BIOGEN INC.
Form 10-Q
October 23, 2018

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

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

For the quarterly period ended September 30, 2018
OR

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

Commission File Number 0-19311
BIOGEN INC.
(Exact name of registrant as specified in its charter)

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

225 Binney Street, Cambridge, 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 x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes x No o

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 x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

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

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

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of October 19, 2018, was 201,482,595 shares.

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For the Quarterly Period Ended September 30, 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,” "goal," “intend,” “may,” “plan,” “potential,” “possible,” “will” and other v of similar meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration or acquisition agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets; and liabilities and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from generics, biosimilars, prodrugs and other products approved under alternative regulatory pathways;
- adverse safety events involving our marketed products or generic or biosimilar products marketed by others;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- 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;
- our plans and investments in our core and emerging growth areas;
- the drivers for growing our business, including our plans and intent to commit resources relating to research and development programs and business development opportunities as well as the anticipated timing to complete certain business development transactions;
- 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 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;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- 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 anticipated benefits and the potential costs and expenses related to our current or future initiatives to streamline our operations and reallocate resources;
- 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 on our results of operations and liquidity of the United Kingdom's (U.K.) intent to voluntarily depart from the European Union (E.U.);
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, including the Tax Cuts and Jobs Act of 2017, regulatory requirements, judicial decisions and accounting standards; and
- the anticipated costs and tax treatment of the spin-off of our hemophilia business.

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

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

- "Biogen," the "company," "we," "us" and "our" refer to Biogen Inc. and its consolidated subsidiaries;
- "RITUXAN" refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan); 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 Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product, net	$2,780.1	$2,622.5	$8,061.1	$7,642.3
Revenues from anti-CD20 therapeutic programs	511.7	406.5	1,445.3	1,144.2
Other	147.2	48.8	420.2	180.4
Total revenues	3,439.0	3,077.8	9,926.6	8,966.9
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	460.8	370.0	1,327.8	1,120.8
Research and development	507.9	446.4	1,985.6	1,666.0
Selling, general and administrative	497.7	433.4	1,515.2	1,361.9
Amortization of acquired intangible assets	281.9	108.9	493.2	674.9
Collaboration profit (loss) sharing	47.5	35.2	129.2	82.5
Acquired in-process research and development	27.5	—	112.5	120.0
Restructuring charges	6.0	—	9.2	—
(Gain) loss on fair value remeasurement of contingent consideration	(87.9)	30.0	(91.6)	61.2
Total cost and expenses	1,741.4	1,423.9	5,481.1	5,087.3
Income from operations	1,697.6	1,653.9	4,445.5	3,879.6
Other income (expense), net	115.1	(44.0)	39.6	(150.6)
Income before income tax expense and equity in loss of investee, net of tax	1,812.7	1,609.9	4,485.1	3,729.0
Income tax expense	369.8	383.8	956.0	892.6
Equity in loss of investee, net of tax	—	—	—	—
Net income	1,442.9	1,226.1	3,529.1	2,836.4
Net income (loss) attributable to noncontrolling interests, net of tax	(1.5)	—	45.2	(0.1)
Net income attributable to Biogen Inc.	$1,444.4	$1,226.1	$3,483.9	$2,836.5
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$7.17	$5.80	$16.86	$13.32
Diluted earnings per share attributable to Biogen Inc.	$7.15	$5.79	$16.83	$13.30
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	201.4	211.4	206.6	213.0
Diluted earnings per share attributable to Biogen Inc.	201.9	211.8	207.0	213.3

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 Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income attributable to Biogen Inc.	$1,444.4	$1,226.1	$3,483.9	$2,836.5
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	(0.2)	1.0	(1.8)	6.6
Unrealized gains (losses) on cash flow hedges, net of tax	5.2	(35.5)	109.0	(162.3)
Unrealized gains (losses) on pension benefit obligation, net of tax	(0.2)	—	0.2	(0.5)
Currency translation adjustment, net of tax	8.5	43.9	(38.8)	146.7
Total other comprehensive income (loss), net of tax	13.3	9.4	68.6	(9.5)
Comprehensive income attributable to Biogen Inc.	1,457.7	1,235.5	3,552.5	2,827.0
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	(1.5)	—	45.2	(0.1)
Comprehensive income	$1,456.2	$1,235.5	$3,597.7	$2,826.9

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 September 30, 2018	As of December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$2,386.7	$1,573.8
Marketable securities	2,041.7	2,115.2
Accounts receivable, net	2,017.3	1,787.0
Due from anti-CD20 therapeutic programs	508.4	532.6
Inventory	916.6	902.7
Other current assets	848.3	962.0
Total current assets	8,719.0	7,873.3
Marketable securities	1,244.5	3,057.3
Property, plant and equipment, net	3,538.9	3,182.4
Intangible assets, net	3,379.0	3,879.6
Goodwill	5,440.1	4,632.5
Deferred tax assets	2,160.9	595.9
Investments and other assets	1,009.8	431.6
Total assets	$25,492.2	$23,652.6
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$—	$3.2
Taxes payable	254.1	68.2
Accounts payable	342.3	395.5
Accrued expenses and other	2,578.5	2,901.3
Total current liabilities	3,174.9	3,368.2
Notes payable	5,931.1	5,935.0
Deferred tax liabilities	1,114.6	122.6
Other long-term liabilities	1,511.8	1,628.7
Total liabilities	11,732.4	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	47.8	97.8
Accumulated other comprehensive loss	(248.3)	(318.4)
Retained earnings	16,944.1	15,810.4
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	13,766.6	12,612.8
Noncontrolling interests	(6.8)	(14.7)
Total equity	13,759.8	12,598.1
Total liabilities and equity	$25,492.2	$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 Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net income	$3,529.1	$2,836.4
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	686.9	872.0
Acquired in-process research and development	112.5	120.0
Share-based compensation	119.0	97.4
Contingent consideration	(91.6)	61.2
Deferred income taxes	(44.8)	(39.7)
Other	(68.2)	65.7
Changes in operating assets and liabilities, net:		
Accounts receivable	(254.0)	(225.8)
Inventory	(31.9)	(170.3)
Accrued expenses and other current liabilities	100.7	(504.5)
Income tax assets and liabilities	315.6	170.5
Other changes in operating assets and liabilities, net	(81.0)	(250.2)
Net cash flows provided by operating activities	4,292.3	3,032.7
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	7,994.7	4,472.6
Purchases of marketable securities	(6,093.8)	(4,093.9)
Contingent consideration paid related to Fumapharm AG acquisition	(1,200.0)	(900.0)
Purchases of property, plant and equipment	(544.7)	(636.8)
Acquired in-process research and development	(112.5)	(120.0)
Acquisitions of intangible assets	(3.0)	(910.4)
Purchase of Ionis Pharmaceuticals, Inc. stock	(462.9)	—
Other	1.2	(5.1)
Net cash flows used in investing activities	(421.0)	(2,193.6)
Cash flows from financing activities:		
Purchases of treasury stock	(3,000.0)	(1,365.4)
Payments related to issuance of stock for share-based compensation arrangements, net	(6.7)	(10.7)
Repayment of borrowings	(3.2)	(3.2)
Net distribution to noncontrolling interest	(36.9)	—
Net cash contribution to Bioverativ Inc.	—	(302.7)
Other	11.8	10.1
Net cash flows used in financing activities	(3,035.0)	(1,671.9)
Net increase (decrease) in cash and cash equivalents	836.3	(832.8)
Effect of exchange rate changes on cash and cash equivalents	(23.4)	54.4
Cash and cash equivalents, beginning of the period	1,573.8	2,326.5
Cash and cash equivalents, end of the period	$2,386.7	$1,548.1

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

References in these notes to "Biogen," the "company," "we," "us" and "our" refer to Biogen Inc. and its consolidated subsidiaries.

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 are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of 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 our core and emerging growth 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 pursuant to our collaboration arrangements 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 RMS. For additional information on our collaboration arrangements with Genentech and AbbVie, please read Note 17, Collaborative and Other Relationships, to these unaudited condensed consolidated financial statements (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, Parkinson's disease, ALS, pain, cognitive impairment associated with schizophrenia (CIAS) and stroke.

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 Co., Ltd. (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, FLIXABI, an infliximab biosimilar referencing REMICADE, and IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the European Union (E.U.). For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to these condensed consolidated financial statements.

Basis of Presentation

In the opinion of management, our 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 audited 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 report. 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

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(unaudited, continued)

three and nine months ended September 30, 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.

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.

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 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

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(unaudited, continued)

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 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 United States (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 are calculated based upon a consistent application of our methodology utilizing the expected value method. These estimates 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 808, Collaborative Agreements, which provides guidance on the presentation and disclosure of collaborative arrangements. Our share of

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(unaudited, continued)

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.

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; and

(ii) 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 relationship 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

We have 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. 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.

Our development and commercialization arrangements with AbbVie, Genentech and Samsung Bioepis represent collaborative arrangements as each party is an active participant in one or more joint operating activities and is exposed to significant risks and rewards of these arrangements. These arrangements resulted from an exchange of a license and utilize the sales and usage-based royalty exception. Therefore, revenues relating to royalties or profit-sharing amounts received are recognized as the underlying sales occur.

For additional information on our collaboration arrangements with AbbVie, Genentech and Samsung Bioepis, please read Note 17, 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 the 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 and have standard payment terms that generally require payment within 30 to 90 days.

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

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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.

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, 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 this new standard resulted in a change in the income statement classification with respect to where we recognize changes in fair value related to certain equity security investments. Prior to the adoption of ASU 2016-01, we recognized changes in fair value in accumulated other comprehensive income (loss), net. Upon the 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 model that requires all lessees to recognize right-of-use 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.

The FASB subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019, and which we collectively refer to as the new leasing standards:

- ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which amends certain narrow aspects of the guidance issued in ASU 2016-02.
- ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.

We are in the process of reviewing our existing lease contracts and continue to evaluate the impact that the new leasing standards may have on our consolidated results of operations, financial position and disclosures. We expect that the adoption of the new leasing standards will result in the recognition of material right-of-use assets and liabilities in our condensed consolidated balance sheets. The adoption of the new leasing standards is not expected to have a material impact to our condensed consolidated statements of income.

We will adopt the new leasing standards using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019.

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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 deferred tax assets and liabilities are utilized.

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

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 statements of income 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 the adoption 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 statements of income. For the three and nine months ended September 30, 2017, $0.4 million and $1.2 million, respectively, were reclassified from operating income to other income (expense), net in our condensed consolidated statements of income 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 to the earliest call date. This new standard will be effective for us on January 1, 2019. Upon adoption, we will decrease our marketable securities for the amended amortization period with a corresponding adjustment to retained earnings. We do not expect that the adoption of this new standard will have a material impact on our financial position or results of operations due to the shortening of the amortization period. The ultimate impact of adopting this new standard will depend on our marketable debt securities as of the adoption date.

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 and a change in the income statement classification with respect to where we recognize ineffective hedge transaction gains and losses. Prior to the adoption of ASU 2017-12 on January 1, 2018, to the extent

ineffective, hedge transaction gains and losses were reported in other income (expense), net. Effective January 1, 2018, we recognize all fair value changes of derivatives in earnings, including any ineffective portion, in

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the same line item in our condensed consolidated statements of income that has been impacted by the hedged item. 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 our 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.

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

Fair Value Measurements

In August 2018 the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. This new standard modifies certain disclosure requirements on fair value measurements. This new standard will be effective for us on January 1, 2020. We do not expect that the adoption of this new standard will have a material impact on our disclosures.

2. Acquisitions

BIIB100 Acquisition

In January 2018 we acquired the Phase 1 ready investigational oral compound BIIB100 (formerly known as KPT-350) for the treatment of certain neurological and neurodegenerative conditions, primarily in ALS, from Karyopharm Therapeutics Inc. (Karyopharm). 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 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. We may also pay Karyopharm up to $207.0 million in additional milestone payments as well as tiered royalties on potential net commercial sales in the mid-single digit to low-teen percentages.

BIIB104 Acquisition

In April 2018 we acquired BIIB104 (formerly known as PF-04958242) from Pfizer Inc. (Pfizer). BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for CIAS, representing our first program in neuropsychiatry. 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.

We accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of $75.0 million to Pfizer, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB104 has not yet reached technological feasibility. We may also pay Pfizer up to $515.0 million in additional development and commercialization milestone payments as well as tiered royalties on potential net commercial sales in the low to mid-teen percentages. The next expected milestone would be $10.0 million upon the dosing of the first patient in the Phase 2b study, which will be recorded as research and development expense in our condensed consolidated statements of income.

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TMS Co., Ltd.

In June 2018 we entered into an exclusive option agreement with TMS Co., Ltd. (TMS) granting us the option to acquire TMS-007, a plasminogen activator with a novel mechanism of action (MOA) associated with breaking down blood clots, which is in Phase 2 development in Japan, and backup compounds for the treatment of stroke. In exchange for the purchase option, we made a $4.0 million upfront payment to TMS, which was recorded as research and development expense in our condensed consolidated statements of income as TMS-007 has not yet reached technological feasibility.

If we exercise the purchase option, we will make an additional payment of $18.0 million upon closing of the asset acquisition, which will be recorded as acquired in-process research and development expense in our condensed consolidated statements of income as TMS-007 will not have reached technological feasibility at that time. In addition, we may also pay TMS up to $335.0 million in additional development and commercialization milestone payments as well as tiered royalties on potential net commercial sales in the high-single digit to low-teen percentages. If we exercise the purchase option, consummation of the asset acquisition may be subject to the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S.

