BIOGEN INC.
Form 10-Q
October 24, 2017

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, 2017
OR

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

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

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

225 Binney Street, Cambridge, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes x No o

Indicate by check mark 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
(Do not check if a smaller reporting company)	Emerging growth company o

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

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

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of October 20, 2017 was 211,476,936 shares.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the Act. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “possible,” “will” and other words a similar meaning. Reference is made in particular to forward-looking statements regarding:

- the anticipated amount, timing and accounting of revenues, contingent payments, milestone, royalty and other payments under licensing, collaboration or acquisition agreements, tax positions and contingencies, collectability of receivables, pre-approval inventory, cost of sales, research and development costs, compensation and other selling, general and administrative expenses, amortization of intangible assets, foreign currency exchange risk, estimated fair value of assets and liabilities and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- the costs and timing of potential clinical trials, filings and approvals, and the potential therapeutic scope of the development and commercialization of our and our collaborators’ pipeline products;
- the drivers for growing our business, including our plans and intent to commit resources relating to business development opportunities and research and development programs;
- the anticipated benefits and the potential costs and expenses related to our corporate restructurings or other initiatives to streamline our operations and reallocate resources;
- our manufacturing capacity, use of third-party contract manufacturing organizations and plans and timing relating to the expansion of our manufacturing capabilities, including anticipated investments and activities in new manufacturing facilities;
- the potential impact on our results of operations and liquidity of the United Kingdom's (U.K.) intent to voluntarily depart from the European Union (E.U.);
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs to limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- the anticipated benefits, costs and tax treatment of the spin-off of our hemophilia business;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- our ability to finance our operations and business initiatives and obtain funding for such activities; and
- the impact of new laws and accounting standards.

These forward-looking statements involve risks and uncertainties, including those that are described in the “Risk Factors” section of this report and elsewhere in this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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NOTE REGARDING COMPANY AND PRODUCT REFERENCES

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™, CIRARA™, FLIXABI™, FUMADERM™ and IMRALDI™ are trademarks of Biogen. ALPROLIX®, ELOCTATE®, ENBREL®, FAMPYRA™, GAZYVA®, HUMIRA®, OCREVUS®, REMICADE®, RITUXAN HYCELA™ 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,	
	2017	2016	2017	2016
Revenues:				
Product, net	$2,622.5	$2,539.6	$7,642.3	$7,315.0
Revenues from anti-CD20 therapeutic programs	406.5	317.6	1,144.2	996.3
Other	48.8	98.6	180.4	265.5
Total revenues	3,077.8	2,955.8	8,966.9	8,576.8
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	370.0	416.9	1,120.8	1,100.2
Research and development	446.4	529.0	1,666.0	1,439.4
Selling, general and administrative	433.8	462.7	1,363.1	1,452.4
Amortization of acquired intangible assets	108.9	99.7	674.9	281.4
Acquired in-process research and development	—	—	120.0	—
Collaboration profit (loss) sharing	35.2	4.7	82.5	(0.9)
(Gain) loss on fair value remeasurement of contingent consideration	30.0	5.9	61.2	18.8
Restructuring charges	—	11.6	—	21.3
Total cost and expenses	1,424.3	1,530.5	5,088.5	4,312.6
Income from operations	1,653.5	1,425.3	3,878.4	4,264.2
Other income (expense), net	(43.6)	(58.1)	(149.4)	(169.4)
Income before income tax expense and equity in loss of investee, net of tax	1,609.9	1,367.2	3,729.0	4,094.8
Income tax expense	383.8	337.0	892.6	1,047.0
Equity in loss of investee, net of tax	—	—	—	—
Net income	1,226.1	1,030.2	2,836.4	3,047.8
Net income (loss) attributable to noncontrolling interests, net of tax	—	(2.7)	(0.1)	(5.8)
Net income attributable to Biogen Inc.	$1,226.1	$1,032.9	$2,836.5	$3,053.6
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$5.80	$4.72	$13.32	$13.95
Diluted earnings per share attributable to Biogen Inc.	$5.79	$4.71	$13.30	$13.92
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	211.4	218.9	213.0	219.0
Diluted earnings per share attributable to Biogen Inc.	211.8	219.4	213.3	219.4

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,	
	2017	2016	2017	2016
Net income attributable to Biogen Inc.	$1,226.1	$1,032.9	$2,836.5	$3,053.6
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	1.0	(5.4)	6.6	1.6
Unrealized gains (losses) on cash flow hedges, net of tax	(35.5)	1.3	(162.3)	(17.0)
Unrealized gains (losses) on pension benefit obligation, net of tax	—	0.4	(0.5)	1.3
Currency translation adjustment	43.9	(14.4)	146.7	(62.8)
Total other comprehensive income (loss), net of tax	9.4	(18.1)	(9.5)	(76.9)
Comprehensive income attributable to Biogen Inc.	1,235.5	1,014.8	2,827.0	2,976.7
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	—	(2.6)	(0.1)	(5.7)
Comprehensive income	$1,235.5	$1,012.2	$2,826.9	$2,971.0

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, 2017	As of December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$1,548.1	$2,326.5
Marketable securities	1,960.2	2,568.6
Accounts receivable, net	1,567.5	1,441.6
Due from anti-CD20 therapeutic programs	518.0	300.6
Inventory	1,007.2	1,001.6
Other current assets	967.0	1,093.3
Total current assets	7,568.0	8,732.2
Marketable securities	3,062.0	2,829.4
Property, plant and equipment, net	2,995.9	2,501.8
Intangible assets, net	4,019.4	3,808.3
Goodwill	4,127.5	3,669.3
Investments and other assets	1,300.4	1,335.8
Total assets	$23,073.2	$22,876.8
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable and other financing arrangements	$573.2	$4.7
Taxes payable	121.3	231.9
Accounts payable	298.7	279.8
Accrued expenses and other	2,455.2	2,903.5
Total current liabilities	3,448.4	3,419.9
Notes payable and other financing arrangements	5,938.3	6,512.7
Deferred tax liability	120.7	93.1
Other long-term liabilities	716.9	722.5
Total liabilities	10,224.3	10,748.2
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	59.2	—
Accumulated other comprehensive loss	(329.4)	(319.9)
Retained earnings	16,107.7	15,071.6
Treasury stock, at cost	(2,977.1)	(2,611.7)
Total Biogen Inc. shareholders' equity	12,860.5	12,140.1
Noncontrolling interests	(11.6)	(11.5)
Total equity	12,848.9	12,128.6
Total liabilities and equity	$23,073.2	$22,876.8

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,	
	2017	2016
Cash flows from operating activities:		
Net income	$2,836.4	$3,047.8
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and acquired in-process research and development	992.0	505.3
Share-based compensation	97.4	117.8
Deferred income taxes	(39.7)	(56.8)
Other	126.9	45.3
Changes in operating assets and liabilities, net:		
Accounts receivable	(225.8)	(238.1)
Inventory	(170.3)	(155.1)
Accrued expenses and other current liabilities	(504.5)	(175.5)
Income tax assets and liabilities	170.5	(147.4)
Other changes in operating assets and liabilities, net	(250.2)	62.0
Net cash flows provided by operating activities	3,032.7	3,005.3
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	4,472.6	5,185.8
Purchases of marketable securities	(4,093.9)	(5,631.7)
Contingent consideration related to Fumapharm AG acquisition	(900.0)	(900.0)
Acquired in-process research and development	(120.0)	—
Purchases of property, plant and equipment	(636.8)	(434.0)
Acquisitions of intangible assets	(910.4)	(110.4)
Other	(5.1)	(12.8)
Net cash flows used in investing activities	(2,193.6)	(1,903.1)
Cash flows from financing activities:		
Purchases of treasury stock	(1,365.4)	(348.9)
Payments related to issuance of stock for share-based compensation arrangements, net	(10.7)	(12.4)
Net cash contribution to Bioverativ Inc.	(302.7)	—
Repayment of borrowings	(3.2)	(2.7)
Other	10.1	37.9
Net cash flows used in financing activities	(1,671.9)	(326.1)
Net (decrease) increase in cash and cash equivalents	(832.8)	776.1
Effect of exchange rate changes on cash and cash equivalents	54.4	0.7
Cash and cash equivalents, beginning of the period	2,326.5	1,308.0
Cash and cash equivalents, end of the period	$1,548.1	$2,084.8

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Summary of Significant Accounting Policies

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to people living with serious neurological and neurodegenerative diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), SPINRAZA for the treatment of spinal muscular atrophy (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 indicated for the treatment of CLL and follicular lymphoma, OCREVUS indicated for the treatment of primary progressive MS and relapsing MS, and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc., a wholly-owned member of the Roche Group.

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within areas of our scientific, manufacturing and technical capabilities. We intend to invest in the future across our core growth areas of MS and neuroimmunology, Alzheimer's disease (AD) and dementia, Parkinson's disease and movement disorders, and neuromuscular diseases including SMA and amyotrophic lateral sclerosis (ALS). Further, we see opportunities to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy.

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

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

For additional information related to the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to these condensed consolidated financial statements.

Basis of Presentation

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The information included in this quarterly report on Form 10-Q should be read in conjunction with our consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2016 (2016 Form 10-K). Our accounting policies are described in the “Notes to Consolidated Financial Statements” in our 2016 Form 10-K and updated, as necessary, in this Form 10-Q. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three and nine months ended September 30, 2017 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, manufacturing and delivering therapies to people living with serious neurological and neurodegenerative diseases.

