2       | 2.0                     | 0.3     | 3.5      |
| Payments/credits relating to sales in current year   | (71.7 )   | (227.7 )                | (0.3 )  | (299.7 ) |
| Payments/credits relating to sales in prior years    | (77.4 )   | (326.4 )                | (8.7 )  | (412.5 ) |
| Balance, as of March 31, 2018                        | \$ 121.1  | \$ 695.1                | \$ 43.1 | \$ 859.3 |

The total reserves above, which are included in our condensed consolidated balance sheets, are summarized as follows:

| (In millions)                           | As of<br>March<br>31,<br>2018 | As of<br>December<br>31,<br>2017 |
|-----------------------------------------|-------------------------------|----------------------------------|
| Reduction of accounts receivable        | \$201.8                       | \$ 189.6                         |
| Component of accrued expenses and other | 657.5                         | 572.0                            |
| Total reserves                          | \$859.3                       | \$ 761.6                         |



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs are summarized as follows:

| (In millions)                                                        | For the Three<br>Months<br>Ended March<br>31, |         |
|----------------------------------------------------------------------|-----------------------------------------------|---------|
|                                                                      | 2018                                          | 2017    |
| Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA | \$349.6                                       | \$323.5 |
| Other revenues from anti-CD20 therapeutic programs                   | 93.6                                          | 17.1    |
| Total revenues from anti-CD20 therapeutic programs                   | \$443.2                                       | \$340.6 |

For additional information on our collaboration with Genentech, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

## Other Revenues

Other revenues are summarized as follows:

| (In millions)                                        | For the Three<br>Months<br>Ended March<br>31, |          |
|------------------------------------------------------|-----------------------------------------------|----------|
|                                                      | 2018                                          | 2017     |
| Revenues from collaborative and other relationships: |                                               |          |
| AbbVie                                               | \$(4.7 )                                      | \$(5.9 ) |
| Samsung Bioepis and other                            | 17.9                                          | 12.2     |
| Other royalty and corporate revenues:                |                                               |          |
| Royalty                                              | 10.6                                          | 25.5     |
| Other corporate                                      | 140.6                                         | 58.2     |
| Total other revenues                                 | \$164.4                                       | \$90.0   |

For additional information related to our collaborations with AbbVie and Samsung Bioepis, please read Note 18, Collaborative and Other Relationships, to these condensed consolidated financial statements.

## 5. Inventory

The components of inventory are summarized as follows:

| (In millions)   | As of                | As of                   |
|-----------------|----------------------|-------------------------|
|                 | March<br>31,<br>2018 | December<br>31,<br>2017 |
| Raw materials   | \$164.3              | \$162.4                 |
| Work in process | 594.3                | 605.7                   |
| Finished goods  | 148.0                | 157.4                   |
| Total inventory | \$906.6              | \$925.5                 |

## Balance Sheet Classification:

|                              |         |         |
|------------------------------|---------|---------|
| Inventory                    | \$890.8 | \$902.7 |
| Investments and other assets | 15.8    | 22.8    |
| Total inventory              | \$906.6 | \$925.5 |

Long-term inventory, which primarily consists of work in process, is included in investments and other assets in our condensed consolidated balance sheets.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 6. Intangible Assets and Goodwill

## Intangible Assets

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

| (In millions)                                     | Estimated<br>Life                     | As of March 31, 2018 |                             |           | As of December 31, 2017 |                             |           |
|---------------------------------------------------|---------------------------------------|----------------------|-----------------------------|-----------|-------------------------|-----------------------------|-----------|
|                                                   |                                       | Cost                 | Accumulated<br>Amortization | Net       | Cost                    | Accumulated<br>Amortization | Net       |
| Out-licensed patents                              | 13-23 years                           | \$543.3              | \$(537.8)                   | \$5.5     | \$543.3                 | \$(535.6)                   | \$7.7     |
| Developed<br>technology                           | 15-23 years                           | 3,005.3              | (2,700.5)                   | 304.8     | 3,005.3                 | (2,689.0)                   | 316.3     |
| In-process research and<br>development            | Indefinite until<br>commercialization | 696.4                | —                           | 696.4     | 680.6                   | —                           | 680.6     |
| Trademarks and<br>tradenames                      | Indefinite                            | 64.0                 | —                           | 64.0      | 64.0                    | —                           | 64.0      |
| Acquired and<br>in-licensed rights<br>and patents | 4-18 years                            | 3,974.7              | (1,250.9)                   | 2,723.8   | 3,971.4                 | (1,160.4)                   | 2,811.0   |
| Total intangible assets                           |                                       | \$8,283.7            | \$(4,489.2)                 | \$3,794.5 | \$8,264.6               | \$(4,385.0)                 | \$3,879.6 |

For the three months ended March 31, 2018, amortization of acquired intangible assets totaled \$103.9 million, as compared to \$448.5 million, in the prior year comparative period. For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in amortization of acquired intangible assets was primarily due to the prior year impairment charge related to our U.S. and rest of world licenses to Forward Pharma A/S's (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, as discussed below.

## Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of March 31, 2018, was \$298.2 million.

## Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Corporation plc and our U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. The net book values of the TYSABRI and TECFIDERA assets as of March 31, 2018, were \$2,178.4 million and \$322.5 million, respectively.

## TECFIDERA License Rights

In January 2017 we entered into a settlement and license agreement among Biogen Swiss Manufacturing GmbH, Biogen International Holding Ltd., Forward Pharma and certain related parties, which was effective as of February 1, 2017. 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.

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 March 2018 the European Patent Office (EPO) issued 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





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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

amortize the remaining net book value of the U.S. and rest of world intangible assets in our condensed consolidated statements of income utilizing an economic consumption model.

For additional information on these disputes, please read Note 21, Litigation, to our consolidated financial statements included in our 2017 Form 10-K.

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

|                              | As of   |
|------------------------------|---------|
| (In millions)                | March   |
|                              | 31,     |
|                              | 2018    |
| 2018 (remaining nine months) | \$330.7 |
| 2019                         | 402.6   |
| 2020                         | 379.5   |
| 2021                         | 255.0   |
| 2022                         | 242.2   |
| 2023                         | 211.2   |

Goodwill

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

|                               | As of     |
|-------------------------------|-----------|
| (In millions)                 | March     |
|                               | 31,       |
|                               | 2018      |
| Goodwill, beginning of period | \$4,632.5 |
| Increase to goodwill          | 270.5     |
| Other                         | 4.8       |
| Goodwill, end of period       | \$4,907.8 |

The increase in goodwill during the three months ended March 31, 2018, was related to \$300.0 million in contingent milestones achieved (exclusive of \$29.5 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights.

For additional information on future contingent payments to the former shareholders of Fumapharm AG or holders of their rights, please read Note 22, Commitments and Contingencies, to our consolidated financial statements included in our 2017 Form 10-K.

Other includes changes in foreign currency exchange rate fluctuations. As of March 31, 2018, we had no accumulated impairment losses related to goodwill.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 7. Fair Value Measurements

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

| As of March 31, 2018 (In millions)         | Total            | Quoted Prices<br>in Active<br>Markets<br>(Level 1) | Significant<br>Observable<br>Inputs<br>(Level 2) | Other<br>Inputs<br>(Level 3) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|--------------------------------------------|------------------|----------------------------------------------------|--------------------------------------------------|------------------------------|----------------------------------------------------|
| <b>Assets:</b>                             |                  |                                                    |                                                  |                              |                                                    |
| Cash equivalents                           | \$3,773.7        | \$ —                                               | \$ 3,773.7                                       |                              | \$ —                                               |
| <b>Marketable debt securities:</b>         |                  |                                                    |                                                  |                              |                                                    |
| Corporate debt securities                  | 1,557.9          | —                                                  | 1,557.9                                          |                              | —                                                  |
| Government securities                      | 1,143.2          | —                                                  | 1,143.2                                          |                              | —                                                  |
| Mortgage and other asset backed securities | 307.1            | —                                                  | 307.1                                            |                              | —                                                  |
| Marketable equity securities               | 22.8             | 22.8                                               | —                                                |                              | —                                                  |
| Derivative contracts                       | 3.2              | —                                                  | 3.2                                              |                              | —                                                  |
| Plan assets for deferred compensation      | 28.3             | —                                                  | 28.3                                             |                              | —                                                  |
| <b>Total</b>                               | <b>\$6,836.2</b> | <b>\$ 22.8</b>                                     | <b>\$ 6,813.4</b>                                |                              | <b>\$ —</b>                                        |
| <b>Liabilities:</b>                        |                  |                                                    |                                                  |                              |                                                    |
| Derivative contracts                       | \$147.7          | \$ —                                               | \$ 147.7                                         |                              | \$ —                                               |
| Contingent consideration obligations       | 498.0            | —                                                  | —                                                |                              | 498.0                                              |
| <b>Total</b>                               | <b>\$645.7</b>   | <b>\$ —</b>                                        | <b>\$ 147.7</b>                                  |                              | <b>\$ 498.0</b>                                    |
| As of December 31, 2017 (In millions)      | Total            | Quoted Prices<br>in Active<br>Markets<br>(Level 1) | Significant<br>Observable<br>Inputs<br>(Level 2) | Other<br>Inputs<br>(Level 3) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| <b>Assets:</b>                             |                  |                                                    |                                                  |                              |                                                    |
| Cash equivalents                           | \$1,229.4        | \$ —                                               | \$ 1,229.4                                       |                              | \$ —                                               |
| <b>Marketable debt securities:</b>         |                  |                                                    |                                                  |                              |                                                    |
| Corporate debt securities                  | 2,609.8          | —                                                  | 2,609.8                                          |                              | —                                                  |
| Government securities                      | 1,919.3          | —                                                  | 1,919.3                                          |                              | —                                                  |
| Mortgage and other asset backed securities | 643.4            | —                                                  | 643.4                                            |                              | —                                                  |
| Marketable equity securities               | 11.8             | 11.8                                               | —                                                |                              | —                                                  |
| Derivative contracts                       | 2.7              | —                                                  | 2.7                                              |                              | —                                                  |
| Plan assets for deferred compensation      | 28.5             | —                                                  | 28.5                                             |                              | —                                                  |
| <b>Total</b>                               | <b>\$6,444.9</b> | <b>\$ 11.8</b>                                     | <b>\$ 6,433.1</b>                                |                              | <b>\$ —</b>                                        |
| <b>Liabilities:</b>                        |                  |                                                    |                                                  |                              |                                                    |
| Derivative contracts                       | \$111.3          | \$ —                                               | \$ 111.3                                         |                              | \$ —                                               |
| Contingent consideration obligations       | 523.6            | —                                                  | —                                                |                              | 523.6                                              |
| <b>Total</b>                               | <b>\$634.9</b>   | <b>\$ —</b>                                        | <b>\$ 111.3</b>                                  |                              | <b>\$ 523.6</b>                                    |

There have been no material impairments of our assets measured and carried at fair value during the three months ended March 31, 2018. In addition, there were no changes in valuation techniques or inputs utilized or transfers between fair value measurement levels during the three months ended March 31, 2018. The fair values of Level 2 instruments classified as cash equivalents and marketable debt securities were determined through third-party pricing services. For a description of our validation procedures related to prices provided by third-party pricing services, please read Note 1, Summary of Significant Accounting Policies: Fair Value Measurements, to our consolidated

financial statements included in our 2017 Form 10-K.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## Debt Instruments

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

| (In millions)                              | As of March 31,<br>2018 |                   | As of December<br>31, 2017 |                   |
|--------------------------------------------|-------------------------|-------------------|----------------------------|-------------------|
|                                            | Fair<br>Value           | Carrying<br>Value | Fair<br>Value              | Carrying<br>Value |
| Notes payable to Fumedica AG               | \$3.3                   | \$3.3             | \$3.2                      | \$3.2             |
| 2.900% Senior Notes due September 15, 2020 | 1,490.7                 | 1,476.0           | 1,517.7                    | 1,482.4           |
| 3.625% Senior Notes due September 15, 2022 | 1,007.3                 | 994.6             | 1,032.9                    | 994.3             |
| 4.050% Senior Notes due September 15, 2025 | 1,788.8                 | 1,736.7           | 1,851.9                    | 1,736.3           |
| 5.200% Senior Notes due September 15, 2045 | 1,898.2                 | 1,722.1           | 2,077.6                    | 1,722.0           |
| Total                                      | \$6,188.3               | \$5,932.7         | \$6,483.3                  | \$5,938.2         |

The fair value of our notes payable to Fumedica AG was estimated using market observable inputs, including current interest and foreign currency exchange rates. The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. For additional information on our debt instruments, please read Note 12, Indebtedness, to our consolidated financial statements included in our 2017 Form 10-K.