BIIB110 Acquisition

In July 2018 we acquired BIIB110 (formerly known as ALG-801) (Phase 1a) and ALG-802 (preclinical) from AliveGen Inc. (AliveGen). BIIB110 and ALG-802 represent novel ways of targeting the myostatin pathway. We initially plan to study BIIB110 in multiple neuromuscular indications, including SMA and ALS.

We accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of $27.5 million to AliveGen, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB110 has not yet reached technological feasibility. We may also pay AliveGen up to $535.0 million in additional development and commercialization milestones.

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.

For the three and nine months ended September 30, 2018, we recognized restructuring charges of $6.0 million and $9.2 million, respectively, in our condensed consolidated statements of income. These restructuring charges were primarily related to severance.

We previously recognized restructuring charges of $0.9 million in our condensed consolidated statements of income during the fourth quarter of 2017, which were primarily related to severance.

Restructuring charges incurred to date under this program are expected to be substantially paid in cash by the end of 2018.

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4. Revenues

Product Revenues

Revenues by product are summarized as follows:

(In millions)	For the Three Months Ended September 30, 2018			2017		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis:						
TECFIDERA	$842.1	$247.9	$1,090.0	$836.3	$233.3	$1,069.6
Interferon*	421.5	168.6	590.1	473.3	188.7	662.0
TYSABRI	253.0	217.2	470.2	266.8	202.6	469.4
FAMPYRA	—	22.5	22.5	—	24.3	24.3
ZINBRYTA	—	—	—	—	14.2	14.2
Spinal Muscular Atrophy:						
SPINRAZA	223.9	243.8	467.7	197.6	73.3	270.9
Other Product Revenues:						
FUMADERM	—	4.8	4.8	—	10.7	10.7
BENEPALI	—	123.4	123.4	—	99.2	99.2
FLIXABI	—	11.4	11.4	—	2.2	2.2
Total product revenues	$1,740.5	$1,039.6	$2,780.1	$1,774.0	$848.5	$2,622.5

*Interferon includes AVONEX and PLEGRIDY.

(In millions)	For the Nine Months Ended September 30, 2018			2017		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis:						
TECFIDERA	$2,396.8	$766.9	$3,163.7	$2,462.4	$676.0	$3,138.4
Interferon*	1,237.5	528.4	1,765.9	1,439.8	561.1	2,000.9
TYSABRI	768.2	631.3	1,399.5	861.7	648.7	1,510.4
FAMPYRA	—	69.9	69.9	—	67.4	67.4
ZINBRYTA	—	1.4	1.4	—	41.0	41.0
Spinal Muscular Atrophy:						
SPINRAZA	617.8	636.5	1,254.3	438.8	82.4	521.2
Hemophilia:						
ELOCTATE	—	—	—	42.2	6.2	48.4
ALPROLIX	—	—	—	21.0	5.0	26.0
Other Product Revenues:						
FUMADERM	—	17.3	17.3	—	30.7	30.7
BENEPALI	—	359.9	359.9	—	253.2	253.2
FLIXABI	—	29.2	29.2	—	4.7	4.7
Total product revenues	$5,020.3	$3,040.8	$8,061.1	$5,265.9	$2,376.4	$7,642.3

*Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 30.7% and 19.3% of gross product revenues for the three months ended September 30, 2018, and 32.4% and 18.0% of gross product revenues for the nine months ended

September 30, 2018.

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We recognized revenues from two wholesalers accounting for 33.7% and 20.8% of gross product revenues for the three months ended September 30, 2017, and 34.9% and 21.0% of gross product revenues for the nine months ended September 30, 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	498.9	1,949.6	18.0	2,466.5
Adjustments relating to prior years	(0.3)	(7.0)	0.1	(7.2)
Payments/credits relating to sales in current year	(373.7)	(1,285.8)	(0.8)	(1,660.3)
Payments/credits relating to sales in prior years	(107.8)	(495.2)	(21.8)	(624.8)
Balance, as of September 30, 2018	$ 126.7	$ 767.6	$ 41.5	$ 935.8

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

(In millions)	As of September 30, 2018	As of December 31, 2017
Reduction of accounts receivable	$ 177.3	$ 189.6
Component of accrued expenses and other	758.5	572.0
Total reserves	$ 935.8	$ 761.6

Revenues from Anti-CD20 Therapeutic Programs

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Biogen’s share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$358.0	$325.1	$1,066.6	$996.1
Other revenues from anti-CD20 therapeutic programs	153.7	81.4	378.7	148.1
Total revenues from anti-CD20 therapeutic programs	$511.7	$406.5	$1,445.3	$1,144.2

For additional information on our relationship 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:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Revenues from collaborative and other relationships:				
AbbVie	$(0.7)	$(2.8)	$(7.9)	$(12.6)
Samsung Bioepis and other	48.1	9.0	80.7	34.1
Other royalty and corporate revenues:				
Royalty	7.9	11.8	35.8	49.1
Other corporate	91.9	30.8	311.6	109.8

Total other revenues	$147.2	$48.8	$420.2	$180.4

For additional information on our collaboration arrangements with AbbVie and Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to these condensed consolidated financial statements.

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5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of September 30, 2018	As of December 31, 2017
Raw materials	$ 181.8	$ 162.4
Work in process	608.0	605.7
Finished goods	136.5	157.4
Total inventory	$ 926.3	$ 925.5
Balance Sheet Classification:		
Inventory	$ 916.6	$ 902.7
Investments and other assets	9.7	22.8
Total inventory	$ 926.3	$ 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.

6. Intangible Assets and Goodwill

Intangible Assets

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

		As of September 30, 2018			As of December 31, 2017		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	$543.3	$ (541.6)	$1.7	$543.3	$ (535.6)	$7.7
Developed technology	15-23 years	3,005.3	(2,724.0)	281.3	3,005.3	(2,689.0)	316.3
In-process research and development	Indefinite until commercialization	480.9	—	480.9	680.6	—	680.6
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	4-18 years	3,974.2	(1,423.1)	2,551.1	3,971.4	(1,160.4)	2,811.0
Total intangible assets		$8,067.7	$ (4,688.7)	$3,379.0	$8,264.6	$ (4,385.0)	$3,879.6

For the three and nine months ended September 30, 2018, amortization of acquired intangible assets totaled $281.9 million and $493.2 million, respectively, compared to $108.9 million and $674.9 million, respectively, in the prior year comparative periods.

Amortization of acquired intangible assets for the three and nine months ended September 30, 2018, compared to the same periods in 2017, reflects the impact of impairment charges related to certain in-process research and development (IPR&D) assets associated with our vixotrigine (BIIB074) program totaling $189.3 million, as discussed below.

Amortization of acquired intangible assets for the nine months ended September 30, 2017, reflects the impact of a $328.2 million impairment charge recognized in the first quarter of 2017 related to our U.S. and rest of world licenses to Forward Pharma A/S' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, as discussed below.

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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 September 30, 2018, was $275.3 million.

IPR&D - Vixotrigine

IPR&D represents the fair value assigned to research and development assets that we acquired and had not yet reached technological feasibility at the date of acquisition. We review amounts capitalized as acquired IPR&D for impairment annually and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable.

During the third quarter of 2018 we completed a Phase 2b study for vixotrigine in painful lumbosacral radiculopathy (PLSR). The study did not meet its primary or secondary efficacy endpoints and we will discontinue development in PLSR. As a result, we recognized an impairment charge of approximately $60.0 million during the third quarter of 2018 to reduce the fair value of the IPR&D intangible asset to zero.

In addition, we have delayed the initiation of the Phase 3 studies of vixotrigine in trigeminal neuralgia (TGN) as we await the outcome of ongoing interactions with the U.S. Food and Drug Administration (FDA) regarding the design of the Phase 3 studies, a more detailed review of the data from the Phase 2b study of vixotrigine in PLSR and insights from the Phase 2 study of vixotrigine in small fiber neuropathy. We have reassessed the fair value of the TGN program using reduced expected lifetime revenues, higher expected clinical development costs and a lower cumulative probability of success. As a result, we recognized an impairment charge of $129.3 million during the third quarter of 2018 to reduce the fair value of the TGN IPR&D intangible asset to $41.8 million. We also adjusted the value of our contingent consideration obligations related to this program to reflect the lower cumulative probabilities of success resulting in a gain of $89.6 million in the third quarter of 2018.

The IPR&D impairment charges were included in amortization of acquired intangible assets and the gain resulting from the remeasurement of our contingent consideration obligation was recorded in (gain) loss on fair value remeasurement of contingent consideration in our condensed consolidated statements of income. The fair values of the intangible assets and contingent consideration obligations were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenues, costs and probabilities of success.

We may recognize additional impairment charges in the future depending upon our ability to advance vixotrigine for the treatment of TGN or other indications.

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 September 30, 2018, were $2,073.6 million and $262.6 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, of which $795.2 million was recognized as an intangible asset in the first quarter of 2017.

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 a $328.2 million impairment charge in the first quarter of 2017

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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) revoked Forward Pharma's European Patent No. 2 801 355. Forward Pharma has filed an appeal to the Technical Board of Appeal of the EPO and the appeal is pending.

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.

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 and programs acquired through business combinations. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of our TECFIDERA, AVONEX and TYSABRI products. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of any of these products. Impairments are recorded in the period in which they are incurred.

Our most recent long-range planning cycle was completed in the third quarter of 2018. Based upon this analysis, the estimated future amortization of acquired intangible assets for the next five years is expected to be as follows:

(In millions)	As of September 30, 2018
2018 (remaining three months)	$ 91.7
2019	367.0
2020	366.8
2021	249.4
2022	250.5
2023	230.0

Goodwill

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

(In millions)	As of September 30, 2018
Goodwill, beginning of period	$ 4,632.5
Increase to goodwill	810.7
Other	(3.1)
Goodwill, end of period	$ 5,440.1

The increase to goodwill during the nine months ended September 30, 2018, was related to $900.0 million in contingent milestones achieved (exclusive of $89.3 million in tax benefits) and payable to the former shareholders of Fumapharm AG and holders of their rights.

For additional information on future contingent payments to the former shareholders of Fumapharm AG and 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 September 30, 2018, we had no accumulated impairment losses related to goodwill.

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7. Fair Value Measurements

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

As of September 30, 2018 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$1,900.9	$ —	$ 1,900.9	$ —
Marketable debt securities:				
Corporate debt securities	1,951.6	—	1,951.6	—
Government securities	1,060.9	—	1,060.9	—
Mortgage and other asset backed securities	273.7	—	273.7	—
Marketable equity securities	624.8	95.6	529.2	—
Derivative contracts	35.1	—	35.1	—
Plan assets for deferred compensation	26.4	—	26.4	—
Total	$5,873.4	$ 95.6	$ 5,777.8	$ —
Liabilities:				
Derivative contracts	$31.2	$ —	$ 31.2	$ —
Contingent consideration obligations	412.0	—	—	412.0
Total	$443.2	$ —	$ 31.2	$ 412.0

As of December 31, 2017 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$1,229.4	$ —	$ 1,229.4	$ —
Marketable debt securities:				
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	—
Total	$6,444.9	$ 11.8	$ 6,433.1	$ —
Liabilities:				
Derivative contracts	$111.3	$ —	$ 111.3	$ —
Contingent consideration obligations	523.6	—	—	523.6
Total	$634.9	$ —	$ 111.3	$ 523.6

There have been no impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2018. In addition, there were no changes in valuation techniques or inputs utilized or transfers between fair value measurement levels during the three and nine months ended September 30, 2018. The fair values of Level 2 instruments classified as cash equivalents, marketable debt securities and our marketable equity security investment in Ionis Pharmaceuticals, Inc. (Ionis) were determined through third-party pricing services. For additional information on our new agreement with Ionis, please read Note 17, Collaborative and Other Relationships, to these

condensed consolidated financial statements. For a description of our validation procedures

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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.

Debt Instruments

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

(In millions)	As of September 30, 2018		As of December 31, 2017	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Notes payable to Fumedica AG	$—	$—	$3.2	$3.2
2.900% Senior Notes due September 15, 2020	1,491.6	1,476.2	1,517.7	1,482.4
3.625% Senior Notes due September 15, 2022	1,001.7	995.2	1,032.9	994.3
4.050% Senior Notes due September 15, 2025	1,756.6	1,737.4	1,851.9	1,736.3
5.200% Senior Notes due September 15, 2045	1,861.1	1,722.3	2,077.6	1,722.0
Total	$6,111.0	$5,931.1	$6,483.3	$5,938.2

In connection with our 2006 distribution agreement with Fumedica AG, we issued notes totaling 61.4 million Swiss Francs that were payable to Fumedica AG in varying amounts from June 2008 through June 2018. In June 2018 we redeemed our remaining note payable to Fumedica AG.

The fair value of our notes payable to Fumedica AG, as of December 31, 2017, 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 Ltd., Stromedix Inc. (Stromedix) 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 Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Fair value, beginning of period	$499.9	$492.1	$523.6	$467.6
Changes in fair value	(87.9)	30.0	(91.6)	61.2
Payments	—	—	(20.0)	(6.7)
Fair value, end of period	$412.0	$522.1	$412.0	$522.1

As of September 30, 2018 and December 31, 2017, $330.5 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.