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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 ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

New Accounting Pronouncements

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

We adopted the following new standards effective January 1, 2017:

- Accounting Standards Update (ASU) No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments;
- ASU No. 2016-07, Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting; and
- ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.

The adoption of these standards did not have a material impact on our financial position, results of operations or statement of cash flows; however, the adoption of ASU No. 2016-09 resulted in the reclassification of certain prior year amounts in our condensed consolidated statements of cash flows to conform to our current year presentation. Specifically, amounts previously disclosed in net cash flows used in financing activities related to our excess tax benefit from share-based compensation have been reclassified to net cash flows provided by operating activities and amounts related to cash paid when withholding shares for tax withholding purposes, previously disclosed in net cash flows provided by operating activities, have been reclassified to net cash flows used in financing activities.

For additional information related to these standards, please read Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements, to our consolidated financial statements included in our 2016 Form 10-K.

In May 2014 the 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. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that

reflects the consideration that the company expects to receive for those goods or services. The FASB has subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date of

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BIOGEN INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited, continued)

January 1, 2018. We expect to adopt these standards using the modified retrospective method. We have performed a review of the new standards as compared to our current accounting policies and our review of customer contracts and collaborative relationships remains in process. As of September 30, 2017, we have not identified any accounting changes that would materially impact the amount of reported revenues with respect to our product revenues and revenues from anti-CD20 therapeutic programs. During the fourth quarter of 2017 we plan to finalize our assessments over the impact that these standards may have on our results of operations, financial position and disclosures.

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. The new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in a company's results of operations. The new standard does not apply to investments accounted for under the equity method of accounting or those 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. The new standard will be effective for us on January 1, 2018. Based on our current investment holdings, the adoption of this standard is not expected to have a material impact on our financial position or results of operations; however, it will result in the reclassification of certain investments.

In February 2016 the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on their balance sheet and disclose qualitative and quantitative information about their leasing arrangements. The new standard will be effective for us on January 1, 2019. We are currently evaluating the impact that this standard may have on our results of operations, financial position and disclosures. The adoption of this standard is not expected to have a material impact on our net financial position, but may materially impact the reported amount of total assets and total liabilities.

In June 2016 the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard changes the impairment model for most financial assets and certain other instruments. Under the new standard, entities holding financial assets and net investment in leases that are not accounted for at fair value through net income are to be presented at the net amount expected to be collected. An allowance for credit losses will be a valuation account that will be deducted from the amortized cost basis of the financial asset to present the net carrying value at the amount expected to be collected on the financial asset. The new standard will be effective for us on January 1, 2020. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In August 2016 the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The new standard will be effective for us on January 1, 2018. The adoption of this standard is not expected to have a material impact on

our statements of cash flows upon adoption.

In October 2016 the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory. The new standard eliminates the deferral of the tax effects of intra-entity transfers of an asset other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. The new standard will be effective for us on January 1, 2018. We expect to adopt this standard using the modified retrospective method applied through a

cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. The adoption of this standard is expected to have a material impact on our net financial position; however, the final effect of the adoption of this standard will depend on the nature and amount of future transactions.

In January 2017 the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. The new standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The new standard will be effective for us on January 1, 2018; however, we have adopted this standard as of January 1, 2017, with prospective application to any business development transaction.

In January 2017 the FASB issued ASU No. 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test of Goodwill Impairment. The new standard eliminates Step 2 from the goodwill impairment test. Under the amendments in ASU No. 2017-04, an entity should recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds that reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The new standard will be effective for us on January 1, 2020; however, early adoption is permitted. We intend to early adopt this standard as of October 31, 2017, during our annual review of goodwill. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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. The new standard will require that an employer disaggregate the service cost component from the other components of net benefit cost. The new standard also provides explicit guidance on how to present the service cost component and the other components of net benefit cost in the income statement and allow 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 the condensed consolidated statements of income. The new standard will be effective for us on January 1, 2018. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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. The new standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. The new standard will be effective for us on January 1, 2019. We are currently evaluating the potential impact that this standard may have on our financial position and results of operations.

In May 2017 the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new standard will be effective for us on January 1, 2018; however, early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In August 2017 the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. The 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. The 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. The new standard will be effective for us on January 1, 2019; however, early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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2. Acquisitions

On May 15, 2017, we completed an asset purchase of the Phase 3 candidate, CIRARA (now known as BIIB093), from Remedy Pharmaceuticals Inc. (Remedy). The target indication for BIIB093 is large hemispheric infarction (LHI), a severe form of ischemic stroke where brain swelling (cerebral edema) often leads to a disproportionately large share of stroke-related morbidity and mortality. The U.S. Food and Drug Administration (FDA) recently granted BIIB093 Orphan Drug designation for severe cerebral edema in patients with acute ischemic stroke. The FDA has also granted BIIB093 Fast Track designation. Under the terms of the purchase agreement, we will have responsibility for the future development and commercialization of BIIB093 and have agreed to pay Remedy certain development and sales based milestone payments, which are substantially payable upon or after regulatory approval, as well as royalties on future commercial sales. Remedy will share in the cost of development for the target indication for BIIB093 in LHI stroke. We accounted for this transaction as an asset acquisition as we did not acquire any employees from Remedy nor did we acquire any significant processes required in the development of BIIB093. Upon closing of the transaction, we made a $120.0 million upfront payment, which was recorded as acquired in-process research and development in our condensed consolidated statements of income as BIIB093 has not yet reached technological feasibility.

3. Hemophilia Spin-Off

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

In connection with the distribution, Biogen and Bioverativ entered into a separation agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between the two companies going forward. They also provide for the performance of services by each company for the benefit of the other for a period of time. In addition, under the terms of the separation agreement, Bioverativ is obligated to indemnify us for liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation.

The services under these agreements generally commenced on February 1, 2017 (the distribution date), and are expected to terminate within 12 months of the distribution date, with the exception of the manufacturing and supply agreement, which has an initial term of five years, with a five year extension at Bioverativ's sole discretion and a further five year extension with Bioverativ's and our consent.

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In connection with the distribution we made a net cash contribution to Bioverativ, during the first quarter of 2017, totaling $302.7 million. The following table summarizes the assets and liabilities that were charged against equity as a result of the spin-off of our hemophilia business:

(In millions)	
Assets	
Cash	$302.7
Accounts receivable	144.7
Inventory	116.1
Property, plant and equipment, net	20.2
Intangible assets, net	56.8
Goodwill	314.1
Other, net	53.7
Assets transferred, net	$1,008.3
Liabilities	
Accrued expenses and other current liabilities	$87.8
Other long-term liabilities	67.7
Liabilities transferred, net	$155.5

Under the manufacturing and supply agreement, we manufacture and supply certain products and materials to Bioverativ. For the three and nine months ended September 30, 2017, we recognized $5.0 million and $12.1 million, respectively, in revenues in relation to these services, which is reflected as a component of other revenues in our condensed consolidated statements of income. We also recorded $4.5 million and $11.1 million as cost of sales in relation to these services during the three and nine months ended September 30, 2017, respectively.

Pursuant to the terms of our agreements with Bioverativ, upon completion of the spin-off, we distributed ALPROLIX and ELOCTATE on behalf of Bioverativ until Bioverativ obtained appropriate regulatory authorizations in certain countries, including a Biologics License Application transfer in the United States (U.S.), which was received in September 2017. Accordingly, commencing October 2017, we ceased distribution of ALPROLIX and ELOCTATE on behalf of Bioverativ under this arrangement. Under this arrangement, we distributed these products as an agent of Bioverativ and also provided related cash management services in connection with sales transactions, including the collection of receivables and the remittance of applicable discounts and allowances. Our consolidated financial position and results of operations did not reflect recognition of activity or balances related to these transactions.

Amounts earned under the non-manufacturing and supply related transaction service agreements are recorded as a reduction of costs and expenses in their respective expense line items, primarily in selling, general and administrative expenses, in our condensed consolidated statements of income. For the three and nine months ended September 30, 2017, these amounts were not significant.

Hemophilia related product revenues reflected in our condensed consolidated statements of income for the nine months ended September 30, 2017, totaled $74.4 million, as compared to $217.0 million and $604.7 million for the three and nine months ended September 30, 2016, respectively. Results for the nine months ended September 30, 2017, only reflect hemophilia-related product revenues through January 31, 2017.

Patents

Prior to the spin-off of our hemophilia business, we were awarded various methods of treatment and composition of matter patents related to ELOCTATE and ALPROLIX. Upon completion of the spin-off, these patents were transferred to the patent portfolio of Bioverativ.

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4. Reserves for Discounts and Allowances

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, 2016	$ 71.6	$ 482.7	$ 51.2	$ 605.5
Current provisions relating to sales in current year	422.0	1,681.2	20.0	2,123.2
Adjustments relating to prior years	(0.2)	11.2	(8.6)	2.4
Payments/credits relating to sales in current year	(320.1)	(1,227.1)	(0.1)	(1,547.3)
Payments/credits relating to sales in prior years	(70.4)	(431.6)	(17.2)	(519.2)
Balance, as of September 30, 2017	$ 102.9	$ 516.4	$ 45.3	$ 664.6

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

(In millions)	As of September 30, 2017	As of December 31, 2016
Reduction of accounts receivable	$ 197.4	$ 166.9
Component of accrued expenses and other	467.2	438.6
Total reserves	$ 664.6	$ 605.5

5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of September 30, 2017	As of December 31, 2016
Raw materials	$ 208.1	$ 170.4
Work in process	647.6	698.7
Finished goods	175.5	170.3
Total inventory	$ 1,031.2	$ 1,039.4
Balance Sheet Classification:		
Inventory	$ 1,007.2	$ 1,001.6
Investments and other assets	24.0	37.8
Total inventory	$ 1,031.2	$ 1,039.4

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

Balances in the table above as of September 30, 2017, also reflect the elimination of certain amounts transferred to Bioverativ in connection with the completion of the spin-off of our hemophilia business. Balances transferred to Bioverativ related to work in process and finished goods inventory totaled $84.5 million and $31.6 million, respectively.