## Contingent Consideration Obligations

In connection with our acquisitions of Convergence Pharmaceuticals, Stromedix Inc. and Biogen International Neuroscience GmbH in 2015, 2012 and 2010, respectively, we agreed to make additional payments based upon the achievement of certain milestone events. The following table provides a roll forward of the fair values of our contingent consideration obligations, which includes Level 3 measurements:

| (In millions)                   | For the Three<br>Months<br>Ended March 31, |         |
|---------------------------------|--------------------------------------------|---------|
|                                 | 2018                                       | 2017    |
| Fair value, beginning of period | \$523.6                                    | \$467.6 |
| Changes in fair value           | (5.6 )                                     | 10.0    |
| Payments                        | (20.0 )                                    | (6.7 )  |
| Fair value, end of period       | \$498.0                                    | \$470.9 |

As of March 31, 2018 and December 31, 2017, \$273.7 million and \$279.0 million, respectively, of the fair value of our contingent consideration obligations was reflected as a component of other long-term liabilities in our condensed consolidated balance sheets with the remaining balance reflected as a component of accrued expenses and other. Changes in the fair value of our contingent consideration obligations were primarily due to an increase in the probability of achieving certain developmental milestones in the prior year period and an increase in the interest rate used to revalue our contingent consideration liabilities for the current year.

## 8. Financial Instruments

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

| (In millions)                           | As of<br>March<br>31,<br>2018 | As of<br>December<br>31,<br>2017 |
|-----------------------------------------|-------------------------------|----------------------------------|
| Commercial paper                        | \$51.5                        | \$ 30.5                          |
| Overnight reverse repurchase agreements | —                             | 3.6                              |
| Money market funds                      | 3,561.2                       | 948.0                            |
| Short-term debt securities              | 161.0                         | 247.3                            |

Total \$3,773.7 \$ 1,229.4

The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and short-term debt securities approximate fair value due to their short-term

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

maturities. Upon adoption of ASU 2016-01, our marketable equity securities gains (losses) are recorded in other income (expense), net in our condensed consolidated statements of income.

The following tables summarize our marketable debt and equity securities, classified as available-for-sale:

| As of March 31, 2018 (In millions)         | Fair Value | Gross Unrealized Gains | Gross Unrealized Losses | Amortized Cost |
|--------------------------------------------|------------|------------------------|-------------------------|----------------|
| Corporate debt securities                  |            |                        |                         |                |
| Current                                    | \$912.9    | \$ —                   | \$ (0.8 )               | \$ 913.7       |
| Non-current                                | 645.0      | 0.3                    | (0.7 )                  | 645.4          |
| Government securities                      |            |                        |                         |                |
| Current                                    | 895.0      | —                      | (0.5 )                  | 895.5          |
| Non-current                                | 248.2      | 0.1                    | (0.3 )                  | 248.4          |
| Mortgage and other asset backed securities |            |                        |                         |                |
| Current                                    | 0.1        | —                      | —                       | 0.1            |
| Non-current                                | 307.0      | 0.1                    | (1.0 )                  | 307.9          |
| Total marketable debt securities           | \$3,008.2  | \$ 0.5                 | \$ (3.3 )               | \$ 3,011.0     |
| As of December 31, 2017 (In millions)      | Fair Value | Gross Unrealized Gains | Gross Unrealized Losses | Amortized Cost |
| Corporate debt securities                  |            |                        |                         |                |
| Current                                    | \$1,039.3  | \$ —                   | \$ (0.2 )               | \$ 1,039.5     |
| Non-current                                | 1,570.5    | 0.9                    | —                       | 1,569.6        |
| Government securities                      |            |                        |                         |                |
| Current                                    | 1,075.1    | 0.1                    | (0.7 )                  | 1,075.7        |
| Non-current                                | 844.2      | 0.2                    | (1.1 )                  | 845.1          |
| Mortgage and other asset backed securities |            |                        |                         |                |
| Current                                    | 0.8        | —                      | —                       | 0.8            |
| Non-current                                | 642.6      | 1.1                    | (0.8 )                  | 642.3          |
| Total marketable debt securities           | \$5,172.5  | \$ 2.3                 | \$ (2.8 )               | \$ 5,173.0     |
| Marketable equity securities, non-current  | \$11.8     | \$ 1.8                 | \$ (4.4 )               | \$ 14.4        |

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

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

| (In millions)                         | As of March 31, 2018 |                | As of December 31, 2017 |                |
|---------------------------------------|----------------------|----------------|-------------------------|----------------|
|                                       | Estimated Fair Value | Amortized Cost | Estimated Fair Value    | Amortized Cost |
| Due in one year or less               | \$1,808.0            | \$ 1,809.3     | \$ 2,115.2              | \$ 2,116.0     |
| Due after one year through five years | 1,123.0              | 1,124.2        | 2,730.0                 | 2,730.0        |
| Due after five years                  | 77.2                 | 77.5           | 327.3                   | 327.0          |
| Total available-for-sale securities   | \$3,008.2            | \$ 3,011.0     | \$ 5,172.5              | \$ 5,173.0     |

The average maturity of our marketable debt securities available-for-sale as of March 31, 2018 and December 31, 2017, was approximately 7 months and 17 months, respectively.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## Proceeds from Marketable Debt Securities

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

| (In millions)                      | For the Three<br>Months<br>Ended March 31, |           |
|------------------------------------|--------------------------------------------|-----------|
|                                    | 2018                                       | 2017      |
| Proceeds from maturities and sales | \$4,068.9                                  | \$1,884.3 |
| Realized gains                     | \$1.8                                      | \$1.2     |
| Realized losses                    | \$(9.4 )                                   | \$(1.9 )  |

## Strategic Investments

As of March 31, 2018 and December 31, 2017, our strategic investment portfolio was comprised of investments totaling \$81.6 million and \$85.8 million, respectively, which are included in investments and other assets in our condensed consolidated balance sheets. Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and investments in venture capital funds where the underlying investments are in equity securities of biotechnology companies. Our investments in equity securities of certain publicly-traded biotechnology companies are regularly measured and carried at fair value and classified as Level 1 assets.

## 9. Derivative Instruments

In August 2017 the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. We adopted this new standard on January 1, 2018. Among other provisions, the new standard required modifications to existing presentation and disclosure requirements on a prospective basis. As such, certain disclosures for the three months ended March 31, 2017, were modified to conform to the new disclosure requirements. For additional information on this new standard, please read Note 1, Summary of Significant Accounting Policies, to these condensed consolidated financial statements.

## Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of March 31, 2018 and December 31, 2017, had durations of 1 to 21 months. These contracts have been designated as cash flow hedges and any unrealized gains or losses on these foreign currency forward contracts are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses of such contracts are recognized in revenues when the sale of product in the currency being hedged is recognized and in operating expenses when the expense in the currency being hedged is recorded. Prior to the adoption of ASU 2017-12, to the extent ineffective, hedge transaction gains and losses were reported in other income (expense), net. Upon adoption of ASU 2017-12, we recognize all fair value changes of derivatives in earnings in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

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

|                                          | Notional Amount               |                                  |
|------------------------------------------|-------------------------------|----------------------------------|
|                                          | As of<br>March<br>31,<br>2018 | As of<br>December<br>31,<br>2017 |
| Foreign Currency: (In millions)          |                               |                                  |
| Euro                                     | \$1,734.9                     | \$ 1,875.6                       |
| British pound                            | 110.5                         | 150.9                            |
| Canadian dollar                          | 65.5                          | 83.5                             |
| Swiss franc                              | 60.4                          | 88.7                             |
| Total foreign currency forward contracts | \$1,971.3                     | \$ 2,198.7                       |

The pre-tax portion of the fair value of these foreign currency forward contracts that was included in accumulated other comprehensive income (loss) in total equity reflected net losses of \$142.0 million and \$113.0 million as of March 31, 2018 and December 31, 2017, respectively. We expect the net losses of \$142.0 million to be settled over the next 21 months, of which \$127.1 million is expected to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenues or operating expenses. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of March 31, 2018 and December 31, 2017, credit risk did not change the fair value of our foreign currency forward contracts.

The following tables summarize the effect of foreign currency forward contracts designated as hedging instruments in our condensed consolidated statements of income:

For the Three Months Ended March 31, 2018

| Net Gains/(Losses)<br>Reclassified from AOCI into<br>Operating Income (in millions) |            | Net Gains/(Losses)<br>Recognized in<br>Operating Income (in<br>millions) |           |
|-------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------|-----------|
| Location                                                                            | 2018       | Location                                                                 | 2018      |
| Revenues                                                                            | \$ (32.9 ) | Revenues                                                                 | \$ (0.9 ) |
| Operating expenses                                                                  | \$ 1.3     | Operating<br>expenses                                                    | \$ (0.3 ) |

For the Three Months Ended March 31, 2017

| Net Gains/(Losses)<br>Reclassified from AOCI<br>into Operating Income (in<br>millions) |         | Net Gains/(Losses)<br>Recognized Directly into Net<br>Income (in millions) |         |
|----------------------------------------------------------------------------------------|---------|----------------------------------------------------------------------------|---------|
| Location                                                                               | 2017    | Location                                                                   | 2017    |
| Revenues                                                                               | \$6.7   | Other income (expense)                                                     | \$4.0   |
| Operating expenses                                                                     | \$(0.1) | Other income (expense)                                                     | \$(0.2) |

## Interest Rate Contracts - Hedging Instruments

We have entered into interest rate swap contracts on certain borrowing transactions to manage our exposure to interest rate changes.

In connection with the issuance of our 2.90% Senior Notes, we entered into interest rate swaps with an aggregate notional amount of \$675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in the 2.90% Senior Notes attributable to changes in interest rates.

Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recognized as a component of our 2.90% Senior Notes with no net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recognized as a component of interest expense in our condensed consolidated statements of income.

Foreign Currency Forward Contracts - Other Derivatives

We also enter into other foreign currency forward contracts, usually with durations of one month or less, to mitigate the foreign currency risk related to certain balance sheet positions. We have not elected hedge accounting for these transactions.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

The aggregate notional amount of these outstanding foreign currency contracts was \$572.2 million and \$564.9 million as of March 31, 2018 and December 31, 2017, respectively. Net losses of \$5.6 million related to these contracts were recognized as a component of other income (expense), net for the three months ended March 31, 2018, as compared to net gains of \$1.6 million in the prior year comparative period.

## Summary of Derivatives

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

The following table summarizes the fair value and presentation in our condensed consolidated balance sheets of our outstanding derivative instruments, including those designated as hedging instruments:

| (In millions)         | Balance Sheet Location       | Fair Value<br>As of<br>March<br>31,<br>2018 |
|-----------------------|------------------------------|---------------------------------------------|
| Hedging Instruments:  |                              |                                             |
| Asset derivatives     | Other current assets         | \$ 1.8                                      |
| Liability derivatives | Accrued expenses and other   | \$ 114.1                                    |
|                       | Other long-term liabilities  | \$ 32.2                                     |
| Other Derivatives:    |                              |                                             |
| Asset derivatives     | Other current assets         | \$ 1.4                                      |
| Liability derivatives | Accrued expenses and other   | \$ 1.4                                      |
| (In millions)         | Balance Sheet Location       | Fair Value<br>As of<br>December<br>31, 2017 |
| Hedging Instruments:  |                              |                                             |
| Asset derivatives     | Other current assets         | \$ 0.7                                      |
|                       | Investments and other assets | \$ 0.2                                      |
| Liability derivatives | Accrued expenses and other   | \$ 84.7                                     |
|                       | Other long-term liabilities  | \$ 23.6                                     |
| Other Derivatives:    |                              |                                             |
| Asset derivatives     | Other current assets         | \$ 1.8                                      |
| Liability derivatives | Accrued expenses and other   | \$ 3.0                                      |

## 10. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was \$1,631.5 million and \$1,559.1 million as of March 31, 2018 and December 31, 2017, respectively.

## Solothurn, Switzerland Facility

We are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be operational by the end of 2020. 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. As of March 31, 2018 and December 31, 2017, we had approximately \$1.3 billion and \$1.2 billion, respectively, capitalized as construction in progress related to this facility. As of March 31, 2018, we had contractual commitments of \$260.0 million for the construction of this facility.



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 11. Equity

Total equity as of March 31, 2018, increased \$1.4 billion compared to December 31, 2017. This increase was primarily driven by net income attributable to Biogen Inc. of approximately \$1.2 billion and a net cumulative-effect adjustment of approximately \$0.5 billion recognized to retained earnings upon the adoptions of ASUs 2016-16 and 2016-01, partially offset by share repurchases totaling \$250.0 million, as described below.

For additional information related to the adoption of ASUs 2016-16 and 2016-01, please read Note 1, Summary of Significant Accounting Policies, to these condensed consolidated financial statements.