For the three and nine months ended September 30, 2018, changes in the fair value of our contingent consideration obligations were primarily due to lower cumulative probabilities of success related to our vixotrigine program for the treatment of TGN, an increase in interest rates used to revalue our contingent consideration liabilities and the passage of time. In addition, we dosed our first patient in the Phase 2b for BG00011 (STX-100) in September 2018 and expect to pay an $81.5 million milestone payment to former shareholders of Stromedix during the fourth quarter of 2018. For additional information on our IPR&D intangible asset related to our vixotrigine program for the treatment of TGN,

please read Note 6, Intangible Assets and Goodwill, to these condensed consolidated financial statements.
For the three and nine months ended September 30, 2017, changes in the fair value of our contingent consideration obligations were primarily due to an increase in the probability of achieving certain developmental milestones based upon the progression of underlying clinical programs.

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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 September 30, 2018	As of December 31, 2017
Commercial paper	$ 125.3	$ 30.5
Overnight reverse repurchase agreements	23.7	3.6
Money market funds	1,695.1	948.0
Short-term debt securities	56.8	247.3
Total	$ 1,900.9	$ 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 maturities.

Upon the 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 September 30, 2018 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	$1,273.7	$ 0.1	$ (0.4)	$ 1,274.0
Non-current	677.9	0.5	(0.8)	678.2
Government securities				
Current	767.9	—	(0.5)	768.4
Non-current	293.0	—	(0.6)	293.6
Mortgage and other asset backed securities				
Current	0.1	—	—	0.1
Non-current	273.6	0.1	(0.6)	274.1
Total marketable debt securities	$3,286.2	$ 0.7	$ (2.9)	$ 3,288.4
Marketable equity securities, non-current	$624.8	$ 132.6	$ (4.4)	$ 496.6

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

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Summary of Contractual Maturities: Available-for-Sale Securities

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

	As of September 30, 2018		As of December 31, 2017	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$2,041.7	$2,042.5	$2,115.2	$2,116.0
Due after one year through five years	1,111.2	1,112.3	2,730.0	2,730.0
Due after five years	133.3	133.6	327.3	327.0
Total available-for-sale securities	$3,286.2	$3,288.4	$5,172.5	$5,173.0

The average maturity of our marketable debt securities available-for-sale as of September 30, 2018 and December 31, 2017, was approximately 11 months and 17 months, respectively.

Proceeds from Marketable Debt Securities

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Proceeds from maturities and sales	$1,192.0	$888.1	$7,994.7	$4,472.6
Realized gains	$0.4	$0.3	$3.0	$2.7
Realized losses	$(0.6)	$(1.2)	$(10.8)	$(4.4)

Strategic Investments

As of September 30, 2018 and December 31, 2017, our strategic investment portfolio was comprised of investments totaling $687.8 million and $85.8 million, respectively, which are included in investments and other assets in our condensed consolidated balance sheets. The increase in our strategic investment portfolio is a result of our investment in Ionis' common stock, as discussed below.

Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and venture capital funds where the underlying investments are in equity securities of certain 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 marketable equity securities within our disclosures included in Note 7, Fair Value Measurements, to these condensed consolidated financial statements. Our investment in Ionis' common stock will be regularly measured and carried at fair value and classified as a Level 2 marketable equity security within our disclosures in Note 7, Fair Value Measurements, to these condensed consolidated financial statements.

Ionis Pharmaceuticals, Inc.

In June 2018 we closed a new ten-year exclusive agreement with Ionis to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases for a total payment of $1.0 billion consisting of an upfront payment of $375.0 million and the purchase of approximately 11.5 million shares of Ionis' common stock at a cost of $625.0 million.

Our investment in Ionis' common stock is remeasured each reporting period and carried at fair value. The effects of the holding period restrictions are estimated using an option pricing valuation model. The most significant assumptions within the model are the term of the restrictions and the stock price volatility, which is based upon historical volatility of similar companies. We also use a constant maturity risk-free interest rate to match the

remaining term of the restrictions on our investment in Ionis' common stock and a dividend yield of zero based upon the fact that Ionis and similar companies generally have not historically granted cash dividends.

For additional information on our new agreement with Ionis, please read Note 17, Collaborative and Other Relationships, to these condensed consolidated financial statements.

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9. Derivative Instruments

In August 2017 the FASB issued ASU 2017-12. 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 and a change in the income statement classification with respect to where we recognize ineffective hedge transaction gains and losses. For additional information on this new standard, please read Note 1, Summary of Significant Accounting Policies - New Accounting Pronouncements, 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 September 30, 2018 and December 31, 2017, had durations of 1 to 15 months and 1 to 21 months, respectively. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test 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 on January 1, 2018, to the extent ineffective, hedge transaction gains and losses were reported in other income (expense), net. Effective January 1, 2018, we recognize all fair value changes of derivatives in earnings, including any ineffective portion, in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.

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	
Foreign Currency: (In millions)	As of September 30, 2018	As of December 31, 2017
Euro	$1,662.5	$ 1,875.6
British pound	34.9	150.9
Canadian dollar	26.9	83.5
Swiss franc	9.4	88.7
Total foreign currency forward contracts	$1,733.7	$ 2,198.7

The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net losses of $3.3 million and $113.0 million as of September 30, 2018 and December 31, 2017, respectively. We expect the net losses of $3.3 million to be settled over the next 15 months, of which $7.0 million of these losses are 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 September 30, 2018 and December 31, 2017, credit risk did not change the fair value of our foreign currency forward contracts.

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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 September 30, 2018				For the Nine Months Ended September 30, 2018			
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized in Operating Income (in millions)		Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized in Operating Income (in millions)	
Location	2018	Location	2018	Location	2018	Location	2018
Revenues	$(8.4)	Revenues	$0.3	Revenues	$(51.7)	Revenues	$7.3
Operating expenses	$(0.3)	Operating expenses	$0.4	Operating expenses	$0.6	Operating expenses	$—

For the Three Months Ended September 30, 2017				For the Nine Months Ended September 30, 2017			
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized Directly into Net Income (in millions)		Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized Directly into Net Income (in millions)	
Location	2017	Location	2017	Location	2017	Location	2017
Revenues	$(18.8)	Other income (expense)	$0.7	Revenue	$(15.1)	Other income (expense)	$6.7
Operating expenses	$0.5	Other income (expense)	$0.2	Operating expenses	$0.7	Other income (expense)	$(0.1)

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 our 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, these contracts are assumed to be highly effective 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.

The aggregate notional amount of these outstanding foreign currency contracts was $691.7 million and $564.9 million as of September 30, 2018 and December 31, 2017, respectively. Net gains of $5.2 million and $4.8 million related to these contracts were recognized as a component of other income (expense), net for the three and nine months ended September 30, 2018, respectively, compared to net gains of $1.2 million and $5.7 million, respectively, in the prior year comparative periods.

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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 As of September 30, 2018
Hedging Instruments:		
Asset derivatives	Other current assets	$ 25.6
	Investments and other assets	$ 5.4
Liability derivatives	Accrued expenses and other	$ 10.9
	Other long-term liabilities	$ 18.7
Other Derivatives:		
Asset derivatives	Other current assets	$ 4.1
Liability derivatives	Accrued expenses and other	$ 1.6

(In millions)	Balance Sheet Location	Fair Value As of December 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 $1,730.6 million and $1,559.1 million as of September 30, 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 September 30, 2018 and December 31, 2017, we had approximately $1.6 billion and $1.2 billion, respectively, capitalized as construction in progress related to this facility. As of September 30, 2018, we had contractual commitments of approximately $200.0 million outstanding related to the construction of this facility.

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11. Equity

Total equity as of September 30, 2018, increased $1.2 billion compared to December 31, 2017. This increase was primarily due to net income attributable to Biogen Inc. of approximately $3.5 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 $3.0 billion, as described below.

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

Share Repurchases

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program). Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2018 Share Repurchase Program during the three and nine months ended September 30, 2018.

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), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired 10.5 million shares of our common stock at a cost of $3.0 billion during the nine months ended September 30, 2018, and we repurchased and retired 3.7 million shares of our common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of our common stock under our 2016 Share Repurchase Program during the three months ended September 30, 2017.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of our common stock (2011 Share Repurchase Program), which was completed as of March 31, 2017. Share repurchases under our 2011 Share Repurchase Program were principally used to offset common stock issuances under our share-based compensation programs. Under our 2011 Share Repurchase Program, we repurchased 1.2 million shares of our common stock at a cost of $365.4 million during the nine months ended September 30, 2017.

Noncontrolling Interests

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
NCI, beginning of period	$(7.2)	$(11.6)	$(14.7)	$(11.5)
Net income (loss) attributable to NCI, net of tax	(1.5)	—	45.2	(0.1)
Capital contribution by noncontrolling interest	2.0	—	13.1	—
Distribution to noncontrolling interest	—	—	(50.0)	—
Translation adjustment and other	(0.1)	—	(0.4)	—
NCI, end of period	$(6.8)	$(11.6)	$(6.8)	$(11.6)

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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 Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Translation 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	(7.9)	58.3	0.2	(38.8)	11.8
Amounts reclassified from accumulated other comprehensive income (loss)	6.1	50.7	—	—	56.8
Net current period other comprehensive income (loss)	(1.8)	109.0	0.2	(38.8)	68.6
Balance, September 30, 2018	$ (1.9)	$ 4.5	$ (36.6)	$ (214.3)	$ (248.3)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Translation Adjustments	Total
Balance, December 31, 2016	$ (10.8)	$ 57.8	$ (32.7)	$ (334.2)	$ (319.9)
Other comprehensive income (loss) before reclassifications	5.5	(176.5)	(0.5)	146.7	(24.8)
Amounts reclassified from accumulated other comprehensive income (loss)	1.1	14.2	—	—	15.3
Net current period other comprehensive income (loss)	6.6	(162.3)	(0.5)	146.7	(9.5)
Balance, September 30, 2017	$ (4.2)	$ (104.5)	$ (33.2)	$ (187.5)	$ (329.4)

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

(In millions)	Income Statement Location	Amounts Reclassified from Accumulated Other Comprehensive Income			
		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
		2018	2017	2018	2017

Gains (losses) on securities available for sale	Other income (expense)	$(0.1)	$(0.9)	$(7.7)	$(1.7)
	Income tax benefit (expense)	—	0.3	1.6	0.6
Gains (losses) on cash flow hedges	Revenues	(8.4)	(18.8)	(51.7)	(15.1)
	Operating expenses	(0.3)	0.5	0.6	0.7
	Other income (expense)	0.1	0.1	0.2	0.2
	Income tax benefit (expense)	—	—	0.2	—
Total reclassifications, net of tax		$(8.7)	$(18.8)	$(56.8)	$(15.3)

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13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Numerator:				
Net income attributable to Biogen Inc.	$1,444.4	$1,226.1	$3,483.9	$2,836.5
Denominator:				
Weighted-average number of common shares outstanding	201.4	211.4	206.6	213.0
Effect of dilutive securities:				
Stock options and employee stock purchase plan	—	0.1	—	—
Time-vested restricted stock units	0.4	0.2	0.3	0.2
Market stock units	0.1	0.1	0.1	0.1
Performance stock units settled in stock	—	—	—	—
Dilutive potential common shares	0.5	0.4	0.4	0.3
Shares used in calculating diluted earnings per share	201.9	211.8	207.0	213.3

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:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Research and development	$21.0	$19.5	$60.5	$55.7
Selling, general and administrative	29.4	23.6	83.1	71.9
Subtotal	50.4	43.1	143.6	127.6
Capitalized share-based compensation costs	(3.5)	(2.5)	(9.7)	(7.6)
Share-based compensation expense included in total cost and expenses	46.9	40.6	133.9	120.0
Income tax effect	(7.7)	(10.9)	(21.8)	(31.8)
Share-based compensation expense included in net income attributable to Biogen Inc.	$39.2	$29.7	$112.1	$88.2

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Market stock units	$7.4	$4.5	$20.6	$17.1
Time-vested restricted stock units	29.9	26.7	96.6	81.2
Cash settled performance units	5.8	7.0	9.4	13.0
Performance units	3.0	3.2	4.2	8.9
Performance stock units settled in stock	1.3	—	3.4	—
Performance stock units settled in cash	1.1	—	1.5	—
Employee stock purchase plan	1.9	1.7	7.9	7.4
Subtotal	50.4	43.1	143.6	127.6
Capitalized share-based compensation costs	(3.5)	(2.5)	(9.7)	(7.6)
Share-based compensation expense included in total cost and expenses	$46.9	$40.6	$133.9	$120.0

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 upon the achievement of cumulative three-year 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 PSUs granted based on the degree of achievement of the applicable performance metric. 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 nine months ended September 30, 2018, 67,000 PSUs that will settle in stock were granted at a weighted average grant date fair value of $317.09.

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 upon the achievement of three annual 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 PSUs granted based on the degree of achievement of the applicable performance metric. 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 PSUs 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 nine months ended September 30, 2018, 45,000 PSUs that will settle in cash were granted.

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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 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 resulting from 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 three months ended September 30, 2018, we recognized a net reduction of $34.6 million in our estimated Transition Toll Tax, an expense of $5.1 million to remeasure our deferred tax balances and an $11.0 million expense to reflect other aspects of the 2017 Tax Act. During the nine months ended September 30, 2018, the remeasurement of our deferred tax balances resulted in an expense totaling $12.7 million.