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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, 2017			As of December 31, 2016		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	$543.3	$ (532.7)	$10.6	$543.3	$ (523.6)	$19.7
Developed technology	15-23 years	3,005.3	(2,675.8)	329.5	3,005.3	(2,634.3)	371.0
In-process research and development	Indefinite until commercialization	680.6	—	680.6	648.0	—	648.0
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	4-18 years	4,002.6	(1,067.9)	2,934.7	3,481.7	(776.1)	2,705.6
Total intangible assets		$8,295.8	$ (4,276.4)	$4,019.4	$7,742.3	$ (3,934.0)	$3,808.3

Balances in the table above as of September 30, 2017, reflect the elimination of certain amounts transferred to Bioverativ in connection with the completion of the spin-off of our hemophilia business. For additional information relating to the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to these condensed consolidated financial statements. In-process research and development balances include adjustments related to foreign currency exchange rate fluctuations.

For the three and nine months ended September 30, 2017, amortization of acquired intangible assets totaled $108.9 million and $674.9 million, respectively, as compared to $99.7 million and $281.4 million, respectively, in the prior year comparative periods. Amortization of acquired intangible assets for the three and nine months ended September 30, 2017, includes $30.4 million and $413.4 million, respectively, of amortization and impairment charges related to our U.S. and rest of world licenses to Forward Pharma A/S' (Forward Pharma) intellectual property related to TECFIDERA, as further discussed below.

Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of September 30, 2017, was $322.5 million.

Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Corporation plc. The net book value of this asset as of September 30, 2017, was $2,293.9 million. The increase in acquired and in-licensed rights and patents during the nine months ended September 30, 2017, reflects the $50.0 million and $40.0 million milestone payments due to Ionis Pharmaceuticals, Inc., which became payable upon the approval of SPINRAZA for the treatment of SMA in the E.U. and Japan, respectively, the $25.0 million milestone payment due to Samsung Bioepis, which became payable upon the approval of IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U. and net amounts related to our TECFIDERA license rights, as described 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 the 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 agreed to pay Forward Pharma $1.25 billion in cash. During the fourth quarter of 2016, we recognized a pre-tax charge of

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$454.8 million related to this agreement, representing the fair value of our license to Forward Pharma's intellectual property for the period April 2014, when we started selling TECFIDERA, through December 31, 2016. For additional information related to this agreement, please read Note 21, Commitments and Contingencies, to our consolidated financial statements included in our 2016 Form 10-K.

We paid the $1.25 billion in February 2017 and recognized an intangible asset of $795.2 million. The asset represented the fair value of the U.S. and rest of world licenses to Forward Pharma's intellectual property related to TECFIDERA revenues for the period January 2017, the month in which we entered into this agreement, through December 2020, the last month before royalty payments could first commence pursuant to this agreement.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the E.U., concerning intellectual property related to TECFIDERA. In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma has appealed to the U.S. Court of Appeals for the Federal Circuit and the appeal is pending. For additional information related to these disputes, please read Note 19, Litigation, to these condensed consolidated financial statements.

As we prevailed in the U.S. proceeding in March 2017, we evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded an impairment charge 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. We also 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.

Estimated Future Amortization of Intangible Assets

Our amortization expense is based on the economic consumption of intangible assets. Our most significant intangible assets are related to our TECFIDERA, AVONEX and TYSABRI products. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of TECFIDERA, AVONEX and TYSABRI. This analysis is also updated whenever we determine events or changes in circumstances would significantly affect the anticipated lifetime revenues of either product. Our most recent long range planning cycle was completed in the third quarter of 2017.

Based upon the above, the estimated future amortization of acquired intangible assets is expected to be as follows:

(In millions)	As of September 30, 2017
2017 (remaining three months)	$ 106.8
2018	421.3
2019	404.0
2020	389.6
2021	256.6
2022	244.7

Goodwill

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

(In millions)	As of September 30, 2017
Goodwill, beginning of period	$ 3,669.3
Elimination of goodwill allocated to our hemophilia business	(314.1)
Increase to goodwill	762.4
Other	9.9

Goodwill, end of period	$ 4,127.5

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The elimination of goodwill represents an allocation based upon the relative enterprise fair value of the hemophilia business as of the distribution date. For additional information relating to the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to these condensed consolidated financial statements.

The increase in goodwill during the nine months ended September 30, 2017, was related to $900.0 million in contingent milestones achieved (exclusive of $137.6 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights. Other includes changes in foreign currency exchange rates. For additional information related to future contingent payments to the former shareholders of Fumapharm AG or holders of their rights, please read Note 21, Commitments and Contingencies, to our consolidated financial statements included in our 2016 Form 10-K.

As of September 30, 2017, we had no accumulated impairment losses related to goodwill.

7. Fair Value Measurements

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

As of September 30, 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	$1,184.3	$ —	$ 1,184.3	$ —
Marketable debt securities:				
Corporate debt securities	2,584.7	—	2,584.7	—
Government securities	1,870.0	—	1,870.0	—
Mortgage and other asset backed securities	567.5	—	567.5	—
Marketable equity securities	11.8	11.8	—	—
Derivative contracts	1.6	—	1.6	—
Plan assets for deferred compensation	30.1	—	30.1	—
Total	$6,250.0	$ 11.8	$ 6,238.2	$ —
Liabilities:				
Derivative contracts	$106.2	$ —	$ 106.2	$ —
Contingent consideration obligations	522.1	—	—	522.1
Total	$628.3	$ —	$ 106.2	$ 522.1

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As of December 31, 2016 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$2,039.6	$ —	$ 2,039.6	$ —
Marketable debt securities:				
Corporate debt securities	2,663.8	—	2,663.8	—
Government securities	2,172.5	—	2,172.5	—
Mortgage and other asset backed securities	561.7	—	561.7	—
Marketable equity securities	24.9	24.9	—	—
Derivative contracts	61.0	—	61.0	—
Plan assets for deferred compensation	34.5	—	34.5	—
Total	$7,558.0	$ 24.9	$ 7,533.1	$ —
Liabilities:				
Derivative contracts	$13.6	$ —	$ 13.6	$ —
Contingent consideration obligations	467.6	—	—	467.6
Total	$481.2	$ —	$ 13.6	$ 467.6

There have been no material impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2017. 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, 2017. The fair values of Level 2 instruments classified as cash equivalents and marketable debt securities were determined through third party pricing services. For a description of our validation procedures related to prices provided by third party pricing services, please read Note 1, Summary of Significant Accounting Policies: Fair Value Measurements, to our consolidated financial statements included in our 2016 Form 10-K.

Debt Instruments

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

	As of September 30, 2017		As of December 31, 2016	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
Notes payable to Fumedica AG	$3.2	$3.3	$6.1	$6.0
6.875% Senior Notes due March 1, 2018	561.7	553.1	583.7	558.5
2.900% Senior Notes due September 15, 2020	1,536.2	1,486.5	1,521.5	1,485.3
3.625% Senior Notes due September 15, 2022	1,049.4	994.0	1,026.6	993.2
4.050% Senior Notes due September 15, 2025	1,867.0	1,735.9	1,796.0	1,734.8
5.200% Senior Notes due September 15, 2045	2,030.8	1,721.9	1,874.5	1,721.5
Total	$7,048.3	$6,494.7	$6,808.4	$6,499.3

The fair value of our notes payable to Fumedica AG was estimated using market observable inputs, including current interest and foreign currency exchange rates. The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. For additional information related to our debt instruments, please read Note 11, Indebtedness, to our consolidated financial statements included in our 2016 Form 10-K.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2017	2016	2017	2016
Fair value, beginning of period	$492.1	$515.7	$467.6	$506.0
Additions	—	—	—	—
Changes in fair value	30.0	5.9	61.2	18.8
Payments	—	—	(6.7)	(3.2)
Fair value, end of period	$522.1	$521.6	$522.1	$521.6

As of September 30, 2017 and December 31, 2016, approximately $280.0 million and $246.8 million, respectively, of our contingent consideration obligations valued using Level 3 measurements were reflected as components of other long-term liabilities in our condensed consolidated balance sheets with the remaining balances reflected as a component of accrued expenses and other.

8. Financial Instruments

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

(In millions)	As of September 30, 2017	As of December 31, 2016
Commercial paper	$ 126.4	$ 31.0
Overnight reverse repurchase agreements	42.0	—
Money market funds	871.1	741.7
Short-term debt securities	144.8	1,266.9
Total	$ 1,184.3	$ 2,039.6

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.