## Share Repurchases

In July 2016 our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2016 Share Repurchase Program). Our 2016 Share Repurchase Program does not have an expiration date. All share repurchases under our 2016 Share Repurchase Program will be retired. Under our 2016 Share Repurchase Program, we repurchased and retired 0.9 million shares of common stock at a cost of \$250.0 million during the three months ended March 31, 2018, and we repurchased and retired 0.8 million shares of common stock at a cost of \$218.2 million during the three months ended March 31, 2017. As of March 31, 2018, approximately \$2.8 billion remains available for share repurchase 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 common stock (2011 Share Repurchase Program). Shares repurchased under our 2011 Share Repurchase Program were principally used to offset common stock issuances under our share-based compensation programs. Our 2011 Share Repurchase Program was completed as of March 31, 2017. Under our 2011 Share Repurchase Program, we repurchased 1.2 million shares of common stock at a cost of \$365.4 million during the three months ended March 31, 2017.

## Noncontrolling Interests

The following table reconciles equity (deficit) attributable to noncontrolling interests (NCI):

|                                                   | For the Three<br>Months<br>Ended March<br>31, |          |
|---------------------------------------------------|-----------------------------------------------|----------|
| (In millions)                                     | 2018                                          | 2017     |
| NCI, beginning of period                          | \$(14.7)                                      | \$(11.5) |
| Net income (loss) attributable to NCI, net of tax | (1.7 )                                        | (0.1 )   |
| Translation adjustment and other                  | 0.2                                           | —        |
| NCI, end of period                                | \$(16.2)                                      | \$(11.6) |

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 12. Accumulated Other Comprehensive Income (Loss)

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

| (In millions)                                                           | Unrealized<br>Gains<br>(Losses)<br>on<br>Securities<br>Available<br>for Sale,<br>Net of<br>Tax | Unrealized<br>Gains<br>(Losses)<br>on Cash<br>Flow<br>Hedges,<br>Net of<br>Tax | Unfunded<br>Status of<br>Postretirement<br>Benefit<br>Plans, Net of<br>Tax | Translation<br>Adjustments | Total       |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------|-------------|
| Balance, December 31, 2017                                              | \$ (1.6 )                                                                                      | \$ (104.5 )                                                                    | \$ (36.8 )                                                                 | \$ (175.5 )                | \$ (318.4 ) |
| Amount reclassified, net of tax, upon adoption of ASU 2016-01           | 1.5                                                                                            | —                                                                              | —                                                                          | —                          | 1.5         |
| Balance, January 1, 2018                                                | (0.1 )                                                                                         | (104.5 )                                                                       | (36.8 )                                                                    | (175.5 )                   | (316.9 )    |
| Other comprehensive income (loss) before reclassifications              | (8.2 )                                                                                         | (60.4 )                                                                        | (0.5 )                                                                     | 44.7                       | (24.4 )     |
| Amounts reclassified from accumulated other comprehensive income (loss) | 6.0                                                                                            | 31.4                                                                           | —                                                                          | —                          | 37.4        |
| Net current period other comprehensive income (loss)                    | (2.2 )                                                                                         | (29.0 )                                                                        | (0.5 )                                                                     | 44.7                       | 13.0        |
| Balance, March 31, 2018                                                 | \$ (2.3 )                                                                                      | \$ (133.5 )                                                                    | \$ (37.3 )                                                                 | \$ (130.8 )                | \$ (303.9 ) |

| (In millions)                                                           | Unrealized<br>Gains<br>(Losses)<br>on<br>Securities<br>Available<br>for Sale,<br>Net of<br>Tax | Unrealized<br>Gains<br>(Losses)<br>on Cash<br>Flow<br>Hedges,<br>Net of<br>Tax | Unfunded<br>Status of<br>Postretirement<br>Benefit<br>Plans, Net of<br>Tax | Translation<br>Adjustments | Total       |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------|-------------|
| Balance, December 31, 2016                                              | \$ (10.8 )                                                                                     | \$ 57.8                                                                        | \$ (32.7 )                                                                 | \$ (334.2 )                | \$ (319.9 ) |
| Other comprehensive income (loss) before reclassifications              | (2.0 )                                                                                         | (17.1 )                                                                        | 0.1                                                                        | 20.0                       | 1.0         |
| Amounts reclassified from accumulated other comprehensive income (loss) | 0.4                                                                                            | (6.7 )                                                                         | —                                                                          | —                          | (6.3 )      |
| Net current period other comprehensive income (loss)                    | (1.6 )                                                                                         | (23.8 )                                                                        | 0.1                                                                        | 20.0                       | (5.3 )      |
| Balance, March 31, 2017                                                 | \$ (12.4 )                                                                                     | \$ 34.0                                                                        | \$ (32.6 )                                                                 | \$ (314.2 )                | \$ (325.2 ) |

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

| (In millions) | Income Statement Location | Amounts<br>Reclassified<br>from<br>Accumulated<br>Other<br>Comprehensive<br>Income<br>For the Three<br>Months |
|---------------|---------------------------|---------------------------------------------------------------------------------------------------------------|
|               |                           |                                                                                                               |

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|                                                 |                              | Ended March |          |
|-------------------------------------------------|------------------------------|-------------|----------|
|                                                 |                              | 31,         |          |
|                                                 |                              | 2018        | 2017     |
| Gains (losses) on securities available for sale | Other income (expense)       | \$(7.6 )    | \$(0.7 ) |
|                                                 | Income tax benefit (expense) | 1.6         | 0.3      |
| Gains (losses) on cash flow hedges              | Revenues                     | (32.9 )     | 6.7      |
|                                                 | Operating expenses           | 1.3         | (0.1 )   |
|                                                 | Other income (expense)       | 0.1         | 0.1      |
|                                                 | Income tax benefit (expense) | 0.1         | —        |
| Total reclassifications, net of tax             |                              | \$(37.4 )   | \$6.3    |

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

| (In millions)                                         | For the Three<br>Months<br>Ended March 31, |         |
|-------------------------------------------------------|--------------------------------------------|---------|
|                                                       | 2018                                       | 2017    |
| Numerator:                                            |                                            |         |
| Net income attributable to Biogen Inc.                | \$1,172.9                                  | \$747.6 |
| Denominator:                                          |                                            |         |
| Weighted-average number of common shares outstanding  | 211.4                                      | 215.6   |
| Effect of dilutive securities:                        |                                            |         |
| Stock options and employee stock purchase plan        | —                                          | —       |
| Time-vested restricted stock units                    | 0.2                                        | 0.2     |
| Market stock units                                    | 0.1                                        | 0.1     |
| Performance stock units settled in stock              | —                                          | —       |
| Dilutive potential common shares                      | 0.3                                        | 0.3     |
| Shares used in calculating diluted earnings per share | 211.7                                      | 215.9   |

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

## 14. Share-based Payments

## Share-based Compensation Expense

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

| (In millions)                                                                       | For the Three<br>Months<br>Ended March<br>31, |         |
|-------------------------------------------------------------------------------------|-----------------------------------------------|---------|
|                                                                                     | 2018                                          | 2017    |
| Research and development                                                            | \$21.9                                        | \$18.7  |
| Selling, general and administrative                                                 | 28.5                                          | 29.4    |
| Subtotal                                                                            | 50.4                                          | 48.1    |
| Capitalized share-based compensation costs                                          | (3.4 )                                        | (2.7 )  |
| Share-based compensation expense included in total cost and expenses                | 47.0                                          | 45.4    |
| Income tax effect                                                                   | (7.6 )                                        | (12.4 ) |
| Share-based compensation expense included in net income attributable to Biogen Inc. | \$39.4                                        | \$33.0  |



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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

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

| (In millions)                                                        | For the Three<br>Months<br>Ended March<br>31, |        |
|----------------------------------------------------------------------|-----------------------------------------------|--------|
|                                                                      | 2018                                          | 2017   |
| Market stock units                                                   | \$6.1                                         | \$9.6  |
| Time-vested restricted stock units                                   | 36.1                                          | 26.9   |
| Cash settled performance units                                       | 4.3                                           | 3.5    |
| Performance units                                                    | (0.8 )                                        | 4.5    |
| Performance stock units settled in stock                             | 0.7                                           | —      |
| Performance stock units settled in cash                              | 0.1                                           | —      |
| Employee stock purchase plan                                         | 3.9                                           | 3.6    |
| Subtotal                                                             | 50.4                                          | 48.1   |
| Capitalized share-based compensation costs                           | (3.4 )                                        | (2.7 ) |
| Share-based compensation expense included in total cost and expenses | \$47.0                                        | \$45.4 |

We estimate the fair value of our obligations associated with our performance units, cash settled performance units and performance stock units settled in cash at the end of each reporting period through expected settlement. Cumulative adjustments to these obligations are recognized each quarter to reflect changes in the stock price and estimated outcome of the performance-related conditions.

**Performance Stock Units (PSUs)****PSUs Settled in Stock**

During the first quarter of 2018, we began granting awards for performance-vested restricted stock units that will settle in stock. PSUs awarded to employees have a three-year performance period and vest on the third anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment. The number of PSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of the third year of the performance period.

Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of the actual performance metric achievement. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

During the three months ended March 31, 2018, 66,000 PSUs that will settle in stock were granted at a weighted average grant date fair value of \$317.58.

**PSUs Settled in Cash**

During the first quarter of 2018, we began granting awards for performance-vested restricted stock units that will settle in cash. PSUs awarded to employees have three performance periods and vest on the third anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment. The number of PSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established when the performance objectives are defined, which will be at the beginning of each year and will end on December 31 of such year.

Participants may ultimately earn between 0% and 200% of the target number of units granted based on the degree of the actual performance metric achievement. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned. PSUs will be settled in cash based on

the 30 calendar day average closing stock price through the vesting date, once the actual vested and earned number of units is determined. Since no shares are issued, these awards do not dilute equity. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

During the three months ended March 31, 2018, 44,000 PSUs that will settle in cash were granted.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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## 15. Income Taxes

## Tax Reform

The Tax Cuts and Jobs Act of 2017 (2017 Tax Act), which was signed into law in December 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 became effective beginning in 2018. We do not recognize deferred taxes for basis differences expected to reverse as GILTI is incurred and instead account for any taxes assessed as period costs.

During the fourth quarter of 2017, we recognized within our provision for income taxes a \$1.2 billion provisional estimate under the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 118. Our provisional estimate included an amount of \$989.6 million associated with a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax), as discussed below, and \$184.0 million related to the impact of remeasuring our deferred tax balances to reflect the new federal statutory rate and other changes to U.S. tax law. During the first quarter of 2018 we recognized no significant adjustments to these estimates.

## Transition Toll Tax

The 2017 Tax Act eliminated 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 was assessed on our share of our foreign corporation's accumulated foreign earnings that were not previously taxed. Earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%.

At December 31, 2017, we considered none of our earnings to be permanently reinvested outside the U.S. and therefore recorded tax liabilities associated with an estimate of the total withholding taxes expected as a result of our repatriation of earnings. As a result, our estimate of the total withholding taxes may change as the amounts are finalized. As of March 31, 2018 and December 31, 2017, we have accrued income tax liabilities of \$989.6 million under the Transition Toll Tax. Of the amounts accrued as of March 31, 2018, approximately \$85.0 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

## Status of our Assessment

The final determination of the Transition Toll Tax and remeasurement of our deferred 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.

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.

For additional information related to the 2017 Tax Act, please read Note 17, Income Taxes, to our consolidated financial statements included in our 2017 Form 10-K.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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## Tax Rate

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

|                                            | For the Three<br>Months<br>Ended March<br>31, |         |
|--------------------------------------------|-----------------------------------------------|---------|
|                                            | 2018                                          | 2017    |
| Statutory rate                             | 21.0 %                                        | 35.0 %  |
| State taxes                                | 0.9                                           | 0.1     |
| Taxes on foreign earnings                  | (0.7 )                                        | (11.2 ) |
| Credits and net operating loss utilization | (0.8 )                                        | (0.7 )  |
| Purchased intangible assets                | 0.6                                           | 1.4     |
| Manufacturing deduction                    | —                                             | (2.1 )  |
| Other permanent items                      | 0.4                                           | 0.7     |
| Other                                      | 0.2                                           | 1.0     |
| Effective tax rate                         | 21.6 %                                        | 24.2 %  |

## Changes in Tax Rate

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in our effective tax rate was primarily due to the enactment of the 2017 Tax Act. The effects of an overall reduction in the federal statutory rate in the U.S. were partially offset by the elimination of the manufacturing deduction, the imposition of the new GILTI tax on international earnings, limits on the deductibility of certain benefits and executive compensation and a reduction in the tax benefit associated with the Orphan Drug Credit, all resulting from the 2017 Tax Act. The effective tax rate for 2017 also reflected the impact of a favorable settlement related to a state tax matter in 2017.