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. The Transition Toll Tax was assessed on our share of our foreign corporations' 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 September 30, 2018 and December 31, 2017, we have accrued income tax liabilities of $695.9 million and $989.6 million, respectively, under the Transition Toll Tax. The decrease in this liability is primarily attributed to our 2018 Transition Toll Tax payment of $85.0 million, the application by the U.S. Internal Revenue Service (IRS) of an approximately $150.0 million overpayment against the accrual and the impact of the $34.6 million adjustment described above. Of the amounts accrued as of September 30, 2018, no amounts are expected to be paid within one year based on our interpretation of how current year payments are applied. 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 and changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries. 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 on 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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Tax Rate

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Statutory rate	21.0 %	35.0 %	21.0 %	35.0 %
State taxes	0.6	0.7	0.7	0.6
Taxes on foreign earnings	0.8	(11.4)	0.1	(11.4)
Credits and net operating loss utilization	(1.0)	(0.7)	(0.8)	(0.8)
Purchased intangible assets	0.3	1.2	0.5	1.3
Manufacturing deduction	—	(2.0)	—	(2.1)
Other permanent items	0.3	0.6	0.3	0.7
Tax reform	(0.6)	—	(0.3)	—
Other	(1.0)	0.4	(0.2)	0.6
Effective tax rate	20.4 %	23.8 %	21.3 %	23.9 %

Changes in Tax Rate

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in our effective tax rates were primarily due to the enactment of the 2017 Tax Act and lower 2018 estimated Branded Pharmaceutical Drug fee expense, which is not tax deductible. 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, and a change in accounting rules related to recording the tax impacts of intercompany transactions. The effective tax rate for the nine months ended September 30, 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 2016-16. 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 deferred tax assets and liabilities 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 IRS and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

International Uncertain Tax Positions

We have made payments totaling approximately $60.0 million to the Danish Tax Authority (SKAT) for assessments received for 2009, 2011 and 2013 regarding withholding taxes and the treatment of certain

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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.

Federal and State Uncertain Tax Positions

It is reasonably possible that we will adjust the value of our uncertain tax positions related to 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 Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Interest income	$26.0	$20.6	$81.4	$54.2
Interest expense	(49.0)	(61.8)	(151.2)	(188.8)
Gain (loss) on investments, net	141.1	(4.0)	132.0	(15.0)
Foreign exchange gains (losses), net	0.2	6.7	(13.8)	8.4
Other, net	(3.2)	(5.5)	(8.8)	(9.4)
Total other income (expense), net	$115.1	$(44.0)	$39.6	$(150.6)

For the three and nine months ended September 30, 2018, gain (loss) on investments, net, as reflected in the table above, substantially relate to marketable equity securities held at September 30, 2018.

Other Current Assets

Other current assets were $848.3 million and $962.0 million as of September 30, 2018 and December 31, 2017, and include prepaid taxes totaling $431.8 million and $657.6 million, respectively.

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2018	As of December 31, 2017
Revenue-related reserves for discounts and allowances	$ 758.5	$ 572.0
Current portion of contingent consideration obligations	381.5	844.6
Employee compensation and benefits	274.1	297.7
Royalties and licensing fees	226.3	206.7
Construction in progress	196.6	159.7
Collaboration expenses	101.5	183.7
Other	640.0	636.9
Total accrued expenses and other	$ 2,578.5	$ 2,901.3

Other Long-term Liabilities

Other long-term liabilities were $1,511.8 million and $1,628.7 million as of September 30, 2018 and December 31, 2017, and include accrued income taxes totaling $786.9 million and $979.8 million, respectively.

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17. Collaborative and Other Relationships

Ionis Pharmaceuticals, Inc.

In June 2018 we closed a new ten-year exclusive agreement with Ionis to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases for a total payment of $1.0 billion consisting of an upfront payment of $375.0 million and the purchase of approximately 11.5 million shares of Ionis' common stock at a cost of $625.0 million.

In the second quarter of 2018 $50.9 million of the $375.0 million upfront payment was recorded as prepaid services in our condensed consolidated balance sheets and the remaining $324.1 million was recorded as research and development expense in our condensed consolidated statements of income. The amount recognized as prepaid services represented the value of the employee resources committed to the arrangement to provide research and discovery services over the term of the agreement.

The 11.5 million shares of Ionis' common stock were purchased at a premium to their fair value at the transaction closing date. The premium consisted of acquiring the shares at a price above the fair value based on the trailing 10-day weighted-average close price prior to entering into thia agreement in April 2018 and the effect of certain holding period restrictions. We recorded an asset of $462.9 million in investments and other assets in our condensed consolidated balance sheets reflecting the fair value of the common stock and a charge of $162.1 million to research and development expense in our condensed consolidated statements of income in the second quarter of 2018, reflecting the premium paid for the common stock.

Our investment in Ionis' common stock is remeasured each reporting period. Changes in the fair value of our investment in Ionis' common stock, including the effect of the holding period restrictions, are reflected in other income (expense), net in our condensed consolidated statements of income. For additional information on the fair value of our investment in Ionis' common stock, please read Note 8, Financial Instruments, to these condensed consolidated financial statements.

We have the option to license therapies arising out of this agreement 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 for each program, depending on the indication, as well as royalties on potential net commercial sales.

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

AbbVie Inc.

We have a collaboration agreement with AbbVie for the development and commercialization of ZINBRYTA, which was approved for the treatment of RMS in the U.S. in May 2016 and in the E.U. in July 2016. In March 2018 we and AbbVie announced the voluntary worldwide withdrawal of ZINBRYTA for RMS.

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.

As a result of the voluntary worldwide 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 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 and nine months ended September 30, 2018, we recognized a net reduction in revenues of $0.7 million and $7.9 million, respectively, to reflect our share of an overall net loss within the collaboration, compared to $2.8 million and $12.6 million, respectively, in the prior year comparative periods. These results include the collaboration's estimate of future returns of product in the U.S.

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In the E.U. and Canada, for the three and nine months ended September 30, 2018, we recognized net profit-sharing income of $0.2 million and $2.0 million, respectively, to reflect AbbVie's 50% sharing of the net collaboration losses, compared to net profit-sharing expense of $0.7 million and $2.0 million, respectively, in the prior year comparative periods to reflect AbbVie's 50% sharing of the net collaboration profits. These results include the collaboration's estimate of future returns of product in the E.U. and Canada.

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.

Eisai Co., Ltd.

BAN2401 and Elenbecestat Collaboration

We have a collaboration agreement with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize BAN2401, a monoclonal antibody that targets amyloid beta aggregates, and elenbecestat, a BACE inhibitor, two Eisai product candidates for the treatment of AD (the BAN2401 and Elenbecestat Collaboration). 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 elenbecestat and share profits equally. In smaller markets, Eisai will distribute these products and pay us a royalty.

For the three and nine months ended September 30, 2018, sales and marketing expenses related to the BAN2401 and Elenbecestat Collaboration were immaterial.

A summary of development expenses related to the BAN2401 and Elenbecestat Collaboration is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Total development expense incurred by the collaboration related to the advancement of BAN2401 and Elenbecestat	$64.9	$38.3	$176.0	$105.0
Biogen's share of BAN2401 and Elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	$32.5	$19.2	$88.0	$52.5

Aducanumab Collaboration Agreement

We also have a collaboration agreement with Eisai to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for the treatment of AD (Aducanumab Collaboration Agreement). Under the Aducanumab Collaboration Agreement, we lead the on-going Phase 3 development of aducanumab.

For the period through March 31, 2018, we were responsible for 100% of development expense incurred by the collaboration for the advancement of aducanumab (aducanumab development expense). For the period April 1, 2018 through December 31, 2018, Eisai is reimbursing us for 15% of aducanumab development expense incurred and, beginning January 1, 2019, will reimburse us for 45% of aducanumab development expense incurred. Upon commercialization, both companies will co-promote aducanumab with a region-based profit split. Sales and marketing expense incurred before commercialization are shared in proportion to the same region-based profit split that will be utilized to co-promote aducanumab.

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A summary of development and sales and marketing expenses related to the Aducanumab Collaboration Agreement is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Total aducanumab development expense	$64.8	$73.3	$204.8	$202.2
Biogen's share of aducanumab development expense reflected in research and development expense in our condensed consolidated statements of income	$55.1	$73.3	$183.6	$202.2
Total aducanumab sales and marketing expense incurred by the collaboration	$12.1	$5.1	$33.3	$14.9
Biogen's share of aducanumab sales and marketing expense reflected in selling, general and administrative expense our condensed consolidated statements of income	$5.1	$5.1	$19.0	$14.9

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

Genentech

We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, CLL and other conditions, GAZYVA for the treatment of CLL and follicular lymphoma, OCREVUS for the treatment of PPMS and RMS and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, a wholly-owned member of the Roche Group.

RITUXAN

Genentech and its affiliates are responsible for the worldwide manufacture of RITUXAN, as well as all development and commercialization activities as follows:

U.S.

We have co-exclusively licensed our rights to develop, commercialize and market RITUXAN in the U.S.

Canada

We have co-exclusively licensed our rights to develop, commercialize and market RITUXAN in Canada.

GAZYVA

The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacture and commercialization of GAZYVA in the U.S. We recognize our share of the development and commercialization expenses of GAZYVA as a reduction of our share of pre-tax profits in revenues from anti-CD20 therapeutic programs.

OCREVUS

In March 2017 the FDA approved OCREVUS for the treatment of RMS and PPMS. Pursuant to the terms of our collaboration arrangements with Genentech, we 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 gross 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 has been approved for treatment of RMS and PPMS in the E.U. and certain other countries.

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

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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.

Revenues from Anti-CD20 Therapeutic Programs

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2018	2017	2018	2017
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$358.0	$325.1	$1,066.6	$996.1
Other revenues from anti-CD20 therapeutic programs	153.7	81.4	378.7	148.1
Total revenues from anti-CD20 therapeutic programs	$511.7	$406.5	$1,445.3	$1,144.2

For additional information on our relationship with Genentech, 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 September 30, 2018, our ownership interest in Samsung Bioepis was approximately 5%, which reflects the effect of additional equity financings in which we did not participate. In June 2018 we exercised an option to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The completion of this share purchase transaction is subject to certain regulatory closing conditions in multiple jurisdictions and is expected to close in the fourth quarter of 2018. Upon closing, we expect to pay approximately $700.0 million to Samsung BioLogics. The exact share purchase price will depend on the timing of the closing and foreign currency exchange rates at that time.

We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting 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 initial investment, we suspended recognizing additional losses. We expect to recommence recognition of our share of Samsung Bioepis' income (losses) upon acquiring the additional interest in Samsung Bioepis.

Commercial Agreement

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 European Commission granted a marketing authorization in the E.U. for IMRALDI, an adalimumab biosimilar referencing HUMIRA. In April 2018 we and Samsung Bioepis entered into an agreement with AbbVie for the commercialization of IMRALDI. Under the terms of the agreement, AbbVie granted us and Samsung Bioepis patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we and Samsung Bioepis make royalty payments to AbbVie. In October 2018 we began to recognize revenues on sales of IMRALDI to third parties in the E.U.

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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 and nine months ended September 30, 2018, we recognized net profit-sharing expense of $47.7 million and $131.2 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to $34.5 million and $80.5 million, respectively, in the prior year comparative periods.

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 and nine months ended September 30, 2018, we recognized $48.1 million and $80.7 million, respectively, in relation to these services in other revenues in our condensed consolidated statements of income, compared to $8.8 million and $23.7 million, respectively, in the prior year comparative periods.

For additional information on our collaboration arrangement with Samsung Bioepis 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.

18. 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 candidate, aducanumab, for the treatment of AD resulted from this collaboration.

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 net 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 this agreement, including on potential commercial sales of aducanumab. In May 2018 we made an additional $50.0 million payment to Neurimmune to further reduce the previously negotiated royalty rates payable on products developed under this agreement, including on potential commercial sales of aducanumab, by an additional 5%. 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 treated these payments as distributions and recognized them as charges to noncontrolling interest in the fourth quarter of 2017 and the second quarter of 2018, as applicable.

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 and nine months ended September 30, 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.

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(unaudited, continued)

Under the terms of the Aducanumab Collaboration Agreement, Eisai had an option to share in the benefit and cost associated with the royalty reductions discussed above; however, Eisai elected to not share in the benefit and cost with respect to either the October 2017 or May 2018 royalty reductions, which will impact the amount of profits (losses) on potential commercial sales of aducanumab to be shared with Eisai. For additional information on our collaboration arrangements with Eisai, please read Note 17, Collaborative and Other Relationships, to these condensed 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 September 30, 2018 and December 31, 2017, the carrying value of our investments in certain biotechnology companies representing unconsolidated variable interest entities totaled $29.2 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.

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 by Michael Bawduniak on behalf of the U.S. 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 was denied in part. No trial date has been set. The U.S. has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

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In May 2018 we were served with a qui tam action filed by SMSF, LLC on behalf of the U.S. and certain states in the U.S. District Court for the District of Massachusetts. The case was filed under seal in July 2016 and unsealed in March 2018 after the U.S. declined to intervene. The case alleges activities by nurse-educators 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. No trial date has been set. An estimate of the possible loss or range of loss cannot be made at this time.