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

As of September 30, 2017 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	$1,042.9	$ 0.2	$ (0.4)	$ 1,043.1
Non-current	1,541.8	2.2	(2.1)	1,541.7
Government securities				
Current	916.0	—	(0.8)	916.8
Non-current	954.0	0.4	(3.4)	957.0
Mortgage and other asset backed securities				
Current	1.3	—	—	1.3
Non-current	566.2	1.3	(1.4)	566.3
Total marketable debt securities	$5,022.2	$ 4.1	$ (8.1)	$ 5,026.2
Marketable equity securities, non-current	$11.8	$ —	$ (2.6)	$ 14.4

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As of December 31, 2016 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	$1,408.6	$ 0.2	$ (0.6)	$ 1,409.0
Non-current	1,255.2	1.2	(4.7)	1,258.7
Government securities				
Current	1,156.0	0.2	(0.3)	1,156.1
Non-current	1,016.5	0.5	(3.4)	1,019.4
Mortgage and other asset backed securities				
Current	4.0	—	—	4.0
Non-current	557.7	0.8	(2.2)	559.1
Total marketable debt securities	$5,398.0	$ 2.9	$ (11.2)	$ 5,406.3
Marketable equity securities, non-current	$24.9	$ 0.7	$ (9.3)	$ 33.5

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, 2017		As of December 31, 2016	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$1,960.2	$ 1,961.2	$2,568.6	$ 2,569.1
Due after one year through five years	2,792.9	2,795.7	2,552.6	2,559.7
Due after five years	269.1	269.3	276.8	277.5
Total available-for-sale securities	$5,022.2	$ 5,026.2	$5,398.0	$ 5,406.3

The average maturity of our marketable debt securities available-for-sale as of September 30, 2017 and December 31, 2016, was approximately 17 months and 12 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)	2017	2016	2017	2016
Proceeds from maturities and sales	$888.1	$2,362.2	$4,472.6	$5,185.8
Realized gains	$0.3	$1.1	$2.7	$2.1
Realized losses	$(1.2)	$(1.1)	$(4.4)	$(2.7)

Strategic Investments

As of September 30, 2017 and December 31, 2016, our strategic investment portfolio was comprised of investments totaling $84.9 million and $99.9 million, respectively, which are included in investments and other assets in our condensed consolidated balance sheets. Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and investments in venture capital funds where the underlying investments are in equity securities of biotechnology companies.

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9. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of September 30, 2017 and December 31, 2016, had durations of 1 to 21 months and 1 to 18 months, respectively. These contracts have been designated as cash flow hedges, and, accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses for the effective portion of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized and in operating expenses when the expense in the currency being hedged is recorded. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net.

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

Foreign Currency: (In millions)	Notional Amount	
	As of September 30, 2017	As of December 31, 2016
Euro	$1,573.4	$ 871.7
British pound	39.7	—
Canadian dollar	19.7	—
Swiss franc	5.1	—
Total foreign currency forward contracts	$1,637.9	$ 871.7

The portion of the fair value of these foreign currency forward contracts that was included in accumulated other comprehensive income (loss) in total equity reflected net losses of $113.0 million and net gains of $49.8 million as of September 30, 2017 and December 31, 2016, respectively. We expect all contracts outstanding as of September 30, 2017, to be settled over the next 21 months with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of September 30, 2017 and December 31, 2016, credit risk did not change the fair value of our foreign currency forward contracts.

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

For the Three Months Ended September 30,

Net Gains/(Losses) Reclassified from AOCI into Operating Income (Effective Portion)			Net Gains/(Losses) Recognized into Net Income (Ineffective Portion)		
Location	2017	2016	Location	2017	2016
Revenue	$(18.8)	$(5.2)	Other income (expense)	$0.7	$(0.6)
Operating expenses	$0.5	$(0.2)	Other income (expense)	$0.2	$—

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For the Nine Months Ended September 30,					
Net Gains/(Losses) Reclassified from AOCI into Operating Income (Effective Portion)			Net Gains/(Losses) Recognized into Net Income (Ineffective Portion)		
Location	2017	2016	Location	2017	2016
Revenue	$(15.1)	$(0.7)	Other income (expense)	$6.7	$3.4
Operating expenses	$0.7	$(0.4)	Other income (expense)	$(0.1)	$(0.3)

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 due September 15, 2020, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in the 2.90% Senior Notes due September 15, 2020 attributable to changes in interest rates. Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recorded as a component of our 2.90% Senior Notes due September 15, 2020 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 $366.2 million and $902.1 million as of September 30, 2017 and December 31, 2016, respectively. Net gains of $1.2 million and $5.7 million related to these contracts were recognized as a component of other income (expense), net for the three and nine months ended September 30, 2017, respectively, as compared to net losses of $0.4 million and $16.6 million, respectively, in the prior year comparative periods.

Summary of Derivatives

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

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

(In millions)	Balance Sheet Location	Fair Value As of September 30, 2017
Hedging Instruments:		
Asset derivatives	Investments and other assets	$ 0.3
Liability derivatives	Accrued expenses and other	$ 80.8
	Other long-term liabilities	$ 24.2
Other Derivatives:		
Asset derivatives	Other current assets	$ 1.3
Liability derivatives	Accrued expenses and other	$ 1.2

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(In millions)	Balance Sheet Location	Fair Value As of December 31, 2016
Hedging Instruments:		
Asset derivatives	Other current assets	$ 50.4
	Investments and other assets	$ 6.6
Liability derivatives	Other long-term liabilities	$ 4.6
Other Derivatives:		
Asset derivatives	Other current assets	$ 4.0
Liability derivatives	Accrued expenses and other	$ 9.0

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 $1,580.6 million and $1,439.3 million as of September 30, 2017 and December 31, 2016, respectively.

Solothurn, Switzerland Facility

During the first quarter of 2016 we purchased land in Solothurn, Switzerland for 64.4 million Swiss Francs (approximately $62.5 million), where we are building a biologics manufacturing facility. As of September 30, 2017 and December 31, 2016, we had $968.8 million and $481.5 million, respectively, capitalized as construction in progress related to the construction of this facility. As of September 30, 2017, we had contractual commitments of approximately $235.0 million for the construction of this facility.

11. Equity

Total equity as of September 30, 2017, increased $720.3 million compared to December 31, 2016. This increase was primarily driven by net income attributable to Biogen Inc. of $2.8 billion, partially offset by share repurchases totaling approximately $1.4 billion, as described below, and an adjustment to retained earnings of $852.8 million reflecting the spin-off of our hemophilia business, as described in Note 3, Hemophilia Spin-Off, to these condensed consolidated financial statements.

Share Repurchases

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock. This authorization does not have an expiration date. All share repurchases under this authorization will be retired. Under this program, we repurchased and retired 3.7 million shares of common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of common stock under this program during the three months ended September 30, 2017. During the three and nine months ended September 30, 2016, we repurchased and retired 1.1 million shares of common stock at a cost of $348.9 million. As of September 30, 2017, approximately $3.0 billion remains available to repurchase shares under this authorization.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of common stock, which was completed as of March 31, 2017. During the nine months ended September 30, 2017, we repurchased 1.3 million shares of common stock at a cost of $365.4 million under this program. We did not repurchase any shares of common stock under this program during the three and nine months ended September 30, 2016.

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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)	2017	2016	2017	2016
NCI, beginning of period	$(11.6)	$(0.1)	$(11.5)	$2.1
Net income (loss) attributable to NCI, net of tax	—	(2.7)	(0.1)	(5.8)
Fair value of net assets and liabilities acquired and assigned to NCI	—	—	—	0.9
Translation adjustment and other	—	0.1	—	0.1
NCI, end of period	$(11.6)	$(2.7)	$(11.6)	$(2.7)

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, as of 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, as of September 30, 2017	$ (4.2)	$ (104.5)	$ (33.2)	$ (187.5)	$(329.4)

(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, as of December 31, 2015	$ (0.8)	$ 10.2	$ (37.8)	$ (195.6)	$(224.0)
Other comprehensive income (loss) before reclassifications	1.2	(17.9)	1.3	(62.8)	(78.2)
Amounts reclassified from accumulated other comprehensive income (loss)	0.4	0.9	—	—	1.3
Net current period other comprehensive income (loss)	1.6	(17.0)	1.3	(62.8)	(76.9)
Balance, as of September 30, 2016	$ 0.8	$ (6.8)	$ (36.5)	$ (258.4)	$(300.9)

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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,	
		2017	2016	2017	2016
Gains (losses) on securities available for sale	Other income (expense)	$(0.9)	$—	$(1.7)	$(0.6)
	Income tax benefit (expense)	0.3	—	0.6	0.2
Gains (losses) on cash flow hedges	Revenues	(18.8)	(5.2)	(15.1)	(0.7)
	Operating expenses	0.5	(0.2)	0.7	(0.4)
	Other income (expense)	0.1	0.1	0.2	0.2
	Income tax benefit (expense)	—	—	—	—
Total reclassifications, net of tax		$(18.8)	$(5.3)	$(15.3)	$(1.3)

13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Numerator:				
Net income attributable to Biogen Inc.	$1,226.1	$1,032.9	$2,836.5	$3,053.6
Denominator:				
Weighted-average number of common shares outstanding	211.4	218.9	213.0	219.0
Effect of dilutive securities:				
Stock options and employee stock purchase plan	0.1	0.1	—	0.1
Time-vested restricted stock units	0.2	0.2	0.2	0.2
Market stock units	0.1	0.2	0.1	0.1
Dilutive potential common shares	0.4	0.5	0.3	0.4
Shares used in calculating diluted earnings per share	211.8	219.4	213.3	219.4

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

The adjustments related to the spin-off of our hemophilia business did not have a material impact on the potentially dilutive securities to be considered in the calculation of diluted earnings per share of common stock.