## Deferred Tax Assets and Liabilities

In addition to deferred tax assets and liabilities, we have recorded prepaid tax and deferred charges related to intercompany transactions. In October 2016 the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory. This new standard eliminates the deferral of the tax effects of intra-entity asset transfers other than inventory. As a result, the income tax consequences from the intra-entity transfer of an asset other than inventory and associated changes to deferred taxes will be recognized when the transfer occurs. We adopted this new standard on January 1, 2018, using the modified retrospective method, through a cumulative-effect adjustment to retained earnings as of that date. Upon adoption, we recognized additional deferred tax assets of approximately \$2.0 billion offset by a corresponding increase to deferred tax liabilities of approximately \$1.5 billion and an increase to retained earnings of approximately \$0.5 billion. We will recognize incremental deferred income tax expense thereafter as these net deferred tax assets are utilized.

## Accounting for Uncertainty in Income Taxes

We and our subsidiaries are routinely examined by various taxing authorities. We file income tax returns in various U.S. states and in U.S. federal and other foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal tax examination for years before 2013 or state, local or non-U.S. income tax examinations for years before 2010.

The Internal Revenue Service and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

## International Uncertain Tax Positions

We have made payments totaling approximately \$65 million to the Danish Tax Authority (SKAT) for assessments received for fiscal 2009, 2011 and 2013 regarding withholding taxes and the treatment of certain intercompany transactions involving a Danish affiliate and another of our affiliates. We continue to dispute the assessments for all of

these periods and believe that the positions taken in our historical filings are valid. It is reasonably possible that we will adjust the value of our uncertain tax positions related to Danish withholding taxes based on potential European court decisions expected in 2018 on similar matters.

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## BIOGEN INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## Federal and State Uncertain Tax Positions

It is reasonably possible that we will adjust the value of our uncertain tax positions related to our revenues from anti-CD20 therapeutic programs and certain transfer pricing issues as we receive additional information from various taxing authorities, including reaching settlements with such authorities.

## 16. Other Consolidated Financial Statement Detail

## Other Income (Expense), Net

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

|                                      | For the Three<br>Months<br>Ended March<br>31, |          |
|--------------------------------------|-----------------------------------------------|----------|
| (In millions)                        | 2018                                          | 2017     |
| Interest income                      | \$26.7                                        | \$16.7   |
| Interest expense                     | (50.5 )                                       | (63.4 )  |
| Gain (loss) on investments, net      | (14.4 )                                       | 2.4      |
| Foreign exchange gains (losses), net | (1.0 )                                        | 4.0      |
| Other, net                           | (1.8 )                                        | 2.3      |
| Total other income (expense), net    | \$(41.0)                                      | \$(38.0) |

## Other Current Assets

Other current assets were \$895.9 million and \$962.0 million as of March 31, 2018 and December 31, 2017, and include prepaid taxes totaling \$587.5 million and \$657.6 million, respectively.

## Accrued Expenses and Other

Accrued expenses and other consists of the following:

| (In millions)                                           | As of<br>March<br>31,<br>2018 | As of<br>December<br>31,<br>2017 |
|---------------------------------------------------------|-------------------------------|----------------------------------|
| Revenue-related reserves for discounts and allowances   | \$657.5                       | \$ 572.0                         |
| Current portion of contingent consideration obligations | 524.3                         | 844.6                            |
| Royalties and licensing fees                            | 194.6                         | 206.7                            |
| Employee compensation and benefits                      | 186.7                         | 297.7                            |
| Construction in progress                                | 178.2                         | 159.7                            |
| Collaboration expenses                                  | 176.4                         | 183.7                            |
| Other                                                   | 653.4                         | 636.9                            |
| Total accrued expenses and other                        | \$2,571.1                     | \$ 2,901.3                       |

## 17. Investments in Variable Interest Entities

## Consolidated Variable Interest Entities

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

## Neurimmune SubOne AG

In November 2007 we entered into a collaboration and license agreement with Neurimmune Subone AG (Neurimmune) for the development and commercialization of antibodies for the treatment of AD. We are responsible for the development, manufacturing and commercialization of all collaboration products. This agreement is effective for the longer of the duration of certain patents relating to a licensed product or 12 years from the first commercial sale of any product using such a licensed compound. Our anti-amyloid beta antibody, aducanumab, for the treatment of AD resulted from this collaboration.



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We consolidate the results of Neurimmune as we determined that we are the primary beneficiary of Neurimmune because we have the power through the collaboration to direct the activities that most significantly impact the entity's economic performance and we are required to fund 100% of the research and development costs incurred in support of the collaboration. Under this agreement, we are also required to pay royalties on sales of any resulting commercial products and make payments upon the achievement of certain milestone events.

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 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 amended agreement, including on potential commercial sales of aducanumab, will now range from the high single digits to low teens. As we consolidate the results of Neurimmune, we recognized this payment as a charge to noncontrolling interest in the fourth quarter of 2017 and treated it as a distribution. Under the amended agreement, we also have an option that will expire on April 30, 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.

Research and development costs for which we reimburse Neurimmune are reflected in research and development expense in our condensed consolidated statements of income. During the three months ended March 31, 2018 and 2017 amounts reimbursed were immaterial.

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

Under the terms of our collaboration agreement with Eisai Co. Ltd. (Eisai) for the joint development and commercialization of aducanumab (Aducanumab Collaboration Agreement), Eisai may elect to share in the benefit and cost associated with the royalty reductions discussed above. Eisai has elected to not share in the benefit and cost of the October 2017 royalty reduction. For additional information on our collaboration arrangement with Eisai, please read Note 18, Collaborative and Other Relationships, to these consolidated financial statements.

**Unconsolidated Variable Interest Entities**

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

As of March 31, 2018 and December 31, 2017, the carrying value of our investments in biotechnology companies totaled \$28.5 million and \$48.3 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

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

For additional information on our investments in Neurimmune and other variable interest entities, please read Note 19, Investments in Variable Interest Entities, to our consolidated financial statements included in our 2017 Form 10-K.



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18. Collaborative and Other Relationships

AbbVie Inc.

We have a collaboration agreement with AbbVie Inc. (AbbVie) for the development and commercialization of ZINBRYTA, which was approved for the treatment of relapsing forms of MS in the U.S. in May 2016 and in the E.U. in July 2016. In March 2018 we and AbbVie announced the voluntary withdrawal of ZINBRYTA for relapsing MS, as discussed below.

Under this agreement, we and AbbVie conducted ZINBRYTA co-promotion activities in the U.S., E.U. and Canadian territories (Collaboration Territory) where development and commercialization costs and profits were shared equally. Outside of the Collaboration Territory, we were solely responsible for development and commercialization of ZINBRYTA and paid a tiered royalty to AbbVie as a percentage of net sales in the low to high teens.

Article 20 Procedure and Voluntary Withdrawal of ZINBRYTA

In July 2017 the European Medicines Agency (EMA) announced a review (referred to as an Article 20 Procedure) of the use of ZINBRYTA following the report of a case of fatal fulminant liver failure, as well as four cases of serious liver injury, and recommended restrictions on its use. In January 2018 the European Commission (EC) adopted a final and legally-binding decision restricting ZINBRYTA's 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. For additional information on the Article 20 Procedure of ZINBRYTA please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

The EMA subsequently started a second review following cases of serious inflammatory brain disorders including encephalitis and meningoencephalitis. In parallel, we and AbbVie began discussions with the EMA, and in March 2018 announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing MS as we and AbbVie believe that characterizing the complex and evolving benefit/risk profile of ZINBRYTA will not be possible going forward given the limited number of patients being treated. Subsequent to the voluntary worldwide withdrawal of ZINBRYTA, the EMA recommended the immediate suspension of ZINBRYTA's marketing authorization and a recall of ZINBRYTA from pharmacies and hospitals in the E.U. As a result of our voluntary withdrawal of ZINBRYTA, we recognized \$2.4 million in inventory charges and \$12.8 million in losses related to the termination of research and development contracts and clinical trials related to our voluntary worldwide withdrawal of ZINBRYTA in our condensed consolidated statements of income, net of an expected AbbVie reimbursement, in the first quarter of 2018.

Co-promotion Profits and Losses

In the U.S. for the three months ended March 31, 2018, we recognized a net reduction in revenues of \$4.9 million to reflect our share of an overall net loss within the collaboration, as compared to \$5.9 million in the prior year comparative period. These results include the collaboration's estimate of future returns of product in the U.S.

In the E.U. and Canada, for the three months ended March 31, 2018, we recognized net income of \$1.3 million to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada. These results include the collaboration's estimate of future returns of product in the E.U. and Canada. For the three months ended March 31, 2017, our recognition of income to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada was not significant.

For additional information on our collaboration arrangement with AbbVie, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

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Eisai Co., Ltd.

**BAN2401 and E2609 Collaboration**

We have a collaboration agreement with Eisai to jointly develop and commercialize E2609, a BACE inhibitor, and BAN2401, a monoclonal antibody that targets amyloid beta aggregates, two Eisai product candidates for the treatment of AD. Eisai serves as the global operational and regulatory lead for both compounds with all costs, including research, development and sales and marketing expenses shared equally by us and Eisai; and, if applicable, following marketing approval in major markets, such as the U.S., the E.U. and Japan, we and Eisai will co-promote BAN2401 and E2609 and share profits equally. In smaller markets, Eisai will distribute these products and pay us a royalty.

During the three months ended March 31, 2018, \$26.1 million was reflected in research and development expense in our condensed consolidated statements of income related to the advancement of our E2609 and BAN2401 programs, as compared to \$20.8 million in the prior year comparative period.

**Aducanumab Collaboration Agreement**

We also have the Aducanumab Collaboration Agreement with Eisai for the joint development and commercialization of aducanumab. Under the Aducanumab Collaboration Agreement, we will continue to lead the on-going Phase 3 development of aducanumab and will remain responsible for 100% of development costs for aducanumab incurred in support of this agreement 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. During the three months ended March 31, 2018, \$63.6 million was reflected in research and development expense in our condensed consolidated statements of income related to the advancement of our aducanumab program, as compared to \$53.3 million in the prior year comparative period.

We and Eisai also 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.

For additional information on our collaboration arrangements with Eisai, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

**Samsung Bioepis**

**Joint Venture Agreement**

In February 2012 we entered into a joint venture agreement with Samsung Biologics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. As of March 31, 2018, our ownership interest was approximately 5%, which reflects the effect of additional equity financings in which we did not participate. We maintain an option to purchase additional stock in Samsung Bioepis that would allow us to increase our ownership percentage to 49.9%. The exercise of this option is within our control and is based on paying for 49.9% of the total investment made by Samsung Biologics into Samsung Bioepis in excess of what we have already contributed under the joint venture agreement plus a rate that will represent their return on capital. If we do not exercise this option by mid-2018, this option will expire and Samsung Biologics will have the right to purchase all of Samsung Bioepis' shares then held by us. Should we exercise this option, our ownership percentage would increase to 49.9%.

We recognize our share of the results of operations related to our investment in Samsung Bioepis one quarter in arrears when the results of the entity become available, which is reflected as equity in loss of investee, net of tax in our condensed consolidated statements of income. During 2015, as our share of losses exceeded the carrying value of our investment, we suspended recognizing additional losses and will continue to do so unless we commit to providing additional funding.

**Commercial Agreement**

We began to recognize revenues on sales of BENEPALI and FLIXABI in the E.U. in the first and third quarters of 2016, respectively. We reflect revenues on sales of BENEPALI and FLIXABI to third parties in product revenues, net

in our condensed consolidated statements of income and record the related cost of revenues and sales and marketing expenses in our condensed consolidated statements of income to their respective line items when these costs are incurred. In August 2017 the EC granted a marketing authorization in the E.U. for IMRALDI, an adalimumab biosimilar referencing HUMIRA.

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In April 2018 we and Samsung Bioepis announced an agreement with AbbVie for the commercialization of IMRALDI. Under the terms of the agreement, AbbVie will grant patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we and Samsung Bioepis will make royalty payments to AbbVie. We expect to launch IMRALDI in Europe in October 2018.

We share 50% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income. For the three months ended March 31, 2018, we recognized net expense of \$43.8 million to reflect Samsung Bioepis's 50% sharing of the net collaboration profits, as compared to \$20.8 million in the prior year comparative period.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a license agreement, a technical development services agreement and a manufacturing agreement with Samsung Bioepis. For the three months ended March 31, 2018, we recognized \$17.9 million in revenues in relation to these services, which is reflected as a component of other revenues in our condensed consolidated statements of income, as compared to \$2.2 million in the prior year comparative period.

For additional information on to these and our other significant collaboration arrangements, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

19. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read Note 1, Summary of Significant Accounting Policies, to our consolidated financial statements included in our 2017 Form 10-K.