In July 2018 we and certain other drug manufacturers and pharmacy benefit managers were served with a qui tam action filed by John Borzilleri on behalf of the U.S. and certain states in the U.S. District Court for the District of Rhode Island. The case was filed under seal in January 2014 and unsealed in April 2018 after the U.S. declined to intervene. The case alleges agreements with pharmacy benefit managers in violation of the False Claims Act and state law counterparts and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. No trial date has been set. 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. The plaintiff's appeal is pending. An estimate of the possible loss or range of loss cannot be made at this time.

Other Matters

Hatch-Waxman Act Litigation relating to TECFIDERA Orange-Book Listed Patents

In June, July and September 2017 and in January, March and April 2018 we initiated patent infringement proceedings against multiple parties pursuant to the Hatch-Waxman Act in the U.S. District Courts for the District of Delaware, the Central District of California, the District of New Jersey, the Middle District of North Carolina, the Southern District of New York, the District of Colorado and the Northern District of West Virginia. The cases filed against Teva Pharmaceuticals USA, Inc., Banner Life Sciences LLC, Impax Laboratories Inc. (now known as Impax Laboratories LLC) and Par Pharmaceutical Inc. have been dismissed and the cases in all courts other than the U.S. District Courts for the District of Delaware and the Northern District of West Virginia have been dismissed.

Patent infringement proceedings pursuant to the Hatch-Waxman Act are now pending 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., Prinston Pharmaceutical Inc., Slayback Pharma LLC, 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., Sandoz Inc., Sawai USA, Inc. and Zydus Pharmaceuticals (USA) Inc. in the U.S. District Court for the District of Delaware and against Mylan Pharmaceuticals Inc. in the U.S. District Court for the Northern District of West Virginia.

A trial has been set for December 2019 in the Delaware actions, and a trial has been set for February 2020 in the West Virginia action.

Petition for Inter Partes Review filed by Mylan Pharmaceuticals, Inc.

In July 2018 Mylan Pharmaceuticals, Inc. filed a petition with the U.S. Patent Trial and Appeal Board seeking inter partes review of 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 per day as provided for in our TECFIDERA label. The petition is pending.

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 the '514 Patent. 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 the appeal is pending. For additional information on this matter, please read Note 6, Intangibles Assets and Goodwill, to these condensed consolidated financial statements.

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European Patent Office Oppositions

In 2016 the EPO revoked our European patent number 2 137 537 (the '537 Patent). We have appealed to the Technical Board of Appeal of the EPO and the appeal is pending. 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 revoked Forward Pharma's European Patent No. 2 801 355, which was issued in May 2015 and expires in October 2025. Forward Pharma has filed an appeal to the Technical Board of Appeal of the EPO and the appeal is pending. 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, if 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.

TYSABRI 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 (January 2016), the German Patents Court (March 2016) and the Commercial Court of Rome (November 2017) seeking to invalidate the Dutch, German and Italian 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 and German counterparts were ruled invalid and we have appealed. No date for a hearing on the merits has been set in the Polish and Italian actions.

IMRALDI Patent Litigation

In September 2018 Fresenius Kabi Deutschland GmbH (Fresenius Kabi) commenced proceedings for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris, alleging that IMRALDI, the biosimilar adalimumab product of Samsung Bioepis UK Ltd. that Biogen commercializes in Europe, infringes the French counterpart of European Patent No. 3 148 510 (the '510 Patent), which was issued in June 2018 and expires in May 2035. In October 2018 Fresenius Kabi commenced preliminary injunction proceedings against Biogen (Denmark) Manufacturing ApS and Biogen Denmark A/S in Denmark's Maritime and Commercial High Court, alleging infringement of the Danish counterpart of the '510 Patent.

In August 2018 Biogen Idec Ltd. (Biogen UK) and Samsung Bioepis UK Ltd. filed an action in the United Kingdom Patents Court to revoke the U.K. counterpart to the '510 Patent. Fresenius Kabi has filed a counterclaim asserting infringement of the '510 Patent and seeking damages and an injunction to restrain infringement if the patent is found valid and infringed. A trial has been set for July 2019.

'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 (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 '755 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 September 2018, following a trial against EMD Serono and Pfizer, the court granted Biogen's motion for judgment as a matter of law that the '755 Patent is infringed and valid and ordered a new trial on all damages issues. The court has not yet scheduled the new damages trial or a trial against Bayer and Novartis.

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(unaudited, continued)

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 assist 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 the second quarter of 2018 the State Treasury of Goias, Brazil issued tax assessments for the period 2013 through February 2018 relating to tax on the circulation of goods and totaling approximately $70.0 million including interest and penalties. We dispute the assessments and have filed defenses with the Administrative Court of Appeals for the State of Goias, which are pending. We have not formed an opinion that an unfavorable outcome of the dispute is either probable or remote.

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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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 the accompanying notes beginning on page 5 of this quarterly report on Form 10-Q and our audited 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).

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 are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of 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 our core and emerging growth 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 pursuant to our collaboration arrangements 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 RMS. For additional information on our collaboration arrangements with Genentech and AbbVie, please read Note 17, 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 as well as the financial rights we have in our anti-CD20 therapeutic programs and, unless we develop, acquire rights to and/or commercialize new products and technologies, we will be substantially dependent on sales from our principal products and our financial rights in our anti-CD20 therapeutic programs 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 Co., Ltd. (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, FLIXABI, an infliximab biosimilar referencing REMICADE, and IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U. For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

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 condensed consolidated financial statements reflect the financial results of our hemophilia business for all periods through January 31, 2017.

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

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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, biosimilars of existing products, other products approved under alternative regulatory pathways and other technologies.

Sales of our products are dependent, to a significant extent, on the availability and extent of adequate 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.

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.

Our failure to obtain and maintain adequate coverage, pricing or reimbursement for our products could have an adverse effect on our business, reputation, 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 or volatility in our stock price.

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 the competition and pricing risks that could negatively impact our product sales, please read Item 3. Quantitative and Qualitative Disclosures About Market Risk and Item 1A. Risk Factors included in this report.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was $7.15 for the three months ended September 30, 2018, representing an increase of 23.5% over $5.79 in the same period in 2017.

As described below under "Results of Operations," our income from operations for the three months ended September 30, 2018, reflects the following:

- Total revenues were $3,439.0 million for the third quarter of 2018, representing an increase of 11.7% over $3,077.8 million in the same period in 2017.
- Product revenues, net totaled $2,780.1 million for the third quarter of 2018, representing an increase of 6.0% over $2,622.5 million in the same period in 2017. This increase was primarily due to higher revenues from SPINRAZA and BENEPALI, partially offset by a decrease in our MS product revenues, primarily due to a decrease in our Interferon product revenues.

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- Revenues from anti-CD20 therapeutic programs totaled $511.7 million for the third quarter of 2018, representing an increase of 25.9% over $406.5 million in the same period in 2017. This increase was primarily due to higher royalty revenues on sales of OCREVUS.
- Other revenues totaled $147.2 million for the third quarter of 2018, representing an increase of 201.6% over $48.8 million in the same period in 2017. This increase was primarily due to higher contract manufacturing revenues resulting from increased shipments of drug product and drug substance production provided to our strategic partners.
- Total cost and expenses totaled $1,741.4 million for the third quarter of 2018, representing an increase of 22.3% over $1,423.9 million in the same period in 2017. This increase was primarily due to impairment charges of $189.3 million related to certain of our in-process research and development (IPR&D) intangible assets, which is reflected as an increase in amortization of acquired intangible assets, a 24.5% increase in cost of sales, a 14.8% increase in selling, general and administrative expenses and a 13.8% increase in research and development. These increases were partially offset by the net change in (gain) loss on fair value remeasurement of our contingent consideration obligations.
- Net income attributable to Biogen Inc. was favorably impacted by a decrease in our effective tax rate to 20.4% for the third quarter of 2018, down from 23.8% for the same period in 2017. This decrease was 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," cash, cash equivalents and marketable securities totaled approximately $5.7 billion and $6.7 billion as of September 30, 2018 and December 31, 2017, respectively.

Acquisitions, Collaborative and Other Relationships

BIIB100 Acquisition

In January 2018 we acquired the Phase 1 ready investigational oral compound BIIB100 (formerly known as KPT-350) for the treatment of certain neurological and neurodegenerative conditions, primarily in ALS, from Karyopharm Therapeutics Inc. (Karyopharm). 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.

ZINBRYTA (daclizumab)

During the first quarter of 2018 the European Medicines 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 RMS as we and AbbVie believe that characterizing the complex and evolving benefit/risk profile of ZINBRYTA is not possible going forward given the limited number of patients being treated. Subsequent to our decision to voluntarily withdraw ZINBRYTA worldwide, the EMA recommended the immediate suspension of ZINBRYTA's marketing authorization and a recall of ZINBRYTA from pharmacies and hospitals in the E.U.

BIIB104 Acquisition

In April 2018 we acquired BIIB104 (formerly known as PF-04958242) from Pfizer Inc. (Pfizer). BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for cognitive impairment associated with schizophrenia (CIAS), representing our first program in neuropsychiatry. 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 June 2018 we closed a new ten-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases.

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TMS Co., Ltd.

In June 2018 we entered into an exclusive option agreement with TMS Co., Ltd. (TMS) granting us the option to acquire TMS-007, a plasminogen activator with a novel mechanism of action (MOA) associated with breaking down blood clots, which is in Phase 2 development in Japan, and backup compounds for the treatment of stroke.

BIIB110 Acquisition

In July 2018 we acquired BIIB110 (formerly known as ALG-801) (Phase 1a) and ALG-802 (preclinical) from AliveGen Inc. (AliveGen). BIIB110 and ALG-802 represent novel ways of targeting the myostatin pathway. We initially plan to study BIIB110 in multiple neuromuscular indications, including SMA and ALS.

Samsung Bioepis

In June 2018 we exercised an option under the joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The completion of this share purchase transaction is subject to certain regulatory closing conditions in multiple jurisdictions and is expected to close in the fourth quarter of 2018. Upon closing, we expect to pay approximately $700.0 million to Samsung BioLogics. The exact share purchase price will depend on the timing of the closing and foreign currency exchange rates at that time.

For additional information on our BIIB100, BIIB104 and BIIB110 acquisitions and our exclusive option agreement with TMS, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report. For additional information on our collaboration arrangements with AbbVie, Ionis and Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Key Pipeline and Product Developments

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 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 (Adalimumab)

In April 2018 we and Samsung Bioepis entered into an agreement with AbbVie for the commercialization of IMRALDI, an adalimumab biosimilar referencing HUMIRA. Under the terms of the agreement, AbbVie granted us and Samsung Bioepis patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we and Samsung Bioepis make royalty payments to AbbVie. In October 2018 we began to recognize revenues on sales of IMRALDI to third parties in the E.U.

Aducanumab (A mAb)

In July 2018 we completed enrollment of ENGAGE and EMERGE, the Phase 3 studies of aducanumab, our anti-amyloid beta antibody candidate for the treatment of AD.

BAN2401 (A mAb)

In December 2017 we and our collaboration partner Eisai Co., Ltd. (Eisai) announced that the Phase 2 study of BAN2401, a monoclonal antibody that targets amyloid beta aggregates, an Eisai product candidate for the treatment of AD, did not achieve its primary outcome measure, which was designed to enable a potentially more rapid entry into Phase 3 development based on Bayesian analysis at 12 months of treatment.

In July 2018, based upon the final analysis of the data at 18 months, we and Eisai announced the topline results of the Phase 2 study. The Phase 2 study achieved statistical significance on secondary endpoints evaluating Alzheimer's Disease Composite Score (ADCOMS) and on reduction of amyloid accumulated in the brain as measured using amyloid-PET (positron emission tomography).

BIIB074 (vixotrigine)

During the third quarter of 2018 we completed a Phase 2b study for vixotrigine in painful lumbosacral radiculopathy (PLSR). The study did not meet its primary or secondary efficacy endpoints and we will discontinue development in PLSR. The safety data were consistent with the safety profile reported in previous studies.

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Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2018		2017		For the Nine Months Ended September 30, 2018		2017	
Product revenues:								
United States	$1,740.5	50.6 %	$1,774.0	57.6 %	$5,020.3	50.6 %	$5,265.9	58.7 %
Rest of world	1,039.6	30.2 %	848.5	27.6 %	3,040.8	30.6 %	2,376.4	26.5 %
Total product revenues	2,780.1	80.8 %	2,622.5	85.2 %	8,061.1	81.2 %	7,642.3	85.2 %
Revenues from anti-CD20 therapeutic programs	511.7	14.9 %	406.5	13.2 %	1,445.3	14.6 %	1,144.2	12.8 %
Other revenues	147.2	4.3 %	48.8	1.6 %	420.2	4.2 %	180.4	2.0 %
Total revenues	$3,439.0	100.0%	$3,077.8	100.0%	$9,926.6	100.0%	$8,966.9	100.0%

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2018		2017		For the Nine Months Ended September 30, 2018		2017	
Multiple Sclerosis:								
TECFIDERA	$1,090.0	39.2 %	$1,069.6	40.8 %	$3,163.7	39.2 %	$3,138.4	41.1 %
Interferon*	590.1	21.2 %	662.0	25.2 %	1,765.9	21.9 %	2,000.9	26.2 %
TYSABRI	470.2	16.9 %	469.4	17.9 %	1,399.5	17.4 %	1,510.4	19.8 %
FAMPYRA	22.5	0.8 %	24.3	0.9 %	69.9	0.9 %	67.4	0.9 %
ZINBRYTA	—	— %	14.2	0.5 %	1.4	— %	41.0	0.5 %
Spinal Muscular Atrophy:								
SPINRAZA	467.7	16.8 %	270.9	10.3 %	1,254.3	15.6 %	521.2	6.8 %
Hemophilia:								
ELOCTATE	—	— %	—	— %	—	— %	48.4	0.6 %
ALPROLIX	—	— %	—	— %	—	— %	26.0	0.3 %
Other Product Revenues:								
FUMADERM	4.8	0.2 %	10.7	0.4 %	17.3	0.2 %	30.7	0.4 %
BENEPALI	123.4	4.4 %	99.2	3.8 %	359.9	4.5 %	253.2	3.3 %
FLIXABI	11.4	0.4 %	2.2	0.1 %	29.2	0.4 %	4.7	0.1 %
Total product revenues	$2,780.1	100.0%	$2,622.5	100.0%	$8,061.1	100.0%	$7,642.3	100.0%

*Interferon includes AVONEX and PLEGRIDY.