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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)	2017	2016	2017	2016
Research and development	$19.5	$22.7	$55.7	$65.6
Selling, general and administrative	23.6	31.2	71.9	94.6
Restructuring charges	—	—	—	(1.8)
Subtotal	43.1	53.9	127.6	158.4
Capitalized share-based compensation costs	(2.5)	(3.2)	(7.6)	(10.7)
Share-based compensation expense included in total cost and expenses	40.6	50.7	120.0	147.7
Income tax effect	(10.9)	(14.6)	(31.8)	(42.5)
Share-based compensation expense included in net income attributable to Biogen Inc.	$29.7	$36.1	$88.2	$105.2

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)	2017	2016	2017	2016
Market stock units	$4.5	$5.7	$17.1	$27.0
Time-vested restricted stock units	26.7	28.5	81.2	92.5
Cash settled performance units	7.0	7.9	13.0	12.7
Performance units	3.2	9.1	8.9	17.3
Employee stock purchase plan	1.7	2.7	7.4	8.9
Subtotal	43.1	53.9	127.6	158.4
Capitalized share-based compensation costs	(2.5)	(3.2)	(7.6)	(10.7)
Share-based compensation expense included in total cost and expenses	$40.6	$50.7	$120.0	$147.7

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

Spin-off Related Equity Adjustments

Pursuant to an employee matters agreement entered into in connection with the spin-off of our hemophilia business and the provisions of our existing share-based compensation arrangements, we made certain adjustments to the number and terms of our outstanding stock options, restricted stock units, cash settled performance units and other share-based awards to preserve the intrinsic value of the awards immediately before and after the spin-off. For purposes of the vesting of these equity awards, continued employment or service with Biogen or with Bioverativ was treated as continued employment for purposes of both Biogen’s and Bioverativ’s equity awards with the outstanding awards continuing to vest over their respective original vesting periods. Outstanding unvested awards for employees transferring to Bioverativ were converted to unvested Bioverativ awards.

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Adjustments to the number of our share-based compensation awards were made using an adjustment ratio based upon the weighted-average closing price of our common stock for the 10 calendar days prior to the effective date of the spin-off and the volume weighted-average prices for the 10 calendar days of our common stock following the effective date of the spin-off. For stock options, the exercise prices of the awards were modified to maintain the pre-spin intrinsic value of the awards in relation to the post-spin stock price of Biogen. The difference between the fair value of the awards based upon the adjustment ratio and the opening price on the distribution date was not material.

2017 Omnibus Equity Plan

In June 2017 our shareholders approved the Biogen Inc. 2017 Omnibus Equity Plan (2017 Omnibus Equity Plan) for share-based awards to our employees. Awards granted from the 2017 Omnibus Equity Plan may include stock options, shares of restricted stock, restricted stock units, performance shares, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the plan. Shares of common stock available for grant under the 2017 Omnibus Equity Plan consist of 8.0 million shares reserved for this purpose, plus shares of common stock that remained available for grant under our 2008 Omnibus Equity Plan as of June 7, 2017 or that could again become available for grant if outstanding awards under the 2008 Omnibus Equity Plan as of June 7, 2017 are cancelled, surrendered or terminated in whole or in part. The 2017 Omnibus Equity Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares available under the plan in a 1.5-to-1 ratio.

We have not made any awards pursuant to the 2008 Omnibus Equity Plan since our shareholders approved the 2017 Omnibus Equity Plan, and do not intend to make any awards pursuant to the 2008 Omnibus Equity Plan in the future, except that unused shares under the 2008 Omnibus Equity Plan have been carried over for use under the 2017 Omnibus Equity Plan.

15. Income Taxes

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,	
	2017	2016	2017	2016
Statutory rate	35.0 %	35.0 %	35.0 %	35.0 %
State taxes	0.7	1.1	0.6	1.0
Taxes on foreign earnings	(11.4)	(10.1)	(11.4)	(9.4)
Credits and net operating loss utilization	(0.7)	(1.4)	(0.8)	(1.3)
Purchased intangible assets	1.2	1.2	1.3	1.1
Manufacturing deduction	(2.0)	(1.8)	(2.1)	(1.7)
Other permanent items	0.6	0.2	0.7	0.5
Other	0.4	0.5	0.6	0.4
Effective tax rate	23.8 %	24.7 %	23.9 %	25.6 %

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in our effective tax rate was primarily due to a lower relative percentage of our earnings being recognized in the U.S., a high tax jurisdiction, along with a higher deduction for U.S. manufacturing activities. The geographic split of our earnings was affected by milestone and upfront payments in the current year and the spin-off of our hemophilia business, partially offset by growth from the U.S. launch of SPINRAZA and increases in our revenues from anti-CD20 therapeutic programs in the U.S. In addition, in 2017 we are earning a lower benefit from the orphan drug credit due to the FDA's approval of SPINRAZA.

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.

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We made payments totaling approximately $60.0 million to the Danish Tax Authority (SKAT) for assessments received for fiscal 2009, 2011 and 2013 regarding withholding taxes and the treatment of certain intercompany transactions involving a Danish affiliate and another of our affiliates. We continue to dispute the assessments for all of these periods and believe that the positions taken in our historical filings are valid.

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)	2017	2016	2017	2016
Interest income	$20.6	$16.4	$54.2	$43.0
Interest expense	(61.8)	(66.0)	(188.8)	(195.2)
Gain (loss) on investments, net	(4.0)	0.8	(15.0)	(0.3)
Foreign exchange gains (losses), net	6.7	(4.9)	8.4	(2.6)
Other, net	(5.1)	(4.4)	(8.2)	(14.3)
Total other income (expense), net	$(43.6)	$(58.1)	$(149.4)	$(169.4)

Other Current Assets

Other current assets include prepaid taxes totaling approximately $714.4 million and $817.0 million as of September 30, 2017 and December 31, 2016, respectively.

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2017	As of December 31, 2016
Current portion of contingent consideration obligations and milestones	$ 611.5	$ 580.8
Revenue-related reserves for discounts and allowances	467.2	438.6
Employee compensation and benefits	241.9	282.9
Collaboration expenses	180.1	130.9
Royalties and licensing fees	190.8	195.8
Construction in progress	157.6	134.0
Accrued TECFIDERA litigation settlement and license charges	—	454.8
Other	606.1	685.7
Total accrued expenses and other	$ 2,455.2	$ 2,903.5

Pricing of TYSABRI in Italy - AIFA

In the first quarter of 2017, we reached an agreement with the Price and Reimbursement Committee of the Italian National Medicines Agency (Agenzia Italiana del Farmaco, or AIFA) resolving all of AIFA's claims relating to sales of TYSABRI in excess of the reimbursement limit for prior periods. As a result, in the first quarter of 2017 we recognized EUR41.8 million (approximately $45.0 million) in revenues for sales which were previously deferred. These amounts were previously accrued for and included in the table above in Other as of December 31, 2016.

For additional information regarding our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 20, Litigation, to our consolidated financial statements included in our 2016 Form 10-K.

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17. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

In 2007 we entered into a collaboration agreement with Neurimmune SubOne AG (Neurimmune), a subsidiary of Neurimmune AG, for the development and commercialization of antibodies for the treatment of AD. Neurimmune conducts research to identify potential therapeutic antibodies and we are responsible for the development, manufacturing and commercialization of all products.

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 are required to fund 100% of the research and development costs incurred in support of the collaboration agreement.

Amounts incurred by Neurimmune for research and development expenses in support of the collaboration and reimbursed by us were immaterial for the three and nine months ended September 30, 2017 and 2016.

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

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, 2017 and December 31, 2016, the total carrying value of our investments in biotechnology companies totaled $49.7 million and $47.4 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 related to our investments in Neurimmune and other variable interest entities, please read Note 18, Investments in Variable Interest Entities, to our consolidated financial statements included in our 2016 Form 10-K.

18. Collaborative and Other Relationships

Bristol-Myers Squibb Company

On June 1, 2017, we finalized an agreement with Bristol-Myers Squibb Company (BMS) to exclusively license BMS-986168 (now known as BIIB092), a Phase 2-ready experimental medicine with potential in AD and progressive supranuclear palsy (PSP), and made an upfront payment of $300.0 million to BMS. BIIB092 is an antibody targeting tau, the protein that forms the deposits, or tangles, in the brain associated with AD and other neurodegenerative tauopathies such as PSP. PSP is a rare condition that affects movement, speech, vision and cognitive function.

Under the agreement, we received worldwide rights to BIIB092 and are responsible for the full development and global commercialization of BIIB092 in AD and PSP. We may pay BMS up to $410.0 million in additional milestone payments, and potential royalties. We also assumed all remaining obligations to the former stockholders of iPierian, Inc. (iPierian) related to BMS's acquisition of iPierian in 2014. In June 2017 we triggered a $60.0 million developmental milestone payable to the former stockholders of iPierian upon dosing of the first patient in the Phase

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2 PSP study for BIIB092 and we may pay the former stockholders of iPierian up to $490.0 million in remaining milestone payments, and potential royalties.

Both the $300.0 million upfront payment and the $60.0 million developmental milestone payment were recognized as research and development expense in our condensed consolidated statements of income for the nine months ended September 30, 2017.

AbbVie Inc.

We have a collaboration agreement with AbbVie Inc. (AbbVie) aimed at advancing the development and commercialization of ZINBRYTA in MS, which was approved for the treatment of relapsing forms of MS in the U.S. in May 2016 and in the E.U. in July 2016. Under the agreement, we and AbbVie conduct ZINBRYTA co-promotion activities in the U.S., E.U. and Canadian territories (Collaboration Territory), where development and commercialization costs and profits are shared equally. Outside of the Collaboration Territory, we are solely responsible for development and commercialization of ZINBRYTA and will pay a tiered royalty to AbbVie as a percentage of net sales in the low to high teens.