With respect to some loss contingencies, an estimate of the possible loss or range of loss cannot be made until management has further information, including, for example, (i) which claims, if any, will survive dispositive motion practice; (ii) information to be obtained through discovery; (iii) information as to the parties' damages claims and supporting evidence; (iv) the parties' legal theories; and (v) the parties' settlement positions.

The claims and legal proceedings in which we are involved also include challenges to the scope, validity or enforceability of the patents relating to our products, pipeline or processes, and challenges to the scope, validity or enforceability of the patents held by others. These include claims by third parties that we infringe their patents. An adverse outcome in any of these proceedings could result in one or more of the following and have a material impact on our business or consolidated results of operations and financial position: (i) loss of patent protection; (ii) inability to continue to engage in certain activities; and (iii) payment of significant damages, royalties, penalties and/or license fees to third parties.

Loss Contingencies

Qui Tam Litigation

In July 2015 a qui tam action filed on behalf of the United States and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts, and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. Our motion to dismiss is pending. The United States has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

Securities Litigation

We and certain current and former officers are defendants in an action filed by a shareholder in October 2016 in the U.S. District Court for the District of Massachusetts alleging violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeking a declaration of the action as a class action and an award of damages, interest and attorneys' fees. In March 2018 the court dismissed the complaint with prejudice. An estimate of the possible loss or range of loss cannot be made at this time.



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Other Matters

Abbreviated New Drug Application (ANDA) Litigation relating to TECFIDERA

In June, July and September 2017, January, March and April 2018, we initiated patent infringement proceedings pursuant to the Hatch-Waxman act in the U.S. District Court for the District of Delaware against Amneal Pharmaceuticals LLC, Aurobindo Pharma U.S.A., Inc., Caribe Holdings (Cayman) Co. Ltd. DBA Puracap Caribe, Graviti Pharmaceuticals Pvt. Ltd., Hetero USA, Inc., Impax Laboratories, Inc., Princeton Pharmaceutical Inc., Slayback Pharma LLC, Teva Pharmaceuticals USA, Inc., Alkem Laboratories Ltd., Cipla Limited, Glenmark Pharmaceuticals Ltd., Lupin Atlantis Holdings SA, Macleods Pharmaceuticals, Ltd., MSN Laboratories Pvt. Ltd., Pharmathen S.A., Shilpa Medicare Limited, Sun Pharma Global FZE, Torrent Pharmaceuticals Ltd., TWi Pharmaceuticals, Inc., Windlas Healthcare Pvt. Ltd., Accord Healthcare Inc., Par Pharmaceutical Inc., Sandoz Inc., Sawai USA, Inc., Zydus Pharmaceuticals (USA) Inc. and Banner Life Sciences LLC. In addition, we initiated patent infringement proceedings pursuant to the Hatch-Waxman act against Stason Pharmaceuticals, Inc. in the U.S. District Court for the Central District of California, Zydus Pharmaceuticals (USA) Inc. in the U.S. District Court for the District of New Jersey, Accord Healthcare Inc. in the U.S. District Court for the Middle District of North Carolina, Par Pharmaceutical Inc. in the U.S. District Court for the Southern District of New York, Sandoz Inc. in the U.S. District Court for the District of Colorado and Mylan Pharmaceuticals Inc. in the U.S. District Court for the Northern District of West Virginia. The cases against Accord Healthcare Inc., Zydus Pharmaceuticals (USA) Inc. and Sandoz Inc. have been dismissed in the North Carolina, New Jersey and Colorado courts but will continue against those parties in Delaware. The cases against Par Pharmaceutical Inc. in both New York and Delaware have been dismissed because Par Pharmaceutical Inc.'s ANDA application has been withdrawn. The case against Stason Pharmaceuticals, Inc. in California has been dismissed, but the case against its partner Sawai USA, Inc. will proceed in Delaware.

A trial has been set in the Delaware actions in December 2019 against all parties other than Banner Life Sciences LLC, and a trial has been set in the West Virginia action in February 2020.

Interference Proceeding with Forward Pharma

In April 2015 the U.S. Patent and Trademark Office (USPTO) declared an interference between Forward Pharma's pending U.S. Patent Application No. 11/576,871 and our U.S. Patent No. 8,399,514 (the '514 patent). The '514 patent includes claims covering the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. In March 2017 the USPTO ruled against Forward Pharma. Forward Pharma has appealed to the U.S. Court of Appeals for the Federal Circuit and oral argument has been set for June 2018. For additional information on this matter, please read Note 6, Intangibles Assets and Goodwill, to these condensed consolidated financial statements.

European Patent Office Oppositions

In 2016 the EPO decided to revoke our European patent number 2 137 537 (the '537 patent), which we have appealed. The '537 patent includes claims covering the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label.

In March 2018 the EPO issued its decision revoking Forward Pharma's European Patent No. 2 801 355, which was issued in May 2015 and expires in October 2025. Forward Pharma has stated that it expects to file an appeal to the Technical Board of Appeal of the EPO. The settlement and license agreement that we entered with Forward Pharma in January 2017 did not resolve the issues pending in this proceeding and we and Forward Pharma intend to permit the Technical Board of Appeal and the Enlarged Board of Appeal, as applicable, to make a final determination. For additional information on this matter, please read Note 6, Intangibles Assets and Goodwill, to these condensed consolidated financial statements.

Patent Revocation Matters

In November 2017 Bioeq GMBH, affiliated with the Polpharma Group, brought an action in the Polish Patent Office seeking to revoke Polish Patent Number 215263 (the Polish '263 Patent), the Polish patent corresponding to our European Patent Number 1 485 127 (the EU '127 Patent) ("Administration of agents to treat inflammation"). The Polish '263 Patent concerns administration of natalizumab (TYSABRI) to treat MS. The Polish '263 Patent was issued in

2013 and expires in February 2023. Swiss Pharma International AG, also affiliated with the Polpharma Group, filed actions in the District Court of The Hague (on January 11, 2016), the German Patents Court (on March 3, 2016) and the Commercial Court of Rome (November 2017) seeking to invalidate the Dutch, German and Italian

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

counterparts of the EU '127 Patent, which was issued in 2011 and also concerns administration of natalizumab (TYSABRI) to treat MS. The EU '127 Patent expires in February 2023. The Dutch counterpart was ruled invalid and we have appealed. In January 2018 the German court announced that the German counterpart was invalid. No date for a hearing on the merits has been set in the Italian action.

'755 Patent Litigation

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

Bayer, Pfizer, Novartis and EMD Serono have all filed counterclaims seeking declaratory judgments of patent invalidity and non-infringement, and seeking monetary relief in the form of costs and attorneys' fees.

In February 2018 a jury found that EMD Serono and Pfizer infringed the '755 patent but that the '755 Patent was invalid under the law of anticipation. Biogen, EMD Serono and Pfizer have filed motions for judgment as a matter of law and these motions are pending. A trial date against Bayer and Novartis has not yet been set.

Government Matters

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

We have received subpoenas and other requests from the federal government for documents and information relating to our relationship with non-profit organizations that provide assistance to patients taking drugs sold by Biogen and Biogen's co-pay assistance programs. We are cooperating with the government.

In July 2016 we received civil investigative demands from the federal government for documents and information relating to our treatment of certain service agreements with wholesalers when calculating and reporting Average Manufacturer Prices in connection with the Medicaid Drug Rebate Program. We are cooperating with the government. In July 2017 we learned that the Prosecution Office of Milan is investigating our interactions with certain healthcare providers in Italy. We are cooperating with the government.

Tax Matter

In April 2018 the tax authority of the State of Goias, Brazil issued assessments for the period January 2016 through February 2018 relating to tax on the circulation of goods and totaling approximately \$30.0 million including interest and penalties. We dispute the assessments. We are unable to provide an estimate of the potential loss or range of loss at this time.

Product Liability and Other Legal Proceedings

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



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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

20. Subsequent Events

Pfizer Inc.

In April 2018 we completed an agreement to acquire from Pfizer BIIB104 (formerly known as PF-04958242), a first-in-class, Phase 2b ready AMPA receptor potentiator for cognitive impairment associated with schizophrenia (CIAS). AMPA receptors mediate fast excitatory synaptic transmission in the central nervous system, a process which can be disrupted in a number of neurological and psychiatric diseases, including schizophrenia.

In connection with the closing of this transaction in the second quarter of 2018, we made an upfront payment of \$75.0 million. We may also pay Pfizer up to \$515.0 million in additional development and commercialization milestone payments, including \$10.0 million upon the dosing of the first patient in Phase 2b, as well as tiered royalties in the low to mid-teen percentages.

Ionis Pharmaceuticals, Inc.

In April 2018 we entered into a new ten-year exclusive collaboration agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases. Under this agreement, we will make an upfront payment of \$375.0 million and purchase \$500.0 million of Ionis' common stock, at a 25% premium based on the closing price of Ionis's common stock for the 10 days prior to the date of this agreement, for a total payment of \$1.0 billion. The premium paid on the equity will be recorded as research and development expense in our condensed consolidated statements of income. We have the option to license therapies arising out of this collaboration and will be responsible for the development and commercialization of such therapies. We may pay development milestones to Ionis of up to \$125.0 million or \$270.0 million, depending on the indication, and royalties on net sales.

The transaction is subject to customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S., and is expected to close in the second quarter of 2018.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements (condensed consolidated financial statements) and accompanying notes beginning on page 5 of this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017 (2017 Form 10-K).

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 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 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 (PPMS) and relapsing MS (RMS) and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. In March 2018 we and AbbVie Inc. (AbbVie) announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing MS. For additional information on our voluntary withdrawal of ZINBRYTA, please read Note 18, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Our current revenues depend upon continued sales of our principal products and, unless we develop, acquire rights to and/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 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.

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

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## Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was \$5.54 for the three months ended March 31, 2018, representing an increase of 60.1% over the same period in 2017.

As described below under "Results of Operations," our income from operations for the three months ended March 31, 2018, reflects the following:

Total revenues were \$3,131.1 million for the first quarter of 2018, representing an increase of 11.4% over the same period in 2017.

Product revenues, net totaled \$2,523.5 million for the first quarter of 2018, representing an increase of 6.0% over the same period in 2017. This increase was primarily driven by revenues from SPINRAZA and BENEPALI and the positive impact of foreign currency exchange gains of \$93.2 million, partially offset by comparative net losses of \$39.6 million recognized under our foreign currency hedging program. These increases were partially offset by a net decrease in MS revenues, primarily due to the recognition in the prior year period of approximately \$45.0 million of previously deferred TYSABRI revenues in Italy relating to the pricing agreement with the Italian National Medicines Agency (Agenzia Italiana del

Farmaco, or AIFA) and a decrease of approximately \$40.0 million of inventory in the channel in the U.S. Product revenues, net, compared to the same period in 2017, were also negatively impacted by the elimination of worldwide ELOCTATE and ALPROLIX revenues resulting from the spin-off of our hemophilia business on February 1, 2017. Revenues from anti-CD20 therapeutic programs totaled \$443.2 million for the first quarter of 2018, representing an increase of 30.1% over the same period in 2017. This increase was primarily driven by royalty revenues on sales of OCREVUS.

Other revenues totaled \$164.4 million for the first quarter of 2018, representing an increase of 82.7% from the same period in 2017. This increase was primarily due to higher contract manufacturing revenues related to the volume of shipments of drug product and drug substance production provided to our strategic partners.

Total cost and expenses totaled \$1,596.4 million for the first quarter of 2018, representing a decrease of 10.6% from the same period in 2017. This decrease was primarily driven by the prior year amortization and impairment charges related to our U.S. and rest of world licenses to Forward Pharma A/S's (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, partially offset by a 17.3% increase in research and development and a 16.0% increase in cost of sales.

Net income attributable to Biogen Inc. was also favorably impacted by a decrease in our effective tax rate to 21.6% for the three months ended March 31, 2018, from 24.2% for the same period in 2017, primarily due to the favorable impact resulting from the enactment of the Tax Cuts and Jobs Act of 2017 (2017 Tax Act) in December 2017.

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

We generated \$1,457.1 million of net cash flows from operations, which were primarily driven by earnings.

Cash, cash equivalents and marketable securities totaled approximately \$7.1 billion as of March 31, 2018.

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We repurchased approximately 0.9 million shares of common stock at a cost of \$250.0 million during the first quarter of 2018 under the share repurchase program authorized by our Board of Directors in July 2016, which allows us to repurchase up to \$5.0 billion of our common stock (2016 Share Repurchase Program).

### Acquisitions

#### BIIB100 Acquisition

In January 2018 we acquired the exclusive worldwide rights to develop and commercialize Karyopharm's Phase 1 ready investigational oral compound BIIB100 (formerly known as KPT-350) for the treatment of certain neurological and neurodegenerative conditions, primarily in ALS. BIIB100 is a novel therapeutic candidate that works by inhibiting a protein known as XPO1, with the goal of reducing inflammation and neurotoxicity, along with increasing neuroprotective responses.