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Multiple Sclerosis (MS)

TECFIDERA

For the three months ended September 30, 2018, compared to the same period in 2017, the increase in U.S. TECFIDERA revenues was primarily due to gross selling price increases, partially offset by an increase in discounts and allowances and a decrease in unit sales volume of 2%.

For the nine months ended September 30, 2018, compared to the same period in 2017, the decrease in U.S. TECFIDERA revenues was primarily due to a decrease in unit sales volumes of 6% and an increase in discounts and allowances, partially offset by gross selling price increases.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in rest of world TECFIDERA revenues were primarily due to increases in unit sales volumes of 20% and 16%, respectively, partially offset by pricing reductions in certain European countries.

Rest of world TECFIDERA revenues for the nine months ended September 30, 2018, compared to the same period in 2017, was also positively impacted by the favorable impact of comparative foreign currency exchange, net of hedge of $28.4 million.

We continue to anticipate a modest increase in TECFIDERA demand on a global basis. We expect sales volumes in the U.S. to stabilize in future periods. We also expect moderate volume growth in our international markets to offset pricing reductions in certain European countries and increased competition from additional treatments for MS.

Interferon

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in U.S. Interferon revenues were primarily due to decreases in Interferon unit sales volumes of 15% and 17%, respectively, which were primarily attributable to patients transitioning to other MS therapies, partially offset by gross selling price increases.

For the three months ended September 30, 2018, compared to the same period in 2017, the decrease in rest of world Interferon revenues was primarily due to pricing reductions in certain European countries.

For the nine months ended September 30, 2018, compared to the same period in 2017, the decrease in rest of world Interferon revenues was primarily due to decreases in Interferon unit sales volumes of 4%, as patients transition to other MS therapies in the E.U., and pricing reductions in certain European countries. These decreases were partially offset by the favorable impact of comparative foreign currency exchange, net of hedge of $22.4 million.

We expect that Interferon revenues will continue to decline compared to prior year periods in both the U.S. and international markets as a result of increasing competition from our other MS products as well as other treatments for MS, including biosimilars.

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TYSABRI

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in U.S. TYSABRI revenues were primarily due to decreases in unit sales volumes of 9% and 11%, respectively, partially offset by gross selling price increases and a decrease in discounts and allowances.

For the three months ended September 30, 2018, compared to the same period in 2017, the increase in rest of world TYSABRI revenues was primarily due to selling price increases and an increase in unit sales volumes of 9%.

For the nine months ended September 30, 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 the Italian National Medicines Agency (Agenzia Italiana de Farmaco or AIFA), as discussed below. This decrease was partially offset by an increase in unit sales volumes of 2% and the favorable impact of comparative foreign currency exchange, net of hedge of $27.0 million.

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 slight decline in TYSABRI demand on a global basis in 2018, compared to 2017, with expected volume declines in the U.S. and Europe due to increased competition from additional treatments for MS, including OCREVUS, exceeding volume growth in other 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 and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in ZINBRYTA revenues were primarily due to the voluntary worldwide withdrawal of ZINBRYTA for RMS in March 2018.

For additional information on our collaboration arrangement with AbbVie, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

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Spinal Muscular Atrophy

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 and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in U.S. SPINRAZA revenues were primarily due to increases in unit sales volumes of 17% and 45%, respectively, partially offset by an increase in discounts and allowances.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in rest of world SPINRAZA revenues were due to increases in unit sales volumes as the product continued to be launched in new markets around the world, partially offset by pricing reductions in certain European countries.

We continue to 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 collaboration arrangements 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. In October 2018 we began to recognize revenues on sales of IMRALDI to third parties in the E.U.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in biosimilar revenues were primarily due to increases in BENEPALI unit sales volumes of 44% and 54%, respectively, partially offset by pricing reductions in certain European countries.

For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, 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 in the U.S. for RITUXAN and GAZYVA:

	For the Three Months Ended September 30,	
(In millions)	2018	2017
Product revenues, net	$1,112.4	$1,039.7
Cost and expenses	157.0	172.8
Pre-tax profits in the U.S.	955.4	866.9
Biogen's share of pre-tax profits	$358.0	$325.1

	For the Nine Months Ended September 30,	
(In millions)	2018	2017
Product revenues, net	$3,350.5	$3,164.5
Cost and expenses	499.9	567.7
Pre-tax profits in the U.S.	2,850.6	2,596.8
Biogen's share of pre-tax profits	$1,066.6	$996.1

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 and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in U.S. product revenues were primarily due to increased net sales of RITUXAN in the U.S., which increased 6% and 5%, respectively. The increases in the U.S. product revenues reflect selling price increases and increases in RITUXAN unit sales volumes of 2% and 1%, respectively. These increases were partially offset by higher discounts and allowances.

The increase in U.S. product revenues also reflects increases in GAZYVA unit sales volumes of 25% and 23%, respectively. This increase was partially offset by higher discounts and allowances.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in collaboration costs and expenses were due to lower Branded Pharmaceutical Drug fee expense and decreases in GAZYVA and RITUXAN research and development costs.

Many uncertainties remain about when specific biosimilar versions of RITUXAN will be approved by the U.S. Food and Drug Administration (FDA). The first biosimilar versions of RITUXAN could come to market in the U.S. in 2019, which may adversely affect the pre-tax profits of the collaboration and therefore our co-promotion profits in the U.S. in future years.

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 in Canada for RITUXAN.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in other revenues from anti-CD20 therapeutic programs were primarily due to the launch of OCREVUS in the second

quarter of 2017. For the three and nine months ended September 30, 2018, royalty revenues on sales of OCREVUS totaled $136.8 million and $326.5 million, respectively, compared to $64.6 million and $82.4 million, respectively, in the prior year comparative periods.

OCREVUS

In March 2017 the FDA approved OCREVUS for the treatment of RMS and PPMS. Pursuant to the terms of our collaboration arrangements with Genentech, we receive a tiered royalty on U.S. net

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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 gross 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 has been approved for treatment of RMS and PPMS in the E.U. and certain other countries.
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 relationship 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:

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
(In millions, except percentages)	2018		2017		2018		2017	
Revenues from collaborative and other relationships	$47.4	32.2 %	$6.2	12.7 %	$72.8	17.3 %	$21.5	11.9 %
Other royalty and corporate revenues	99.8	67.8 %	42.6	87.3 %	347.4	82.7 %	158.9	88.1 %
Total other revenues	$147.2	100.0%	$48.8	100.0%	$420.2	100.0%	$180.4	100.0%

Revenues from Collaborative and Other Relationships
Revenues from collaborative and other relationships include revenues from our technical development and manufacturing services agreements with Samsung Bioepis and royalty revenues on biosimilar products from Samsung Bioepis. Revenues from collaborative and other relationships also include our 50% share of the co-promotion losses of ZINBRYTA in the U.S. with AbbVie.
For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in revenues from collaborative and other relationships were 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 17, 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.

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For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in other royalty and corporate revenues were primarily due to higher contract manufacturing revenues resulting from increased shipments of drug product and drug substance production provided to our strategic partners.

Reserves for Discounts and Allowances

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

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

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

For the three and nine months ended September 30, 2018, reserves for discounts and allowances as a percentage of gross product

revenues were 22.7% and 23.4%, respectively, compared to 21.4% and 21.8%, respectively, in the prior year comparative periods.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in discounts were primarily due to increases in rest of world product revenues, due in part to increases in biosimilar revenues.

Discounts for the nine months ended September 30, 2018, compared to the same period in 2017, were partially offset by the impact resulting 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 and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in contractual adjustments were primarily due to higher managed care rebates 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.

Contractual adjustments for the nine months ended September 30, 2018, compared to the same period in 2017, were partially offset by the impact resulting from the spin-off of our hemophilia business on February 1, 2017.

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 September 30, 2018, compared to the same period in 2017, return reserves were relatively consistent.

For the nine months ended September 30, 2018, compared to the same period in 2017, the increase in return reserves was primarily due to the

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voluntary worldwide withdrawal of ZINBRYTA for RMS in March 2018.

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

Cost and Expenses

A summary of total cost and expenses is as follows:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
(In millions, except percentages)	2018	2017	Change %	2018	2017	Change %
Cost of sales, excluding amortization of acquired intangible assets	$460.8	$370.0	24.5 %	$1,327.8	$1,120.8	18.5 %
Research and development	507.9	446.4	13.8 %	1,985.6	1,666.0	19.2 %
Selling, general and administrative	497.7	433.4	14.8 %	1,515.2	1,361.9	11.3 %
Amortization of acquired intangible assets	281.9	108.9	158.9 %	493.2	674.9	(26.9)%
Collaboration profit (loss) sharing	47.5	35.2	34.9 %	129.2	82.5	56.6 %
Acquired in-process research and development	27.5	—	**	112.5	120.0	(6.3)%
Restructuring charges	6.0	—	**	9.2	—	**
(Gain) loss on fair value remeasurement of contingent consideration	(87.9)	30.0	(393.0)%	(91.6)	61.2	(249.7)%
Total cost and expenses	$1,741.4	$1,423.9	22.3 %	$5,481.1	$5,087.3	7.7 %

** Percentage not meaningful.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Product Cost of Sales

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in product cost of sales were primarily due to higher contract manufacturing shipments of drug product and drug substance production provided to our strategic partners and an increase in biosimilar sales volumes. These increases were partially offset by decreases in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons.

Royalty Cost of Sales

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in royalty cost of sales were primarily due to increased royalties payable to Ionis on higher sales of SPINRAZA, partially offset by the expiration of certain third-party royalties payable on sales of TYSABRI and decreases in royalties payable due to lower sales of TYSABRI and our Interferon products.

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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 and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in research and development expense were primarily due to an increase in milestone and upfront expenses, increases in costs incurred in connection with our early and late stage programs and increased costs incurred in connection with research and discovery. These increases were partially offset by decreased costs incurred with our marketed products. 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.

Milestone and Upfront Expenses

For the nine months ended September 30, 2018, compared to the same period in 2017, the increase in milestone and upfront expenses was primarily due to the recognition of a $486.2 million net charge to research and development expense upon the closing of our new agreement with Ionis to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases. This increase was partially offset by the $300.0 million upfront payment made to Bristol-Myers Squibb Company (BMS) upon the closing of our agreement to exclusively license and develop BIIB092 in AD and progressive supranuclear palsy (PSP) and the recognition of a $60.0 million developmental milestone payable to iPierian, Inc. upon dosing of the first patient in the Phase 2 PSP study for BIIB092 in June 2017. For additional information on our new agreement with Ionis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Early Stage Programs

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in spending related to our early stage programs were primarily due to the development of BIIB092 in AD and PSP pursuant to our license agreement with BMS and the development of BIIB054 in Parkinson's disease.

For the nine month comparative periods, the increase in spending related to our early stage programs also reflects higher costs associated with the development of BIIB080 in AD, the development of opicinumab in MS and the development of BIIB093 in large hemispheric infarction (LHI), a severe form of ischemic stroke, which we advanced to a late stage program in the third quarter of 2018.

Late Stage Programs

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in spending related to our late stage programs were primarily due to the development of BIIB098 in MS pursuant to our license and collaboration agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, and the development of elenbecestat, a BACE inhibitor, in AD pursuant to our collaboration agreement with Eisai. These increases were partially offset by a decrease in costs related to aducanumab reflecting Eisai's 15% reimbursement of aducanumab development expenses beginning April 1, 2018.

For additional information on Eisai's reimbursement of aducanumab development expenses and our collaboration arrangements with Eisai, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Marketed Products

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in spending related to our marketed products were primarily due to decreases in costs associated with our MS related projects.

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Selling, General and Administrative

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the increases in selling, general and administrative expenses were primarily due to increases in operational spending on sales and marketing activities in support of our marketed products, primarily related to increased commercialization costs of SPINRAZA as we continued to expand into new international markets. These increases were partially offset by a decrease in operational spend on ZINBRYTA subsequent to the worldwide voluntary withdrawal of ZINBRYTA for RMS in March 2018 and a reduction in the Branded Pharmaceutical Drug fee expense.

For the nine month comparative periods, the increase in selling, general and administrative expenses also reflects increased costs incurred in support of our recently completed business development activities.

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 and programs acquired through business combinations. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of our TECFIDERA, AVONEX and TYSABRI products. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of any of these products. Impairments are recorded in the period in which they are incurred.