In July 2017 the European Medicines Agency (EMA) announced that it had provisionally restricted the use of ZINBRYTA to adult patients with highly active relapsing disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) or with rapidly evolving severe relapsing MS who are unsuitable for treatment with other DMTs. These restrictions followed the initiation of an EMA review (referred to as an Article 20 Procedure) of ZINBRYTA following the report of a case of fatal fulminant liver failure, as well as four cases of serious liver injury. The outcome of the EMA review process may affect the market for ZINBRYTA, which may result in the impairment of all or a portion of certain assets related to ZINBRYTA. As of September 30, 2017, our condensed consolidated balance sheet includes ZINBRYTA related assets, primarily related to inventory, prepaid tax and intangible assets, totaling approximately $200 million. Offsetting these amounts, we also have an unrecorded tax benefit related to certain ZINBRYTA assets totaling approximately $100 million as of September 30, 2017.

Co-promotion Profits and Losses

In the U.S., AbbVie recognizes revenues on sales to third parties and we recognize our 50% share of the co-promotion profits or losses as a component of other revenues from collaborative and other relationships in our condensed consolidated statements of income. The collaboration began selling ZINBRYTA in the U.S. in the third quarter of 2016. During the three and nine months ended September 30, 2017, we recognized a net reduction in revenue of $2.8 million and $12.6 million, respectively, to reflect our share of an overall net loss within the collaboration, as compared to $13.5 million in each of the prior year comparative periods.

In the E.U. and Canada, we recognize revenues on sales to third parties in product revenues, net and record the related cost of revenues and sales and marketing expenses to their respective line items in our condensed consolidated statements of income as revenues are recognized and related costs are incurred. We also reimburse AbbVie for their 50% share of the co-promotion profits or losses in the E.U. and Canada, which is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income. We began to recognize product revenues on sales of ZINBRYTA in the E.U. in the third quarter of 2016. For the three and nine months ended September 30, 2017, we recognized net expense of $0.7 million and $2.0 million, respectively, to reflect AbbVie's 50% sharing of the net collaboration profits in the E.U. and Canada, as compared to net income recognized of $2.7 million to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada in the prior year comparative periods.

Ionis Pharmaceuticals, Inc.

SPINRAZA (nusinersen)

In January 2012 we entered into an exclusive worldwide option and collaboration agreement with Ionis Pharmaceuticals, Inc. (Ionis) under which both companies develop and commercialize the antisense investigational drug candidate, SPINRAZA, for the treatment of SMA.

Under the terms of the agreement, during the third quarter of 2016, we exercised our option to develop and commercialize SPINRAZA and paid Ionis a $75.0 million license fee in connection with the option exercise. This

amount was recognized as research and development expense in our condensed consolidated statements of income.

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(unaudited, continued)

SPINRAZA was approved for use in the U.S., E.U. and Japan in December 2016, June 2017 and July 2017, respectively. These approvals triggered milestone payments to Ionis totaling $150.0 million during 2017, which were capitalized in intangible assets, net in our condensed consolidated balance sheets.

For the three and nine months ended September 30, 2017, we recognized product revenues totaling $197.6 million and $438.8 million, respectively, on our sales of SPINRAZA in the U.S. and $73.3 million and $82.4 million, respectively, on our sales of SPINRAZA outside of the U.S. Pursuant to 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 in royalty cost of sales within our condensed consolidated statements of income. Royalty cost of sales related to sales of SPINRAZA for the three and nine months ended September 30, 2017 totaled $34.0 million and $64.9 million, respectively.

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, 2017, our ownership interest was approximately 5%, which reflects the effect of additional equity financings in which we did not participate. We maintain an option to purchase additional stock in Samsung Bioepis that would allow us to increase our ownership percentage up to 49.9%. The exercise of this option is within our control.

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

Commercial Agreement

We began to recognize revenue on sales of BENEPALI and FLIXABI in the E.U. in the first and third quarters of 2016, respectively. We reflect revenues on sales of BENEPALI and FLIXABI to third parties in product revenues, net in our condensed consolidated statements of income and record the related cost of revenues and sales and marketing expenses in our condensed consolidated statements of income to their respective line items when these costs are incurred. In August 2017 the European Commission granted a marketing authorization in the E.U. for IMRALDI, an adalimumab biosimilar referencing HUMIRA, triggering an additional $25.0 million milestone payment due to Samsung Bioepis, which was capitalized in intangible assets, net in our condensed consolidated balance sheets as of September 30, 2017.

We share 50% of the profit or loss in accordance with the cost sharing provision of the 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, 2017, we recognized net expense of $34.5 million and $80.5 million, respectively, to reflect Samsung Bioepis's 50% sharing of the net collaboration profits, as compared to net expense recognized of $7.4 million and $1.8 million to reflect sharing of the net collaboration profits 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, 2017, we recognized $8.8 million and $23.7 million, respectively, in connection with these services as a component of other revenues from collaborative and other relationships in our condensed consolidated statements of income, as compared to $0.4 million and $17.3 million, respectively, in the prior year comparative periods.

For additional information related to these and our other significant collaboration arrangements, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2016 Form 10-K.

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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 2016 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

On July 6, 2015, a qui tam action filed on behalf of the United States and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts, and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. Our motion to dismiss is pending. The United States has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

Securities Litigation

We and certain current and former officers are defendants in an action filed by a shareholder on October 20, 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. An estimate of the possible loss or range of loss cannot be made at this time.

Other Matters

Abbreviated New Drug Application Litigation relating to TECFIDERA

In June, July and September 2017 we filed patent infringement actions pursuant to the Hatch-Waxman Act against parties who filed Abbreviated New Drug Applications (ANDAs) for generic versions of TECFIDERA. We have sued the following parties in the United States District Court for the District of Delaware: Amneal Pharmaceuticals LLC, Aurobindo Pharma U.S.A., Inc., Hetero USA, Inc., Impax Laboratories, Inc., Prinston Pharmaceuticals, Inc., Slayback Pharma LLC, Teva Pharmaceuticals USA, Inc., Alkem Laboratories Ltd., Cipla Limited, Glenmark Pharmaceuticals Pvt. Ltd., Lupin Atlantis Holdings SA, Macleods Pharmaceuticals, Ltd., MSN Laboratories Pvt. Ltd., Pharmathen S.A., Shipla Medicare Limited, Sun Pharma Global FZE, Torren Pharmaceuticals, Ltd., TWI Pharmaceuticals, Inc., Windlas Healthcare Pvt., Ltd., Accord Healthcare Inc., Par Pharmaceuticals, Sandoz Inc., Sawai (USA), Inc. and Zydus Pharmaceuticals (USA), Inc. We have also filed actions against Stason Pharmaceuticals, Inc. in the United States District Court for the Central District of California, Zydus Pharmaceuticals (USA), Inc. in the United States District Court for the District of New Jersey, Accord Healthcare Inc. in the Middle District of North Carolina, Par Pharmaceuticals in the Southern District of New York, Sandoz, Inc. in the District of Colorado and Mylan Pharmaceuticals in the United States District Court for the District of West Virginia. No trial has been scheduled in any of these matters.

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Interference Proceeding with Forward Pharma

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

European Patent Office Oppositions

In June 2016 the European Patent Office (EPO) issued a written decision confirming its earlier revocation of our European patent number 2 137 537 (the '537 patent), which we have appealed. The '537 patent includes claims covering the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label.

The EPO has scheduled a hearing for January 2018 on Biogen's and others' oppositions to Forward Pharma's European Patent No. 2 801 355, which was issued in May 2015 and expires in October 2025. 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 EPO and the Technical Board of Appeal and the Enlarged Board of Appeal, as applicable, to make a final determination. For additional information regarding this matter, please read Note 6, Intangibles Assets and Goodwill, to these condensed consolidated financial statements.

Patent Revocation Matter

Swiss Pharma International AG filed actions in the District Court of The Hague (on January 11, 2016) and the German Patents Court (on March 3, 2016) to invalidate the Dutch and German counterparts of our European Patent Number 1 485 127 ("Administration of agents to treat inflammation"), which was issued in June 2011 and concerns administration of natalizumab (TYSABRI) to treat MS. The patent expires in February 2023. In July 2017 the District Court of The Hague ruled that the Dutch counterpart of the patent is invalid and we have appealed. A hearing has been scheduled in the German action for early 2018.

'755 Patent Litigation

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

Bayer, Pfizer, Novartis and EMD Serono have all filed counterclaims in the Consolidated '755 Patent Actions seeking declaratory judgments of patent invalidity and non-infringement, and seeking monetary relief in the form of costs and attorneys' fees, and EMD Serono and Bayer have each filed a counterclaim seeking a declaratory judgment that the '755 Patent is unenforceable based on alleged inequitable conduct. Bayer has also amended its complaint to seek such a declaration. Trial has been set for the first quarter of 2018.

Government Matters

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

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

Biogen's co-pay assistance programs. We are cooperating with the government.

On July 1, 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

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Average Manufacturer Prices in connection with the Medicaid Drug Rebate Program. We are cooperating with the government.

On December 29, 2016, we received a civil investigative demand from the federal government for documents and information relating to our relationships with entities providing clinical education and reimbursement support services. We regard this matter as closed.

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.

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.

20. Subsequent Events

Eisai Co., Ltd.