#### BIIB104 Acquisition

In April 2018 we completed an agreement to acquire from Pfizer Inc. (Pfizer) BIIB104 (formerly known as PF-04958242), a first-in-class, Phase 2b ready AMPA receptor potentiator for cognitive impairment associated with schizophrenia (CIAS). AMPA receptors mediate fast excitatory synaptic transmission in the central nervous system, a process which can be disrupted in a number of neurological and psychiatric diseases, including schizophrenia.

#### Ionis Pharmaceuticals, Inc.

In April 2018 we entered into a new ten-year exclusive collaboration agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases. For additional information on our transaction with Karyopharm, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report. For additional information on our transactions with Pfizer and Ionis, please read Note 20, Subsequent Events, to our condensed 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 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 condensed 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 3. Quantitative and Qualitative Disclosures About Market Risk included in this report.

### Key Pipeline and Product Developments

#### ZINBRYTA (daclizumab)

During the first quarter of 2018, the European Medicine's Agency (EMA) started a review of ZINBRYTA following cases of serious inflammatory brain disorders including encephalitis and meningoencephalitis. In parallel, we and AbbVie began discussions with the EMA and in March 2018 announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing MS as we and AbbVie believe that characterizing the complex and evolving benefit/risk profile of ZINBRYTA will not be possible going forward given the limited number of patients being treated.

Subsequent to the voluntary worldwide withdrawal of ZINBRYTA, the EMA recommended the immediate suspension of ZINBRYTA's marketing authorization and a recall of ZINBRYTA from pharmacies and hospitals in the E.U.

TYSABRI (natalizumab)

In February 2018 we announced that the Phase 2b dose-ranging ACTION 2 study investigating natalizumab in individuals with acute ischemic stroke (AIS) did not meet its primary endpoint. Based on

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these results, we have discontinued development of natalizumab in AIS. The results of the Phase 2b ACTION 2 study do not impact the benefit-risk profile of natalizumab in approved indications, including MS.

**IMRALDI**

In April 2018 we and Samsung Bioepis announced an agreement with AbbVie for the

commercialization of IMRALDI, an adalimumab biosimilar referencing HUMIRA. Under the terms of the agreement, AbbVie will grant patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we and Samsung Bioepis will make royalty payments to AbbVie. We expect to launch IMRALDI in Europe in October 2018.

**Results of Operations****Revenues**

Revenues are summarized as follows:

| (In millions, except percentages)            | For the Three Months<br>Ended March 31, |        |           |        |
|----------------------------------------------|-----------------------------------------|--------|-----------|--------|
|                                              | 2018                                    |        | 2017      |        |
| Product revenues:                            |                                         |        |           |        |
| United States                                | \$1,538.0                               | 49.1 % | \$1,631.0 | 58.0 % |
| Rest of world                                | 985.5                                   | 31.5 % | 749.1     | 26.7 % |
| Total product revenues                       | 2,523.5                                 | 80.6 % | 2,380.1   | 84.8 % |
| Revenues from anti-CD20 therapeutic programs | 443.2                                   | 14.2 % | 340.6     | 12.1 % |
| Other revenues                               | 164.4                                   | 5.3 %  | 90.0      | 3.2 %  |
| Total revenues                               | \$3,131.1                               | 100.0% | \$2,810.7 | 100.0% |

**Product Revenues**

Product revenues are summarized as follows:

| (In millions, except percentages) | For the Three Months<br>Ended March 31, |        |           |        |
|-----------------------------------|-----------------------------------------|--------|-----------|--------|
|                                   | 2018                                    |        | 2017      |        |
| Multiple Sclerosis:               |                                         |        |           |        |
| TECFIDERA                         | \$986.9                                 | 39.1 % | \$958.2   | 40.3 % |
| Interferon*                       | 550.3                                   | 21.8 % | 648.3     | 27.2 % |
| TYSABRI                           | 462.1                                   | 18.3 % | 545.0     | 22.9 % |
| FAMPYRA                           | 24.4                                    | 1.0 %  | 20.5      | 0.9 %  |
| ZINBRYTA                          | 1.4                                     | 0.1 %  | 10.7      | 0.4 %  |
| Spinal Muscular Atrophy:          |                                         |        |           |        |
| SPINRAZA                          | 363.9                                   | 14.4 % | 47.4      | 2.0 %  |
| Hemophilia:                       |                                         |        |           |        |
| ELOCTATE                          | —                                       | — %    | 48.4      | 2.0 %  |
| ALPROLIX                          | —                                       | — %    | 26.0      | 1.1 %  |
| Other Product Revenues:           |                                         |        |           |        |
| FUMADERM                          | 7.0                                     | 0.3 %  | 9.7       | 0.4 %  |
| BENEPALI                          | 120.9                                   | 4.8 %  | 65.3      | 2.7 %  |
| FLIXABI                           | 6.6                                     | 0.3 %  | 0.6       | — %    |
| Total product revenues            | \$2,523.5                               | 100.0% | \$2,380.1 | 100.0% |

\*Interferon includes AVONEX and PLEGRIDY.

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Multiple Sclerosis (MS)

TECFIDERA

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in U.S. TECFIDERA revenues was primarily due to a decrease in unit sales volume of 6% and an increase in discounts and allowances, partially offset by gross selling price increases.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume of 22% in existing markets and new markets where we continue to launch the product and expand our presence around the world. Rest of world TECFIDERA revenues for 2018, compared to the same period in 2017, were also positively impacted by foreign currency exchange gains of \$26.6 million, partially offset by comparative net losses of \$14.9 million recognized under our foreign currency hedging program.

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 the three months ended March 31, 2018, compared to the same period in 2017, the decrease in U.S. Interferon revenues was primarily due to an overall decrease in Interferon unit sales volume of 21%, which was primarily attributable to patients transitioning to other MS therapies, partially offset by gross selling price increases.

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in rest of world Interferon revenues was primarily due to an overall decrease in AVONEX unit sales volume of 9%, primarily due to patients transitioning to other MS therapies in the E.U. Rest of world Interferon revenues for 2018, compared to the same period in 2017, were positively impacted by foreign currency exchange gains of \$21.9 million, partially offset by comparative net losses of \$10.8 million recognized under our foreign currency hedging program.

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.

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**TYSABRI**

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in U.S. TYSABRI revenues was primarily due to a decrease in unit sales volume of 13%, partially offset by gross selling price increases. For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in rest of world TYSABRI revenues was primarily due to the recognition in the prior year period of approximately \$45.0 million of previously deferred revenues in Italy relating to the pricing agreement with AIFA, as discussed below. Rest of world TYSABRI revenues for 2018, compared to the same period in 2017, were positively impacted by foreign currency exchange gains of \$29.7 million, partially offset by comparative net losses of \$12.7 million recognized under our foreign currency hedging program.

In the first quarter of 2017 we reached an agreement with AIFA's Price and Reimbursement Committee resolving all of AIFA's claims relating to sales of TYSABRI in excess of the reimbursement limit for prior periods. For information regarding 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 our 2017 Form 10-K.

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, exceeding 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 the three months ended March 31, 2018, compared to the same period in 2017, the decrease in ZINBRYTA revenues was primarily due to the worldwide voluntary withdrawal of ZINBRYTA for relapsing MS.

For additional information on our relationship with AbbVie, please read Note 18, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.



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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 in the rest of world in the first quarter of 2017.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in U.S. and rest of world SPINRAZA revenues was due to an increase in unit sales volume.

We expect that the rate at which SPINRAZA revenues will grow will moderate over time primarily due to a lower rate of new patient starts combined with the impact of loading dose 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 our 2017 Form 10-K.

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 the three months ended March 31, 2018, compared to the same period in 2017, the increase in biosimilar revenues was primarily due to an increase in BENEPALI unit sales volume of 87% in new and existing markets and foreign currency exchange gains, partially offset by price decreases in certain European countries.

For additional information on our relationship with Samsung Bioepis, please read Note 18, Collaborative and Other Relationships, to our condensed 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 tables provide a summary of amounts comprising our share of pre-tax profits on RITUXAN and GAZYVA in the U.S.:

| (In millions)                     | For the Three<br>Months<br>Ended March 31, |            |
|-----------------------------------|--------------------------------------------|------------|
|                                   | 2018                                       | 2017       |
| Product revenues, net             | \$ 1,096.2                                 | \$ 1,041.0 |
| Cost and expenses                 | 153.7                                      | 201.3      |
| Pre-tax profits in the U.S.       | 942.5                                      | 839.7      |
| Biogen's share of pre-tax profits | \$ 349.6                                   | \$ 323.5   |

Our share of RITUXAN annual pre-tax co-promotion profits in the U.S. in excess of \$50.0 million 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.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in U.S. product revenues was primarily due to selling price increases, an increase in RITUXAN unit sales volume of 1% and an increase in GAZYVA unit sales volume of 19%, partially offset by higher discounts and allowances.

Collaboration costs and expenses for the three months ended March 31, 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 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 the first quarter of 2017, representing Genentech's estimate of our share of these expenses. We remain in discussions with Genentech about a resolution relating to these amounts.

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in collaboration costs and expenses was primarily due to lower RITUXAN cost of sales and a decrease in GAZYVA and RITUXAN research and development costs.

## Other Revenues from Anti-CD20 Therapeutic Programs

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

For the three months ended March 31, 2018, compared to the same period in 2017, other revenues from anti-CD20 therapeutic programs increased primarily due to the launch of OCREVUS in the second quarter of 2017. Royalty revenues on sales of OCREVUS totaled \$76.7 million in the first quarter of 2018.

## OCREVUS

In March 2017 the U.S. Food and Drug Administration (FDA) approved OCREVUS, a humanized anti-CD20 monoclonal antibody, for the treatment of RMS and PPMS. Under the terms of 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 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.



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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 our 2017 Form 10-K.

**Other Revenues**

Other revenues are summarized as follows:

| (In millions, except percentages)                   | For the Three Months<br>Ended March 31, |         |        |         |  |  |
|-----------------------------------------------------|-----------------------------------------|---------|--------|---------|--|--|
|                                                     | 2018                                    |         | 2017   |         |  |  |
| Revenues from collaborative and other relationships | \$13.2                                  | 8.0 %   | \$6.3  | 7.0 %   |  |  |
| Other royalty and corporate revenues                | 151.2                                   | 92.0 %  | 83.7   | 93.0 %  |  |  |
| Total other revenues                                | \$164.4                                 | 100.0 % | \$90.0 | 100.0 % |  |  |

**Revenues from Collaborative and Other Relationships**

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, revenues from our technical development and manufacturing services agreements with Samsung Bioepis and royalty revenues on biosimilar products from Samsung Bioepis.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in revenues from collaborative and other relationships was primarily due to higher revenues earned under our manufacturing services agreement with Samsung Bioepis.

For additional information on our collaborative and other relationships, please read Note 18, Collaborative and Other Relationships, to our condensed 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 the three months ended March 31, 2018, compared to the same period in 2017, the increase in royalty and other corporate revenues was primarily due to higher contract manufacturing revenues related to the volume of shipments of drug product and drug substance production provided to our strategic partners.

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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 three months ended March 31, 2018, reserves for discounts and allowances as a percentage of gross product revenues were 24.3%, as compared to 22.8% in the prior year comparative period.

### Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in discounts was primarily driven by an increase in rest of world product revenues, due in part to an increase in biosimilar revenues. This increase was partially offset by the impact from the spin-off of our hemophilia business on February 1, 2017.

### Contractual Adjustments

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

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in contractual adjustments was primarily due to higher managed care rebates and co-payment assistance in the U.S. and other governmental rebates and allowances in the U.S. and rest of world, due in part to an increase in SPINRAZA sales volumes worldwide and an increase in gross selling prices in the U.S.

### 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 recognized in the period the related revenues are recognized, resulting in a reduction to product sales.

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in return reserves was primarily due to our voluntary worldwide withdrawal of ZINBRYTA. For additional information on our voluntary worldwide withdrawal of ZINBRYTA, please read Note 18, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

For additional information on our revenue reserves, please read Note 4, Revenues, to our condensed 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 Three Months |           |           |
|---------------------------------------------------------------------|----------------------|-----------|-----------|
|                                                                     | Ended March 31,      |           |           |
|                                                                     | 2018                 | 2017      | Change %  |
| Cost of sales, excluding amortization of acquired intangible assets | \$446.0              | \$384.6   | 16.0 %    |
| Research and development                                            | 496.7                | 423.4     | 17.3 %    |
| Selling, general and administrative                                 | 501.3                | 498.7     | 0.5 %     |
| Amortization of acquired intangible assets                          | 103.9                | 448.5     | (76.8 )%  |
| Collaboration profit (loss) sharing                                 | 42.5                 | 20.8      | 104.3 %   |
| Acquired in-process research and development                        | 10.0                 | —         | **        |
| (Gain) loss on fair value remeasurement of contingent consideration | (5.6 )               | 10.0      | (156.0 )% |
| Restructuring charges                                               | 1.6                  | —         | **        |
| Total cost and expenses                                             | \$1,596.4            | \$1,786.0 | (10.6 )%  |

\*\* Percentage not meaningful.