Our most recent long-range planning cycle was completed in the third quarter of 2018. The results of our TECFIDERA, AVONEX and TYSABRI analyses were impacted by changes in the estimated timing and impact of other alternative MS treatments, including OCREVUS, which may compete with TYSABRI, TECFIDERA and AVONEX. The outcome of this most recent analysis resulted in a net decrease in our expected rate of amortization for acquired intangible assets, which was primarily related to higher expected lifetime revenues of TYSABRI.

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 related to 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.

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Amortization of acquired intangible assets for the three and nine months ended September 30, 2018, compared to the same periods in 2017, reflects the impact of impairment charges related to certain IPR&D assets associated with our vixotrigine program totaling $189.3 million, as discussed below.

Amortization of acquired intangible assets for the nine months ended September 30, 2017, reflects the impact of a $328.2 million impairment charge recognized in the first quarter of 2017 related to our U.S. and rest of world licenses to Forward Pharma A/S' (Forward Pharma) 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 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, of which $795.2 million was recognized as an intangible asset in the first quarter of 2017.

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 a $328.2 million 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) revoked Forward Pharma's European Patent No. 2 801 355. Forward Pharma has filed an appeal to the Technical Board of Appeal of the EPO and the appeal is pending.

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

IPR&D represents the fair value assigned to research and development assets that we acquired and had not yet reached technological feasibility at the date of acquisition. We review amounts capitalized as acquired IPR&D for impairment annually and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable.

During the third quarter of 2018 we completed a Phase 2b study for vixotrigine in PLSR. The study did not meet its primary or secondary efficacy endpoints and we will discontinue development in PLSR. As a result, we recognized an impairment charge of approximately $60.0 million during the third quarter of 2018 to reduce the fair value of the IPR&D intangible asset to zero.

In addition, we have delayed the initiation of the Phase 3 studies of vixotrigine in trigeminal neuralgia (TGN) as we await the outcome of ongoing interactions with the FDA regarding the design of the Phase 3 studies, a more detailed review of the data from the Phase 2b study of vixotrigine in PLSR and insights from the Phase 2 study of vixotrigine in small fiber neuropathy. We have reassessed the fair value of the TGN program using reduced expected lifetime revenues, higher expected clinical development costs and a lower cumulative probability of success. As a result, we recognized an impairment charge of $129.3 million during the third quarter of 2018 to reduce the fair value of the TGN IPR&D intangible asset to $41.8 million.

We may recognize additional impairment charges in the future depending upon our ability to advance vixotrigine for the treatment of TGN or other indications.

Overall, the value of our acquired IPR&D assets is dependent upon several variables, including estimates of future revenues and the effects of competition, our ability to secure sufficient pricing in a competitive market, our ability to

confirm safety and efficacy based on data from clinical trials, 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.

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For additional information on the amortization and impairment of our acquired intangible assets, including our TECFIDERA settlement and license agreement and our IPR&D intangible asset related to our vixotrigine program for the treatment of TGN, please read Note 6, Intangible Assets and Goodwill, 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 and nine months ended September 30, 2018, we recognized net profit-sharing expense of $47.7 million and $131.2 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to $34.5 million and $80.5 million, respectively, in the prior year comparative periods. The increases in profit-sharing expenses for the comparative periods were primarily due to increased collaboration profits resulting from increased biosimilar sales.

For the three and nine months ended September 30, 2018, we recognized net profit-sharing income of $0.2 million and $2.0 million, respectively, to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada, compared to net profit-sharing expense of $0.7 million and $2.0 million, respectively, in the prior year comparative periods to reflect AbbVie's 50% sharing of the net collaboration profits in the E.U. and Canada.

For additional information on our collaboration arrangements with Samsung Bioepis and AbbVie, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Acquired In-Process Research and Development

BIIB110 Acquisition

In July 2018 we acquired BIIB110 and ALG-802 from AliveGen. BIIB110 and ALG-802 represent novel ways of targeting the myostatin pathway. In connection with the closing of this transaction, we made an upfront payment of $27.5 million to AliveGen, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB110 has not yet reached technological feasibility.

BIIB104 Acquisition

In April 2018 we acquired BIIB104 from Pfizer. BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for CIAS. In connection with the closing of this transaction, we made an upfront payment of $75.0 million to Pfizer, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB104 has not yet reached technological feasibility.

BIIB100 Acquisition

In January 2018 we acquired the Phase 1 ready investigational oral compound BIIB100 for the treatment of certain neurological and neurodegenerative conditions, primarily in ALS, 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

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condensed consolidated statements of income as BIIB100 has not yet reached technological feasibility.

For additional information on our BIIB110, BIIB104 and BIIB100 acquisitions, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report.

BIIB093 Acquisition

In May 2017 we acquired BIIB093 in LHI from Remedy Pharmaceuticals Inc. (Remedy). In connection with the closing of this transaction, we made an upfront payment of $120.0 million to Remedy, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB093 had not yet reached technological feasibility.

For additional information on our BIIB093 acquisition, please read Note 2, Acquisitions, to our consolidated financial statements included in our 2017 Form 10-K.

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 in connection with this program and our goal is to redirect resources of up to $400.0 million annually by 2020 to prioritized research and development and other value creation opportunities.

For the three and nine months ended September 30, 2018, we recognized restructuring charges of $6.0 million and $9.2 million, respectively, in our condensed consolidated statements of income. These restructuring charges were primarily related to severance.

We previously recognized restructuring charges of $0.9 million in our condensed consolidated statements of income during the fourth quarter of 2017, which were primarily related to severance.

Restructuring charges incurred to date under this program are expected to be substantially paid in cash by the end of 2018.

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

For the three and nine months ended September 30, 2018, changes in the fair value of our contingent consideration obligations were primarily due to lower cumulative probabilities of success related to our vixotrigine program for the treatment of TGN, an increase in interest rates used to revalue our contingent consideration liabilities and the passage of time. For additional information on our IPR&D intangible asset related to our vixotrigine program for the treatment of TGN, please read Note 6, Intangible Assets and Goodwill, to our condensed consolidated financial statements included in this report.

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For the three and nine months ended September 30, 2017, changes in the fair value of our contingent consideration obligations were primarily due to an increase in the probability of achieving certain developmental milestones based upon the progression of underlying clinical programs.

Other Income (Expense), Net

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the changes in other income (expense), net were primarily due to the recognition of net gains recorded in relation to changes in the fair value of our strategic investments, an increase in interest income primarily due to higher interest rates and a decrease in interest expense due to the redemption in November 2017 of our 6.875% Senior Notes due March 1, 2018.

Other income (expense), net for the nine months ended September 30, 2017, also reflects the recognition of other than temporary impairments recorded on strategic investments during the period.

Effective January 1, 2018, other income (expense), net for the three and nine months ended September 30, 2018, reflects the recognition of net gains (losses) recorded in relation to changes in the fair value of our strategic investments following our adoption of Accounting Standards Update (ASU) No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. Changes in the fair value of our strategic investments could have a significant impact on our results of operations in any given period.

Income Tax Provision

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

For the three and nine months ended September 30, 2018, compared to the same periods in 2017, the decreases in our effective tax rates were primarily due to the enactment of the 2017 Tax Act and lower 2018 estimated Branded Pharmaceutical Drug fee expense, which is not tax deductible. 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 global intangible low-taxed income (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, and a change in accounting rules related to recording the tax impacts of intercompany transactions. The effective tax rate for the nine months ended September 30, 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 and nine months ended September 30, 2018 and 2017, please read Note 15, Income Taxes, to our condensed consolidated financial statements included in this report.

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Noncontrolling Interest

For the nine months ended September 30, 2018, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily related to a $50.0 million pre-tax upfront payment made to Neurimmune SubOne AG (Neurimmune) to further reduce the previously negotiated royalty rates payable on products developed under our amended collaboration and license agreement with Neurimmune, including on potential commercial sales of aducanumab, by 5%. For additional information, please read Note 18, Investments in Variable Interest Entities, 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 September 30, 2018	As of December 31, 2017	Change	%
Financial assets:				
Cash and cash equivalents	$ 2,386.7	$ 1,573.8	51.7	%
Marketable securities — current	2,041.7	2,115.2	(3.5)	%
Marketable securities — non-current	1,244.5	3,057.3	(59.3)	%
Total cash, cash equivalents and marketable securities	$ 5,672.9	$ 6,746.3	(15.9)	%
Borrowings:				
Current portion of notes payable	$ —	$ 3.2	(100.0)	%
Notes payable	5,931.1	5,935.0	(0.1)	%
Total borrowings	$ 5,931.1	$ 5,938.2	(0.1)	%
Working capital:				
Current assets	$ 8,719.0	$ 7,873.3	10.7	%
Current liabilities	(3,174.9)	(3,368.2)	(5.7)	%
Total working capital	$ 5,544.1	$ 4,505.1	23.1	%

For the nine months ended September 30, 2018, certain significant cash flows were as follows:

- $4.3 billion in net cash flows provided by operating activities, net of:
  - $698.8 million in total payments for income taxes; and
  - $375.0 million upfront payment made to Ionis upon the closing of our new agreement and a $162.1 million expense reflecting the premium paid for the purchase of Ionis' common stock;
- $3.0 billion used for share repurchases;
- $1.2 billion in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $544.7 million used for purchases of property, plant and equipment;
- $462.9 million payment made to Ionis reflecting the fair value of the common stock purchased upon the closing of our new agreement; and
- $112.5 million in upfront payments made for the acquisitions of BIIB100, BIIB104 and BIIB110.

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For the nine months ended September 30, 2017, certain significant cash flows were as follows:

- $3.0 billion in net cash flows provided by operating activities, net of:
  - $765.4 million in total payments for income taxes;
  - $454.8 million payment made to Forward Pharma for the litigation settlement charge that was accrued as of December 31, 2016; and
  - $300.0 million upfront payment to BMS;
- $1.4 billion used for share repurchases;
- $900.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $795.2 million payment made to Forward Pharma to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA;
- $636.8 million used for purchases of property, plant and equipment;
- $302.7 million net cash contribution made in connection with the spin-off of our hemophilia business on February 1, 2017; and
- $230.0 million in upfront and milestone payments made to Remedy and Ionis.

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 corporations' 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 September 30, 2018 and December 31, 2017, we have accrued income tax liabilities of $695.9 million and $989.6 million, respectively, under the Transition Toll Tax. The decrease in this liability is primarily attributed to our 2018 Transition Toll Tax payment of $85.0 million, the application by the U.S. Internal Revenue Service (IRS) of an approximately $150.0 million overpayment against the accrual and the net reduction of $34.6 million in our estimated Transition Toll Tax. Of the amounts accrued as of September 30, 2018, no amounts are expected to be paid within one year based on our interpretation of how current year payments are applied. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest. For additional information on the 2017 Tax Act, please read Note 15, Income Taxes, to our condensed consolidated financial statements included in this report.

After repatriating approximately $3.5 billion during the first quarter of 2018 as a result of the 2017 Tax Act, approximately 68% of our total cash, cash equivalents and marketable securities as of September 30, 2018 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 3. Quantitative and Qualitative Disclosures About Market Risk and Item 1A. Risk Factors

included in this report.

Share Repurchase Programs

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program). Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases

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under our 2018 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2018 Share Repurchase Program during the three and nine months ended September 30, 2018.

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), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired 10.5 million shares of our common stock at a cost of $3.0 billion during the nine months ended September 30, 2018, and we repurchased and retired 3.7 million shares of our common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of our common stock under our 2016 Share Repurchase Program during the three months ended September 30, 2017.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of our common stock (2011 Share Repurchase Program), which was completed as of March 31, 2017. Share repurchases under our 2011 Share Repurchase Program were principally used to offset common stock issuances under our share-based compensation programs. Under our 2011 Share Repurchase Program, we repurchased 1.2 million shares of our common stock at a cost of $365.4 million during the nine months ended September 30, 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.

As of September 30, 2018, we had cash, cash equivalents and marketable securities totaling approximately $5.7 billion compared to approximately $6.7 billion as of December 31, 2017. The net decrease in cash, cash equivalents and marketable securities at September 30, 2018 from December 31, 2017, was primarily due to cash used for share repurchases, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, payments made to Ionis upon the closing of our new agreement, net purchases of property, plant

and equipment and the upfront payments made to Kayropharm, Pfizer and AliveGen upon the closings of the BIIB100, BIIB104 and BIIB110 acquisitions, respectively. These decreases were partially offset by cash flows from operations.

For additional information on our BIIB100, BIIB104 and BIIB110 acquisitions, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report. For additional information on our new agreement with Ionis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

In addition, investments and other assets in our condensed consolidated balance sheet as of September 30, 2018, includes an asset of $529.2 million reflecting the fair value of our investment in Ionis' common stock, which is subject to certain holding period restrictions.

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 September 30, 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 AG, we issued notes totaling 61.4 million Swiss Francs that were payable to Fumedica AG in varying amounts from June 2008 through June 2018. In June 2018 we redeemed our remaining note payable to Fumedica AG, which had a

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carrying value of 3.1 million Swiss Francs ($3.2 million) as of December 31, 2017.

For a summary of the fair and carrying values of our outstanding borrowings as of September 30, 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 September 30, 2018, from December 31, 2017, reflects an increase in total current assets of approximately $845.7 million and a decrease in total current liabilities of $193.3 million.

The net increase in total current assets was primarily due to a net increase in cash, cash equivalents and accounts receivable, net related to our on-going operations, partially offset by a decrease in prepaid taxes related to intra-entity inventory transactions.