BAN2401 and E2609 Collaboration

In March 2014, we entered into a collaboration agreement (Eisai Collaboration Agreement) with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize two Eisai product candidates for the treatment of AD, BAN2401, a monoclonal antibody that targets amyloid-beta aggregates, and E2609, a BACE inhibitor. Under the Eisai Collaboration Agreement, Eisai had an option to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for AD (Aducanumab Option).

On October 23, 2017, Eisai exercised its Aducanumab Option and we entered into a new collaboration agreement (Aducanumab Agreement) for the joint development and commercialization of aducanumab. Under the Aducanumab Agreement, the two companies will co-promote aducanumab with a region-based profit split. We will receive a 55% share of the potential profits (losses) in the U.S., a 68.5% share of the potential profits (losses) in the E.U. and a 20% share of the potential profits (losses) in Japan and Asia, excluding China and South Korea. The companies will continue to share equally in the potential profits (losses) in rest of world markets.

Under the Aducanumab Agreement, we will continue to lead the ongoing Phase 3 development of aducanumab and will remain responsible for 100% of development costs for aducanumab incurred in support of the agreement until April 2018. Eisai will then reimburse us for 15% of development expenses for the period April 2018 through December 2018, and 45% thereafter.

In addition, both companies will continue to jointly develop BAN2401 and E2609; however, we are no longer required to pay Eisai any milestone payments for products containing BAN2401 and we are no longer entitled to any potential development and commercial milestone payments from Eisai in relation to aducanumab.

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

For additional information related to our collaboration arrangement with Eisai, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2016 Form 10-K.

Neurimmune

On October 23, 2017, we amended the terms of our existing collaboration agreement with Neurimmune. Pursuant to the amended agreement, we agreed to make a one-time $150.0 million payment to Neurimmune in exchange for a 15% reduction in royalty rates payable on potential commercial sales of aducanumab. Our royalty rates payable on potential commercial sales of aducanumab will now range from the high single digits to low-teens. This payment will be recognized in the fourth quarter of 2017.

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(unaudited, continued)

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

Under the terms of the Aducanumab Agreement, Eisai may elect to share in the benefit and cost of the royalty reduction.

For additional information relating to our collaboration agreement with Neurimmune, please read Note 17, Investments in Variable Interest Entities, to these condensed consolidated financial statements.

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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 condensed consolidated financial statements and accompanying notes beginning on page 5 of this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2016 (2016 Form 10-K).

Executive Summary

Introduction

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies to people living with serious neurological and neurodegenerative diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), SPINRAZA for the treatment of spinal muscular atrophy (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 indicated for the treatment of CLL and follicular lymphoma, OCREVUS indicated for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS), and other potential anti-CD20 therapies under a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group.

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

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

Our innovative drug development and commercialization activities are complemented by our biosimilar therapies that expand access to medicines and reduce the cost burden for healthcare systems. We are leveraging our manufacturing capabilities and know-how by developing, manufacturing and marketing biosimilars through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics). Under our commercial agreement, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the E.U. In August 2017 the European Commission (EC) granted a marketing authorization for IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U.

Corporate Strategy Update

In July 2017 we announced an updated strategic framework to optimize the value of our MS business while investing for the future across our core growth areas of MS and neuroimmunology, Alzheimer's disease (AD) and dementia, Parkinson's disease and movement disorders, and neuromuscular diseases including SMA and amyotrophic lateral sclerosis (ALS). Further, we see opportunities to invest in emerging growth areas such as pain, ophthalmology, neuropsychiatry and acute neurology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy.

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

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

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

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

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

Hemophilia Spin-Off

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

Our consolidated results of operations and financial position included in these unaudited condensed consolidated financial statements reflect the financial results of our hemophilia business for all periods through January 31, 2017. For additional information related to the spin-off of our hemophilia business, please read Note 3, Hemophilia Spin-Off, to our condensed consolidated financial statements included in this report.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was $5.79 for the three months ended September 30, 2017, representing an increase of 22.9% over the same period in 2016.

Our income from operations for the three months ended September 30, 2017, reflects the following:

- Total revenues were $3,077.8 million for the third quarter of 2017, representing an increase of 4.1% over the same period in 2016.
- Product revenues, net totaled $2,622.5 million for the third quarter of 2017, representing an increase of 3.3% over the same period in 2016. This increase was driven by revenues from SPINRAZA and BENEPALI, partially offset by the elimination of worldwide ALPROLIX and ELOCTATE revenues resulting from the spin-off of our hemophilia business on February 1, 2017.
- Revenues from anti-CD20 therapeutic programs totaled $406.5 million for the third quarter of 2017, representing an increase of 28.0% over the same period in 2016. This increase was driven by royalty revenues on sales of OCREVUS.

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- Other revenues totaled $48.8 million for the third quarter of 2017, representing a decrease of 50.5% from the same period in 2016.
- Total cost and expenses totaled $1,424.3 million for the third quarter of 2017, representing a decrease of 6.9% from the same period in 2016. This decrease was primarily driven by a 15.6% decrease in research and development, an 11.2% decrease in cost of sales and a 6.2% decrease in selling, general and administrative expenses. These decreases were partially offset by an increase in collaboration profit sharing and losses on fair value remeasurement of contingent consideration.
- We generated $3,032.7 million of net cash flows from operations for the nine months ended September 30, 2017.
- Cash, cash equivalents and marketable securities totaled approximately $6,570.3 million as of September 30, 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. In addition, the commercialization of certain of our own approved MS products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing MS products. Our products may also face increased competitive pressures from the introduction of generic versions or biosimilars of existing products and other technologies.

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

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

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

Key Pipeline and Product Developments

SPINRAZA (nusinersen)

In June 2017 the EC approved the use of SPINRAZA for the treatment of SMA in pediatric and adult patients in the E.U. SPINRAZA was reviewed under the European Medicines Agency's (EMA) accelerated assessment program, intended to expedite access to patients with unmet medical needs.

In July 2017 the Japanese Ministry of Health, Labor and Welfare approved the use of SPINRAZA for the treatment of infantile SMA and in September 2017 the Japanese Ministry of Health, Labor and Welfare approved the use of SPINRAZA for the treatment of pediatric and adult patients with SMA.

ZINBRYTA (daclizumab)

In July 2017 the EMA announced that it had provisionally restricted the use of ZINBRYTA to adult patients with highly active relapsing disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) or with rapidly evolving severe RMS who are unsuitable for treatment with other DMTs. These restrictions followed the initiation of an EMA review (referred to as an Article 20 Procedure) of ZINBRYTA, following the report of a case of fatal fulminant liver failure, as well as four cases of serious liver injury.

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

OCREVUS (Ocrelizumab)

In March 2017 the Roche Group announced that the U.S. Food and Drug Administration (FDA) approved OCREVUS for the treatment of RMS and PPMS.

In July 2017 and September 2017 the Roche Group announced that OCREVUS was approved in Australia and Switzerland, respectively, for the treatment of RMS and PPMS.

For additional information related to our agreements with Genentech, please read the “Revenues from Anti-CD20 Therapeutic Programs” section of this report.

IMRALDI (adalimumab)

In August 2017 the EC granted a marketing authorization for IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U.

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For additional information on our agreements with Samsung Bioepis, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2016 Form 10-K.

Aducanumab (BIIB037)

In August 2017 we announced results from a recently conducted analysis of the long-term extension (LTE) of our ongoing Phase 1b study of aducanumab, our anti-amyloid beta antibody candidate for AD, which included data from the placebo-controlled period and LTE for patients treated with aducanumab up to 24 months in the titration cohort and up to 36 months in the fixed-dose cohorts. The results are consistent with previously reported results from this ongoing Phase 1b study and support the design of the ongoing Phase 3 studies of aducanumab for early AD.

IONIS-MAPT$_{Rx}$

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

BIIB054

In July 2017 we completed enrollment in the Phase 1 study of BIIB054, an anti-alpha synuclein antibody, in both healthy volunteers and patients with early onset Parkinson's disease.

Results of Operations

Revenues

Revenues are summarized as follows:

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
(In millions, except percentages)	2017		2016		2017		2016	
Product revenues:								
United States	$1,774.0	57.6 %	$1,828.6	61.9 %	$5,265.9	58.7 %	$5,269.4	61.4 %
Rest of world	848.5	27.6 %	711.0	24.1 %	2,376.4	26.5 %	2,045.6	23.9 %
Total product revenues	2,622.5	85.2 %	2,539.6	86.0 %	7,642.3	85.2 %	7,315.0	85.3 %
Revenues from anti-CD20 therapeutic programs	406.5	13.2 %	317.6	10.7 %	1,144.2	12.8 %	996.3	11.6 %
Other revenues	48.8	1.6 %	98.6	3.3 %	180.4	2.0 %	265.5	3.1 %
Total revenues	$3,077.8	100.0%	$2,955.8	100.0%	$8,966.9	100.0%	$8,576.8	100.0%

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Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2017			2016			For the Nine Months Ended September 30, 2017			2016		
Multiple Sclerosis:												
TECFIDERA	$1,069.6	40.8	%	$1,033.7	40.7	%	$3,138.4	41.1	%	$2,966.1	40.5	%
Interferon*	662.0	25.2	%	708.3	27.9	%	2,000.9	26.2	%	2,107.0	28.8	%
TYSABRI	469.4	17.9	%	515.5	20.3	%	1,510.4	19.8	%	1,489.9	20.4	%
FAMPYRA	24.3	0.9	%	21.1	0.8	%	67.4	0.9	%	62.9	0.9	%
ZINBRYTA	14.2	0.5	%	1.9	0.1	%	41.0	0.5	%	1.9	—	%
Spinal Muscular Atrophy:												
SPINRAZA	270.9	10.3	%	—	—	%	521.2	6.8	%	—	—	%
Hemophilia:												
ELOCTATE	—	—	%	131.8	5.2	%	48.4	0.6	%	364.2	5.0	%
ALPROLIX	—	—	%	85.2	3.4	%	26.0	0.3	%	240.5	3.2	%
Other Product Revenues:												
FUMADERM	10.7	0.4	%	11.3	0.4	%	30.7	0.4	%	34.5	0.5	%
BENEPALI	99.2	3.8	%	30.7	1.2	%	253.2	3.3	%	47.9	0.7	%
FLIXABI	2.2	0.1	%	0.1	—	%	4.7	0.1	%	0.1	—	%
Total product revenues	$2,622.5	100.0	%	$2,539.6	100.0	%	$7,642.3	100.0	%	$7,315.0	100.0	%

*Interferon includes AVONEX and PLEGRIDY.