## Cost of Sales, Excluding Amortization of Acquired Intangible Assets

## Product Cost of Sales

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in product cost of sales was primarily driven by higher biosimilar sales, higher contract manufacturing shipments of drug product and drug substance production provided to our strategic partners and an increase in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons.

## Royalty Cost of Sales

For the three months ended March 31, 2018, compared to the same period in 2017, royalty cost of sales were relatively consistent with prior year amounts as the recognition of royalties payable to Ionis on sales of SPINRAZA were offset by the expiration of certain third-party royalties related to sales of TYSABRI.

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Research and Development

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

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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 the three months ended March 31, 2018, compared to the same period in 2017, the increase in research and development expense was primarily related to an increase in costs incurred in connection with our early and late stage programs, partially offset by a decrease in costs incurred with our marketed products and other research and development costs.

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.

### Early Stage Programs

The increase in spending associated with early stage programs for the three months ended March 31, 2018, compared to the same period in 2017, was primarily related to spending associated with the development of BIIB092 in AD and progressive supranuclear palsy pursuant to our license agreement with Bristol-Myers Squibb Company, the development of opicinumab in MS and the development of BIIB093 in large hemispheric infarction.

### Late Stage Programs

The increase in spending associated with our late stage programs for the three months ended March 31, 2018, compared to the same period in 2017, was primarily related to increased costs associated with the development of aducanumab and E2609, a BACE inhibitor, in AD and the development of BIIB098 in MS pursuant to our license and collaboration agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc.

### Marketed Products

The decrease in spending associated with our marketed products for the three months ended March 31, 2018, compared to the same period in 2017, was primarily related to a decrease in costs associated with our MS projects, partially offset by costs related to the termination of research and development contracts and clinical trials due to our voluntary worldwide withdrawal of ZINBRYTA.

### Selling, General and Administrative

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in selling, general and administrative expenses was primarily due to an increase in operational spending on sales and marketing activities in support of our marketed products, including increased commercialization costs related to SPINRAZA, partially offset by a decrease in corporate giving and a reduction in operational spending resulting from the spin-off of our hemophilia business.

### 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.



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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 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.

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 the three months ended March 31, 2018, compared to the same period in 2017, the decrease in amortization of acquired intangible assets was primarily due to the prior year impairment charge 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, as discussed below.

**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.

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 March 2018 the European Patent Office (EPO) issued 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 condensed consolidated statements of income utilizing an economic consumption model.

For additional information on these disputes, please read Note 21, Litigation, to our consolidated financial statements included in our 2017 Form 10-K.

**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 one 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 trigeminal neuralgia (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 amortization and impairment of our acquired intangible assets, including our TECFIDERA settlement and license agreement, please read Note 6, Intangible Assets and Goodwill, to our condensed consolidated financial statements included in this report.

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Acquired In-Process Research and Development

Karyopharm Therapeutics Inc.

In January 2018 we completed an asset purchase of investigational oral compound BIIB100, from Karyopharm. In connection with the closing of this transaction, we made an upfront payment of \$10.0 million to Karyopharm, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB100 has not yet reached technological feasibility.

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

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.

For the three months ended March 31, 2018, we shared biosimilar collaboration profits with Samsung Bioepis and therefore recognized net expense of \$43.8 million, as compared to \$20.8 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.

For the three months ended March 31, 2018, we recognized net income of \$1.3 million to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada. Our recognition of income to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada for the three months ended March 31, 2017 was not significant.

For additional information on our agreements with Samsung Bioepis and AbbVie, please read Note 18, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

(Gain) Loss 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 loss (gain) on fair value remeasurement of contingent consideration in our condensed consolidated statements of income.

The change in fair value remeasurement of contingent consideration for the three months ended March 31, 2018, compared to the same period in 2017, was primarily due to an increase in the probability of achieving certain developmental milestones in the prior year and an increase in the interest rate used to revalue our contingent consideration liabilities for the current year.

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Restructuring charges

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.

We recognized restructuring charges of \$0.9 million in our consolidated statements of income during the fourth quarter of 2017. These restructuring charges were substantially incurred and paid in 2017 and were primarily related to severance.

For the three months ended March 31, 2018, we recognized restructuring charges of \$1.6 million in our condensed consolidated statements of income. These restructuring charges, which will be substantially incurred and paid by mid-2018, are primarily related to severance.

Other Income (Expense), Net

For the three months ended March 31, 2018, compared to the same period in 2017, the change in other income (expense), net was primarily due to an increase in losses recorded on our strategic investments upon the adoption of ASU 2016-01, the sale of marketable securities in anticipation of the repatriation of our long-term marketable securities previously held in foreign jurisdictions and an increase in foreign currency exchange losses. These changes are partially offset by a decrease in interest expense as a result of redeeming our 6.875% Senior Notes due March 1, 2018, in November 2017 and an increase in interest income due to higher cash and cash equivalents.

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.

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For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in our effective tax rate was primarily due to the enactment of the 2017 Tax Act. The effects of an overall reduction in the federal statutory rate in the U.S. were partially offset by the elimination of the manufacturing deduction, the imposition of the new GILTI tax on international earnings, limits on the deductibility of certain benefits and executive compensation and a reduction in the tax benefit associated with the Orphan Drug Credit, all resulting from the 2017 Tax Act. The effective tax rate for 2017 also reflected the impact of a favorable settlement related to a state tax matter in 2017.

For additional information on the 2017 Tax Act, our uncertain tax positions and income tax rate reconciliation for the three months ended March 31, 2018 and 2017, please read Note 15, Income Taxes, to our condensed consolidated financial statements included in this report.

## Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

| (In millions, except percentages)                      | As of<br>March 31,<br>2018 | As of<br>December<br>31,<br>2017 | Change | %  |
|--------------------------------------------------------|----------------------------|----------------------------------|--------|----|
| Financial assets:                                      |                            |                                  |        |    |
| Cash and cash equivalents                              | \$4,108.0                  | \$ 1,573.8                       | 161.0  | %  |
| Marketable securities — current                        | 1,808.0                    | 2,115.2                          | (14.5) | )% |
| Marketable securities — non-current                    | 1,200.2                    | 3,057.3                          | (60.7) | )% |
| Total cash, cash equivalents and marketable securities | \$7,116.2                  | \$ 6,746.3                       | 5.5    | %  |
| Borrowings:                                            |                            |                                  |        |    |
| Current portion of notes payable                       | \$3.3                      | \$ 3.2                           | 3.1    | %  |
| Notes payable                                          | 5,929.4                    | 5,935.0                          | (0.1)  | )% |
| Total borrowings                                       | \$5,932.7                  | \$ 5,938.2                       | (0.1)  | )% |
| Working capital:                                       |                            |                                  |        |    |
| Current assets                                         | \$10,195.4                 | \$ 7,873.3                       | 29.5   | %  |
| Current liabilities                                    | (3,152.1 )                 | (3,368.2 )                       | (6.4)  | )% |
| Total working capital                                  | \$7,043.3                  | \$ 4,505.1                       | 56.3   | %  |

For the three months ended March 31, 2018, certain significant cash flows were as follows:

\$1,457.1 million in net cash flows provided by operating activities;

\$600.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;

\$250.0 million used for share repurchases; and

\$194.7 million used for purchases of property, plant and equipment.

For the three months ended March 31, 2017, certain significant cash flows were as follows:

\$235.2 million in net cash flows provided by operating activities, net of:

\$454.8 million payment made to Forward Pharma for the litigation settlement charge that was accrued as of December 31, 2016; and

\$360.0 million in total payments for income taxes;

\$795.2 million payment made to Forward Pharma to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA;

\$583.6 million used for share repurchases;

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\$302.7 million net cash contribution made in connection with the spin-off of our hemophilia business;  
\$300.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;  
and  
\$210.0 million used for purchases of property, plant and equipment.

### Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned from 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

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

The 2017 Tax Act eliminated the deferral of U.S. income tax on the historical unrepatriated earnings by imposing a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). The Transition Toll Tax was assessed on our share of our foreign corporation's accumulated foreign earnings that were not previously taxed.

At December 31, 2017, we considered none of our earnings to be permanently reinvested outside the U.S. and therefore recorded tax liabilities associated with an estimate of the total withholding taxes expected as a result of our repatriation of earnings. As a result, our estimate of the total withholding taxes may change as the amounts are finalized. As of March 31, 2018 and December 31, 2017, we have accrued income tax liabilities of \$989.6 million under the Transition Toll Tax. Of the amounts accrued as of March 31, 2018, approximately \$85.0 million is

expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

After repatriating approximately \$3.5 billion during the first quarter of 2018 as a result of the 2017 Tax Act, approximately 85% of our total cash, cash equivalents and marketable securities at the end of the quarter were held in the U.S.

For additional information on certain risks that could negatively impact our financial position or future results of operations, please read Item 1A. Risk Factors and Item 3. Quantitative and Qualitative Disclosures About Market Risk included in this report.

### Share Repurchase Programs

In July 2016 our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2016 Share Repurchase Program). Our 2016 Share Repurchase Program does not have an expiration date. All share repurchases under our 2016 Share Repurchase Program will be retired. Under our 2016 Share Repurchase Program, we repurchased and retired 0.9 million shares of common stock at a cost of \$250.0 million during the three months ended March 31, 2018, and we repurchased and retired 0.8 million shares of common stock at a cost of \$218.2 million during the three months ended March 31, 2017. As of March 31, 2018, approximately \$2.8 billion remains available for share repurchase 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 common stock (2011 Share Repurchase Program). Shares repurchased under our 2011 Share Repurchase Program were principally used to offset common stock issuances under our share-based compensation programs. Our 2011 Share Repurchase Program was completed as of March 31, 2017. Under our 2011 Share Repurchase Program, we repurchased 1.2 million shares of common stock at a cost of \$365.4 million during the three months ended March 31, 2017.

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.

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As of March 31, 2018, we had cash, cash equivalents and marketable securities totaling approximately \$7.1 billion compared to approximately \$6.7 billion as of December 31, 2017. The net increase in cash, cash equivalents and marketable securities at March 31, 2018 from December 31, 2017, was primarily due to cash flows related to operations, partially offset by cash used for contingent payments made to former shareholders of Fumapharm AG and holders of their rights, cash used for share repurchases and net purchases of property, plant and equipment.

**Borrowings**

The following is a summary of our principal indebtedness:

\$1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020;

\$1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022;

\$1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025; and

\$1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045.

These Senior Notes were issued at a discount, which are amortized as additional interest expense over the period from issuance through maturity.

During the third quarter of 2015, we entered into a \$1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of March 31, 2018, 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 (\$3.3 million) and 3.1 million Swiss Francs (\$3.2 million) as of March 31, 2018 and December 31, 2017, respectively.

For a summary of the fair and carrying values of our outstanding borrowings as of March 31, 2018 and December 31, 2017, please read Note 7, Fair Value Measurements, to our condensed 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 March 31, 2018, from December 31, 2017, reflects an increase in total current assets of approximately \$2.3 billion and a decrease in total current liabilities of \$216.1 million.

The net increase in total current assets was primarily driven by the repatriation of our long-term marketable securities previously held in foreign jurisdictions, which were used to purchase cash equivalents and short-term marketable securities in the U.S., and an increase in accounts receivable.

The net decrease in current liabilities was primarily driven by contingent payments related to FUMADERM and TECFIDERA (together, the Fumapharm Products) totaling \$600.0 million made during the first quarter of 2018 for accruals existing at December 31, 2017. This decrease was partially offset by the accrual of an additional \$300.0 million in the first quarter of 2018 upon reaching \$17.0 billion in total cumulative sales of Fumapharm Products and an increase in income taxes payable.

**Cash Flows**

The following table summarizes our cash flow activity:

| (In millions, except percentages)                         | For the Three Months |           |           |
|-----------------------------------------------------------|----------------------|-----------|-----------|
|                                                           | Ended March 31,      |           |           |
|                                                           | 2018                 | 2017      | % Change  |
| Net cash flows provided by operating activities           | \$1,457.1            | \$235.2   | 519.5 %   |
| Net cash flows provided by (used in) investing activities | \$1,346.6            | \$(744.2) | (280.9) % |
| Net cash flows used in financing activities               | \$(268.6)            | \$(901.4) | (70.2) %  |



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### Operating Activities

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

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

- Non-cash operating items such as depreciation and amortization, impairment charges, 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 the three months ended March 31, 2018, compared to the same period in 2017, the increase in net cash flows provided by operating activities was primarily due to an increase in net income, a decrease in payments for income taxes, the timing of customer payments of accounts receivables and the \$454.8 million payment made to Forward Pharma for the litigation settlement charge in the first quarter of 2017 that was accrued as of December 31, 2016.