The net decrease in current liabilities was primarily due to a reduction in accrued expenses and other and a decrease in accounts payable, partially offset by an increase in taxes payable. The net decrease in accrued expenses and other was primarily related to a decrease in the accrual of contingent payments related to FUMADERM and TECFIDERA (together, the Fumapharm Products) and a decrease in our contingent consideration liabilities due to lower cumulative probabilities of success related to our vixotrigine program for the treatment of TGN.

Cash Flows

The following table summarizes our cash flow activity:

	For the Nine Months Ended September 30,		
(In millions, except percentages)	2018	2017	% Change
Net cash flows provided by operating activities	$4,292.3	$3,032.7	41.5 %
Net cash flows used in investing activities	$(421.0)	$(2,193.6)	(80.8)%
Net cash flows used in financing activities	$(3,035.0)	$(1,671.9)	81.5 %

Operating Activities

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

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

- Non-cash operating items such as depreciation and amortization, impairment charges, acquired IPR&D 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 in the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For the nine months ended September 30, 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, lower prepaid income taxes and income taxes

paid, the relative change in inventory and amounts due from Genentech, partially offset by the effect of the transactions described below.

The net cash flows provided by operating activities for the nine months ended September 30, 2018, reflects the $375.0 million upfront payment made to Ionis upon the closing of our new agreement and a $162.1 million expense reflecting the premium paid for the purchase of Ionis' common stock.

The net cash flows provided by operating activities for the nine months ended September 30, 2017, reflects 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 nine months ended September 30, 2018, compared to the same period in 2017, the decrease in net cash flows used in investing activities was primarily due to an increase in net proceeds of marketable securities and the $795.2 million portion of the payment made in 2017 to license Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, in the first quarter of 2017, as well as a decrease in purchases of property, plant and equipment. These decreases were partially offset by the $462.9 million

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payment made to Ionis reflecting the fair value of the common stock purchased upon the closing of our new agreement and an increase in contingent payments made to former shareholders of Fumapharm AG and holders of their rights.

Financing Activities

For the nine months ended September 30, 2018, compared to the same period in 2017, the increase in net cash flows used in financing activities was primarily due to an increase in cash used for share repurchases and the net distribution to noncontrolling interest reflecting the payment made to Neurimmune in exchange for a 5% reduction in royalty rates payable.

The net cash flows used in financing activities for the nine months ended September 30, 2017, reflects the net cash contribution made in connection with the spin-off of our hemophilia business on February 1, 2017.

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.

Contingent Payments

TYSABRI

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.

SPINRAZA

In the third quarter of 2016 we exercised our option to develop and commercialize SPINRAZA from Ionis. Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net sales of SPINRAZA using a tiered royalty rate between 11% and 15%, which are recognized as cost of sales in our condensed consolidated statements of income. For additional information on our collaboration arrangements with Ionis, please read Note 20, Collaborative and Other Relationships, to our consolidated financial statements included in our 2017 Form 10-K.

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, including an $81.5 million milestone payment to former shareholders of Stromedix during the fourth quarter of 2018 as we dosed our first patient in Phase 2b for BG00011 (STX-100) in September 2018.

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 and 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 nine months ended September 30, 2018, we paid $1.2 billion 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 the $17.0 billion and $18.0 billion cumulative sales levels related to the Fumapharm Products in the first and

second quarters of 2018, respectively. We also accrued $300.0 million upon reaching the $19.0 billion cumulative sales level related to the Fumapharm Products in the third quarter of 2018.

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We will owe an additional $300.0 million contingent payment for every additional $1.0 billion in cumulative sales level of Fumapharm Products reached until the cumulative sales level reaches $20.0 billion, which we expect to occur in the fourth quarter of 2018, at which time no further contingent payments will be due. 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 September 30, 2018, we could make potential future milestone payments to third parties of up to approximately $5.3 billion, including approximately $0.7 billion in development milestones, approximately $1.8 billion in regulatory milestones and approximately $2.8 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of September 30, 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 or commercial milestones.

Provided various development, regulatory or commercial milestones are achieved, we anticipate that we may pay approximately $10.0 million of milestone payments during the remainder of 2018.

Other Funding Commitments

As of September 30, 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 $45.0 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2018. We have approximately $575.0 million in cancellable future commitments based on existing CRO contracts as of September 30, 2018.

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. In June 2018 we exercised an option to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The completion of this share purchase transaction is subject to certain regulatory closing conditions in multiple jurisdictions and is expected to close in the fourth quarter of 2018. Upon closing, we expect to pay approximately $700.0 million to Samsung BioLogics. The exact share purchase price will depend on the timing of the closing and foreign currency exchange rates at that time.

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 September 30, 2018, we have approximately $117.0 million of liabilities associated with uncertain tax positions.

As of September 30, 2018 and December 31, 2017, we have accrued income tax liabilities of $695.9 million and $989.6 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of September 30, 2018, no amounts are expected to be paid within one year based upon our interpretation of how current year payments are applied. 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 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.

Investments, including Fair Value Measures

We invest in various types of securities, including short-term and long-term marketable securities, principally corporate notes, government securities including government sponsored enterprise mortgage-backed securities and credit card and auto loan asset-backed securities, in which our excess cash balances are invested. We also invest in equity securities of certain biotechnology companies and venture capital funds where the underlying investments are in equity securities of certain biotechnology companies.

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

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

values from other pricing sources and analyzing pricing data in certain instances. The option pricing valuation models use assumptions within the model including the term, stock price volatility, constant maturity risk free-interest rate and dividend yield.

Changes in our fair value measurements could have a significant impact on our results of operations in any given period.

Revenue Recognition

In May 2014 the Financial Accounting Standards Board (FASB) issued 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 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

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in exchange for those goods or services. We recognize revenues following the five-step model prescribed under ASU 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 are calculated based upon a consistent application of our methodology utilizing the expected value method. These estimates 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 and have standard payment terms that generally require payment within 30 to 90 days.

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.

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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 deferred tax assets and liabilities are utilized.

For additional information on our income taxes, please read Note 15, Income Taxes, 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.

Item 3. Quantitative and Qualitative Disclosures About 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.

During the second quarter of 2018 the International Practices Task Force of the Center for Audit Quality categorized Argentina as a country with a projected three-year cumulative inflation rate greater than 100%, which indicated that

Argentina's economy is highly inflationary. This categorization did not have a material impact on our results of operations or financial position as of September 30, 2018, and is not expected to have a material impact on our results of operations or financial position in the future.

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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 15 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 statements of cash flows.

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of September 30, 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 $240.0 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.

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 September 30, 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 $17.0 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 September 30, 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 certain international markets in which we operate have implemented measures, and may in the future implement new or additional 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 obtain and maintain adequate prices in a particular country may

adversely affect our ability to secure 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

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care insurance programs and increasing pressure from social sources could significantly influence the way 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. 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 certain drugs.

Our products are also susceptible to increasing competition in many markets from generics, biosimilars, prodrugs and other products approved under alternative regulatory pathways. Generic versions of drugs, biosimilars and other products approved under alternative regulatory pathways are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products, as well as other lower-priced competing products, may significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which will negatively impact our revenues.

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.

We believe that our allowance for doubtful accounts was adequate as of September 30, 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 September 30, 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 September 30, 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 as well as the financial rights we have in our anti-CD20 therapeutic programs and, unless we develop or acquire rights to and/or commercialize new products and technologies, we will be substantially dependent on sales from our principal products and our financial rights in our anti-CD20 therapeutic programs for many years. Further, following the completion of the spin-off of our hemophilia business on February 1, 2017, our revenues are further reliant and concentrated on sales of our MS products in an increasingly competitive market, revenues from sales of our product for SMA and our financial rights in our anti-CD20 therapeutic programs. Any of the following negative developments relating to any of our principal products or any of the anti-CD20 therapeutic programs 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 European Commission and the Japanese Ministry of Health, Labor and Welfare, and is in the early stages of commercial launch in certain 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 in many markets from generics, biosimilars, prodrugs and other products approved under alternative regulatory pathways. Generic versions of drugs, biosimilars, prodrugs and other products approved under alternative regulatory pathways are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products, as well as other lower-priced competing products, may significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which will negatively impact our revenues.

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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, including TECFIDERA, 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 biosimilars, follow-on products, generic versions of branded MS products, prodrugs and products approved under other alternative regulatory pathways, which would be significantly less costly than our products to bring to market and would be offered for sale at lower prices, and could result in a significant percentage of the sales of our products being lost to such biosimilars, follow-on products, generic versions of branded MS products, prodrugs and products approved under other alternative regulatory pathways;
- the 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 generic or biosimilars 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 or generic or biosimilar of 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 obtain and 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, to a significant extent, on the availability and extent of adequate 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 obtain and maintain 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 secure acceptable prices in existing and potential new 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.

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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.

Payors, including managed care organizations, health insurers, pharmacy benefit managers, government health administration authorities, private health insurers and other organizations, increasingly seek ways to reduce their costs. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Payors also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage and control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorization or step therapy. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufactures and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

Our failure to obtain and maintain adequate coverage, pricing or reimbursement for our products could have an adverse effect on our business, reputation, 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 or volatility in our stock price.

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 (PML), 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.

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

Our success depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our products and product candidates. The degree of patent protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We may fail to successfully obtain or preserve patent protection for the technologies incorporated into our products and processes, or the protection we obtain may not be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. Under the Hatch-Waxman Act, a manufacturer may file an Abbreviated New Drug Application, seeking approval of a generic copy of an approved innovator product, or a New Drug Application under Section 505(b)(2), which may be for a new or improved version of the original innovator product. The manufacturers are allowed to rely on the safety and efficacy data of the innovator's product, may not need to conduct clinical trials and can market a competing version of a product after the expiration or loss of patent exclusivity or the expiration or loss of regulatory exclusivity and often charge significantly lower prices. Upon the expiration or loss of patent protection or the expiration or loss of regulatory exclusivity for a product, especially a small molecule product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. If we cannot prevent others from exploiting our inventions, we will not derive the expected benefit from them. Furthermore, our products may be determined to infringe patents or other intellectual property rights held by third parties, which could result in financial, legal, business or reputational harm to us.

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

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

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 the successful development of additional indications for our existing products as well as the 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.

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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 clinical 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 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 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 activities and reporting related to our clinical trials. If this CRO does not adequately perform, many of our trials may be affected. We may need to replace our CROs. Although we believe there are a number of other CROs we could engage to continue these activities, the replacement of an existing CRO may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates.

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

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the 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.

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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 and may in the future implement new or additional 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 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.

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

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

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

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

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- any improper conduct or actions on the part of our collaborators or other third parties could subject us to civil or criminal investigations and monetary and injunctive penalties, and could adversely impact our ability to conduct business, our operating results and our reputation.

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, revenues from products could decline and/or we may not realize the anticipated benefits of the collaboration arrangements.

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 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.

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

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place 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 EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action, which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or otherwise adversely affect the market for our products.

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

unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

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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 became effective 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 in installments over an eight-year period, which started 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 and changes to certain estimates and amounts related to the earnings and profits of certain subsidiaries. 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.

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, net income and value of certain of our investments;
- 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;

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

Our revenues and certain assets and liabilities 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 early termination of a hedge relationship. Our operating results during any one period do not necessarily suggest the anticipated results of future periods.

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Our success in commercializing biosimilars developed by Samsung Bioepis is subject to risks and uncertainties inherent in the development, manufacture and commercialization of biosimilars. If we and Samsung Bioepis are unsuccessful in the development, manufacture and commercialization of biosimilars, we may not realize the anticipated benefits of our investment in Samsung Bioepis.

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

If we and Samsung Bioepis are unsuccessful in the development, manufacture and commercialization of biosimilars, we may not realize the anticipated benefits of our investment in Samsung Bioepis.

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.

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.

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

From time to time our Board of Directors authorizes share repurchase programs, including most recently our 2018 Share Repurchase Program, which is a program to repurchase up to $3.5 billion of our common stock that was authorized by our Board of Directors in August 2018. The amount and timing of share repurchases are subject to capital availability and our determination that share 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 shares. Our ability to repurchase shares 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 repurchases under, or the completion or expiration of, our share repurchase program could have a negative effect on our stock price. We can provide no assurance that we will repurchase shares 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.

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.

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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, in connection with the spin-off of our hemophilia business, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen shareholders. 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 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 spin-off, including any pending or future litigation. It is possible that a court would disregard the allocation agreed to between us and Bioverativ and require us to assume responsibility for obligations allocated to Bioverativ. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation and distribution agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Bioverativ

may be significant. These risks could negatively affect our business, financial condition or results of operations.

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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 2018 Share Repurchase Program during the third 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)
July 2018	—	$ —	—	$ —
August 2018	—	$ —	—	$ 3,500.0
September 2018	—	$ —	—	$ 3,500.0
Total	—	$ —		

In August 2018 our Board of Directors authorized our 2018 Share Repurchase Program, which is a program to repurchase up to $3.5 billion of our common stock. Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2018 Share Repurchase Program during the three and nine months ended September 30, 2018.

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), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired 10.5 million shares of our common stock at a cost of $3.0 billion during the nine months ended September 30, 2018, and we repurchased and retired 3.7 million shares of our common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of our common stock under our 2016 Share Repurchase Program during the three months ended September 30, 2017.

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
31.1+	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

\+ 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,
Chief Financial Officer and
Chief Accounting Officer
(principal financial officer)
October 23, 2018