### Investing Activities

For the three months ended March 31, 2018, compared to the same period in 2017, the increase in net cash flows provided by investing activities was primarily due to the increase in net proceeds from the sales of marketable securities primarily due to the sale of securities in preparation for the repatriation of our long-term marketable securities previously held in foreign jurisdictions and the \$795.2 million payment made to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, in the first quarter of 2017. These amounts were partially offset by an increase in contingent payments made to former shareholders of Fumapharm AG and holders of their rights.

### Financing Activities

For the three months ended March 31, 2018, compared to the same period in 2017, the decrease in net cash flows used in financing activities was

primarily due to a decrease in cash used for share repurchases and the net cash contribution made in the prior year comparative period in connection with the spin-off of our hemophilia business.

### Contractual Obligations and Off-Balance Sheet Arrangements

#### Contractual Obligations

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, long-term debt obligations and defined benefit and other purchase obligations, 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.

There have been no material changes in our contractual obligations since December 31, 2017.

#### TYSABRI Contingent Payments

In 2013 we acquired from Elan Corporation plc (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 condensed 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 Pharmaceuticals Ltd. (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 recognized 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.

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### Fumapharm AG

In 2006 we acquired Fumapharm AG. As part of this acquisition we acquired the Fumapharm Products. We are required to make contingent payments to former shareholders of Fumapharm AG or holders of their rights based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior 12-month period, as defined in the acquisition agreement.

During the three months ended March 31, 2018, we paid \$600.0 million in contingent payments as we reached the \$15.0 billion and \$16.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2017 and accrued \$300.0 million upon reaching \$17.0 billion in total cumulative sales of Fumapharm Products in the first quarter of 2018.

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 will 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 are accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm AG. 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 March 31, 2018, we could make potential future milestone payments to third parties of up to approximately \$4.3 billion, including approximately \$0.5 billion in development milestones, approximately \$1.5 billion in regulatory milestones and approximately \$2.3 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of March 31, 2018, 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 \$50.0 million of milestone payments during the remainder of 2018.

### Other Funding Commitments

As of March 31, 2018, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We recorded accrued expenses of approximately \$55.0 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of March 31, 2018. We have approximately \$450.0 million in cancellable future commitments based on existing CRO contracts as of March 31, 2018.

### 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 March 31, 2018, we have \$89.4 million of liabilities associated with uncertain tax positions.

As of March 31, 2018 and December 31, 2017, we have accrued income tax liabilities of \$989.6 million under the Transition Toll Tax. Of the amounts accrued as of March 31, 2018, approximately \$85.0 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight-year period, which started 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.

New Accounting Standards

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

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## Critical Accounting Estimates

The preparation of our condensed 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 to be reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

## Revenue Recognition

In May 2014 the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry specific guidance. This new standard requires a company to recognize revenues when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB subsequently issued the following amendments to ASU No. 2014-09 that have the same effective date and transition date: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. We adopted these amendments with ASU 2014-09 (collectively, the new revenue standards).

The new revenue standards became effective for us on January 1, 2018, and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018, did not change our revenue recognition as the majority of our revenues continue to be recognized when the customer takes control of our product. As we did not identify any accounting changes that impacted the amount of reported revenues with respect to our product revenues, revenues from anti-CD20 therapeutic programs or other revenues, no adjustment to retained earnings was required upon

adoption. However, the adoption of the new revenue standards may result in a change in the timing of revenue recognition related to certain of our contract manufacturing activities based upon the terms of the underlying agreements.

Under the new revenue standards, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

## Product Revenues

In the U.S. we sell our products primarily to wholesale distributors and specialty pharmacy providers. In other countries, we sell our products primarily to wholesale distributors, hospitals, pharmacies and other third-party distribution partners. These customers subsequently resell our products to health care providers and patients. In addition, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and allowances related to our products.

Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

## Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Our process for estimating reserves established for these variable consideration components do not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns.

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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 of reserves established for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. 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 discounts, rebates and product returns, 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 revenues. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expenses.

For additional information on our revenues, please read Note 4, Revenues, to our condensed consolidated financial statements included in this report.

### Concentrations of Credit Risk

The majority of our accounts receivable arise from product sales and primarily represent amounts due from our wholesale and other third-party distributors, public hospitals, pharmacies and other government entities.

We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale.

In countries where we have experienced a pattern of payments extending beyond our contractual payment term and we expect to collect receivables greater than one year from the time of sale, we have assessed whether the customer has a significant financing component and discounted our receivables and reduced related revenues over the period of time that we estimate those amounts will be paid using the

country's market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets. We accrete interest income on these receivables, which is recognized as a component of other income (expense), net in our condensed consolidated statements of income.

We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve.

The adoption of the new revenue standards did not change our historical accounting methods for our accounts receivable.

For additional information on our concentrations of credit risk associated with our accounts receivable balances, please read the subsection entitled "Credit Risk" in Item 3. Quantitative and Qualitative Disclosures About Market Risk included in this report.

### Income Taxes

In October 2016 the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory. This new standard eliminates the deferral of the tax effects of intra-entity asset transfers other than inventory. As a result, the income tax consequences from the intra-entity transfer of an asset other than inventory and associated changes to deferred taxes will be recognized when the transfer occurs.

We adopted this new standard on January 1, 2018, using the modified retrospective method, through a cumulative-effect adjustment to retained earnings as of that date. We will recognize incremental deferred income tax expense as these net deferred tax assets are utilized.

For additional information on ASU 2016-16, please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements, to our condensed consolidated financial statements included in this report.

For a discussion of our critical accounting estimates, please read Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2017 Form 10-K. Except as discussed above, there

have been no material changes to these critical accounting estimates since our 2017 Form 10-K.



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## Item 3. 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 condensed 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.

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.

## 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 9, Derivative Instruments, to our condensed consolidated financial statements included in this report. Our ability to mitigate the impact of foreign currency exchange rate changes on revenues and net income diminishes as significant foreign currency 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 condensed 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 condensed consolidated statement of cash flows.

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of March 31, 2018 and December 31, 2017, a hypothetical adverse 10% movement in foreign currency exchange 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 \$267.0

million and \$286.0 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.

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### 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 March 31, 2018 and December 31, 2017, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately \$12.0 million and \$50.0 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

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 March 31, 2018 and December 31, 2017, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by \$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 include, among other things, patient access restrictions, suspensions on price increases, prospective and possible 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 condensed 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 condensed consolidated results of operations.

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

### Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale and other third-party distributors, public hospitals, pharmacies and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We operate in certain countries where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and

assess their possible impact on our business. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

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

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We believe that our allowance for doubtful accounts was adequate as of March 31, 2018 and December 31, 2017. 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 4. 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 March 31, 2018. 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 U.S. Securities and Exchange Commission'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 March 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 19, Litigation, to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

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; limitations 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.

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

- the introduction of more efficacious, safer, less expensive or more convenient alternatives to our MS products, including our own products and products of our collaborators;
- the introduction of lower-cost biosimilars, follow-on products or generic versions of branded MS products sold by our competitors, and the possibility of future competition from generic versions or prodrugs of existing therapeutics or from off-label use by physicians of therapies indicated for other conditions to treat MS patients;
- patient dynamics, including the size of the patient population and our ability to attract new patients to our therapies;
- damage to physician and patient confidence in any of our MS products or to our sales and reputation as a result of label changes or adverse experiences or events that may occur with patients treated with our MS products;
- inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key international markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our MS products.

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 adequate 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.

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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.

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 or generic or biosimilar products marketed by others 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

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our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringing product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

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

Our long-term viability and growth will depend upon successful development of additional indications for our existing products as well as successful development of new products and technologies from our research and development activities, our biosimilars joint venture with Samsung Biologics or licenses or acquisitions from third parties.

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects, result in unexpected adverse events or raise other concerns that may significantly reduce the likelihood of regulatory approval. This may result in terminated programs, significant restrictions on use and safety warnings in an approved label, adverse placement within the treatment paradigm or significant reduction in the commercial potential of the product candidate.

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

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.

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Our results of operations may be adversely affected by current and potential future healthcare reforms. In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, 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 Patient Protection and Affordable Care Act (PPACA) have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. These changes have had and are expected to continue to have a significant impact on our business.

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

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

**Global Bulk Supply Risks.** We rely on our principal manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

**Risks Relating to Compliance with current Good Manufacturing Practices (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:

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

the interests of our collaborators or third parties may not always be aligned with our interests, 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, which may prove to be an expensive and time consuming procedure, 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

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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.

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, we may 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 possible 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 European Medicines Agency'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.

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

Our effective tax rate 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 Cooperation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities in the countries in which we operate, could negatively impact our effective tax rate. These recommendations focus on payments from affiliates in high tax jurisdictions to affiliates in lower tax jurisdictions and the activities that give rise to a taxable presence in a particular country.



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Our 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;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- 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 Foreign Corrupt Practices Act (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;

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• milestone payments under license and collaboration agreements; and

• payments in connection with acquisitions and other business development activities.

Our revenues are also subject to foreign 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 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 payers do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;

• **Ability to Provide Adequate Supply.** Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet higher than anticipated demand; and

• **Competitive Challenges.** Biosimilar products face significant competition, including from innovator products and from biosimilar products offered by other companies. In some jurisdictions, local tendering processes may restrict biosimilar products from being marketed and sold in those jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective matter are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area.

Our investments in properties may not be fully realized.

We own or lease real estate primarily consisting of buildings that contain research laboratories, office space and manufacturing operations. For strategic or other operational reasons, we may decide to 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 an owned or 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 our 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. 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 January 2018 Bioverativ was acquired by Sanofi and is now an indirect wholly-owned subsidiary of Sanofi.

In connection with the spin-off, 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 intellectual property matters agreement and certain other commercial agreements). These agreements govern the relationship between us and Bioverativ going forward, including with respect to potential tax-related losses associated with the spin-off. 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.

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## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

## Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity under our 2016 Share Repurchase Program during the first quarter of 2018:

| Period        | Total Number of Shares Purchased (#) | Average Price Paid per Share (\$) | Total Number of Shares Purchased as Part of Publicly Announced Programs (#) | Maximum Approximate Dollar Value of Shares That May Yet Be Purchased Under Our Programs (\$ in millions) |
|---------------|--------------------------------------|-----------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| January 2018  | —                                    | \$ —                              | —                                                                           | \$ 3,000.0                                                                                               |
| February 2018 | 400,000                              | \$ 292.01                         | 400,000                                                                     | \$ 2,883.2                                                                                               |
| March 2018    | 464,782                              | \$ 286.58                         | 464,782                                                                     | \$ 2,750.0                                                                                               |
| Total         | 864,782                              | \$ 289.09                         |                                                                             |                                                                                                          |

In July 2016 our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2016 Share Repurchase Program). Our 2016 Share Repurchase Program does not have an expiration date. All share repurchases under our 2016 Share Repurchase Program will be retired. Under our 2016 Share Repurchase Program, we repurchased and retired 0.9 million shares of common stock at a cost of \$250.0 million during the three months ended March 31, 2018, and we repurchased and retired 0.8 million shares of common stock at a cost of \$218.2 million during the three months ended March 31, 2017. As of March 31, 2018, approximately \$2.8 billion remains available for share repurchase under our 2016 Share Repurchase Program.

## Item 6. Exhibits

The exhibits listed below are filed or furnished as part of this Quarterly Report on Form 10-Q.

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EXHIBIT INDEX

| Exhibit Number | Description of Exhibit                                                                                                                |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------|
| 10.1*+         | <u>Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan.</u>                                |
| 10.2*+         | <u>Form of performance stock units award agreement (cash settled) under the Biogen Inc. 2017 Omnibus Equity Plan.</u>                 |
| 10.3*+         | <u>Form of restricted stock unit award agreement (2018 one-time transition grant) under the Biogen Inc. 2017 Omnibus Equity Plan.</u> |
| 10.4*+         | <u>Letter regarding employment arrangement for Paul McKenzie dated December 14, 2015.</u>                                             |
| 31.1+          | <u>Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>                        |
| 31.2+          | <u>Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>                    |
| 32.1++         | <u>Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>                                                       |

101++ The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Statements of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheets, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

\* Management contract or compensatory plan or arrangement.

+ Filed herewith

++ Furnished herewith

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SIGNATURES

Pursuant to the requirements 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.

/s/ Jeffrey D. Capello  
Jeffrey D. Capello  
Executive Vice President and  
Chief Financial Officer  
(principal financial officer)  
April 24, 2018

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