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Multiple Sclerosis (MS)

TECFIDERA

For the three months ended September 30, 2017, compared to the same period in 2016, the decrease in U.S. TECFIDERA revenues was primarily due to a decrease in unit sales volume of 7%, partially offset by price increases.

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in U.S. TECFIDERA revenues was primarily due to price increases, partially offset by a decrease in unit sales volume of 4% and higher discounts and allowances.

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume of 21% and 20%, respectively, in existing markets and new markets where we continue to launch the product and expand our presence around the world. These increases were partially offset by pricing reductions in certain European countries.

We anticipate relatively stable demand for TECFIDERA on a global basis, with patient growth in our international markets offsetting modest patient declines in the U.S., primarily resulting from increasing competition from additional treatments for MS, including OCREVUS.

Interferon

AVONEX and PLEGRIDY

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in U.S. Interferon revenues was primarily due to an overall decrease in Interferon unit sales volumes of 11% and 12%, respectively, which was primarily attributable to patients transitioning to other MS therapies, partially offset by price increases.

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in rest of world Interferon revenues was primarily due to an overall decrease in AVONEX unit sales volumes of 18% and 15%, respectively, primarily due to patients transitioning to other MS therapies.

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

AVONEX

For the three and nine months ended September 30, 2017, U.S. AVONEX revenues totaled $397.7 million and $1,218.2 million, respectively, as compared to $421.8 million and $1,264.0 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2017, rest of world AVONEX revenues totaled $139.9 million and $413.4 million, respectively, as compared to $158.3 million and $485.8 million, respectively, in the prior year comparative periods.

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PLEGRIDY

For the three and nine months ended September 30, 2017, U.S. PLEGRIDY revenues totaled $75.6 million and $221.6 million, respectively, as compared to $83.9 million and $228.2 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2017, rest of world PLEGRIDY revenues totaled $48.8 million and $147.7 million, respectively, as compared to $44.3 million and $129.0 million, respectively, in the prior year comparative periods.

TYSABRI

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in U.S. TYSABRI revenues was primarily due to a decrease in unit sales volume of 6% and 2%, respectively, and higher discounts and allowances, partially offset by price increases.

For the three months ended September 30, 2017, compared to the same period in 2016, the decrease in rest of world TYSABRI revenues was primarily due to a prior year favorable adjustment of approximately $20.0 million to previous reserves estimates related to a government price reimbursement program in Italy included in our discounts and allowances, partially offset by a 1% increase in unit sales volume.

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in rest of world TYSABRI revenues was primarily due to the recognition of approximately $45.0 million of previously deferred revenue in Italy relating to the pricing agreement with the Italian National Medicines Agency (Agenzia Italiana del Farmaco, or AIFA), as discussed below, and an 8% increase in unit sales volume, partially offset by a

prior year favorable adjustment of approximately $20.0 million to previous reserves estimates related to a government price reimbursement program included in our discounts and allowances.

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 20, Litigation, to our consolidated financial statements included in our 2016 Form 10-K.

We anticipate relatively stable demand for TYSABRI on a global basis, with patient growth in our international markets offsetting modest patient declines in the U.S. primarily resulting from increasing competition from additional treatments for MS, primarily OCREVUS.

ZINBRYTA

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

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

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Spinal Muscular Atrophy (SMA)

SPINRAZA

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

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

Biosimilars

BENEPALI and FLIXABI

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

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

Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN and GAZYVA collaboration operating profits and royalty revenues on other anti-CD20 therapeutic programs are summarized as follows:

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

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

	For the Three Months Ended September 30,	
(In millions)	2017	2016
Product revenues, net	$1,039.7	$961.8
Cost and expenses	172.8	191.7
Pre-tax profits in the U.S.	866.9	770.1
Biogen's share of pre-tax profits	$325.1	$301.0

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	For the Nine Months Ended September 30,	
(In millions)	2017	2016
Product revenues, net	$3,164.5	$2,969.3
Cost and expenses	567.7	544.9
Pre-tax profits in the U.S.	2,596.8	2,424.4
Biogen's share of pre-tax profits	$996.1	$947.6

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

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

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the increase in U.S. product revenues was primarily due to selling price increases, an increase in RITUXAN unit sales volume of 4% and 2%, respectively, and an increase in GAZYVA unit sales volume of 39% and 33%, respectively, partially offset by higher discounts and allowances.

For the three months ended September 30, 2017, compared to the same period in 2016, collaboration costs and expenses decreased primarily due to decreases in selling and marketing and research and development costs. Collaboration costs and expenses for the nine months ended September 30, 2017, as depicted in the table above, excludes certain expenses charged to the collaboration by Genentech that we believe remain the responsibility of Genentech and we are not obligated to pay under the terms of the collaboration agreement. Accordingly, we did not recognize the effect of those expenses in the determination of our share of pre-tax collaboration profits and Genentech has withheld approximately $120 million from amounts due to us in relation to collaboration activity for the first quarter of 2017, representing Genentech’s estimate of our share of these

expenses. We remain in discussions with Genentech about a resolution relating to these amounts.

Excluding amounts under dispute, for the nine months ended September 30, 2017, compared to the same period in 2016, collaboration costs and expenses increased primarily due to an increase in RITUXAN product cost of sales.

Other Revenues from Anti-CD20 Therapeutic Programs

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

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, other revenues from anti-CD20 therapeutic programs increased primarily due to the launch of OCREVUS in the second quarter of 2017.

OCREVUS

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

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

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

For additional information related to our collaboration with Genentech, including information regarding the pre-tax profit sharing formula and its impact on future revenues from anti-CD20 therapeutic programs, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2016 Form 10-K.

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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)	2017		2016		2017		2016	
Other revenues from collaborative and other relationships	$6.2	12.7 %	$(0.9)	(0.9)%	$21.5	11.9 %	$30.2	11.4 %
Other royalty and corporate revenues	42.6	87.3 %	99.5	100.9 %	158.9	88.1 %	235.3	88.6 %
Total other revenues	$48.8	100.0%	$98.6	100.0 %	$180.4	100.0%	$265.5	100.0%

Other Revenues from Collaborative and Other Relationships

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

For the three months ended September 30, 2017, compared to the same period in 2016, the increase in other revenues from collaborative and other relationships was primarily due to a decrease in net losses recognized in the U.S. territory under our collaboration with AbbVie, totaling $2.8 million, as compared to $13.5 million recognized in the prior year comparative period.

For the nine months ended September 30, 2017, compared to the same period in 2016, the decrease in other revenues from collaborative and other relationships was primarily due to the impact of the spin-off of our hemophilia business on February 1, 2017.

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

Other Royalty and Corporate Revenues

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

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in royalty and other corporate revenues was primarily due to lower contract manufacturing revenues related to the volume of shipments of drug substance production provided to a strategic partner.

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Reserves for Discounts and Allowances

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

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

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

For the three and nine months ended September 30, 2017, reserves for discounts and allowances as a percentage of gross product revenues were 21.4% and 21.8%, respectively, as compared to 20.8%, respectively, in both of the prior year comparative periods.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the increase in discounts was primarily driven by an increase in rest of world product revenues, due in part to an increase in biosimilar revenues, as well as an increase in gross selling prices, partially offset by the impact from the spin-off of our hemophilia business on February 1, 2017.

Contractual Adjustments

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

Returns

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

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, return provisions were relatively consistent.

For additional information related to our reserves, please read Note 4, Reserves for Discounts and Allowances, to our condensed consolidated financial statements included in this report.

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Cost and Expenses

A summary of total cost and expenses is as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2017	2016	Change %	For the Nine Months Ended September 30, 2017	2016	Change %
Cost of sales, excluding amortization of acquired intangible assets	$370.0	$416.9	(11.2)%	$1,120.8	$1,100.2	1.9 %
Research and development	446.4	529.0	(15.6)%	1,666.0	1,439.4	15.7 %
Selling, general and administrative	433.8	462.7	(6.2)%	1,363.1	1,452.4	(6.1)%
Amortization of acquired intangible assets	108.9	99.7	9.2 %	674.9	281.4	139.8 %
Acquired in-process research and development	—	—	**	120.0	—	**
Collaboration profit (loss) sharing	35.2	4.7	648.9 %	82.5	(0.9)	**
(Gain) loss on fair value remeasurement of contingent consideration	30.0	5.9	408.5 %	61.2	18.8	225.5 %
Restructuring charges	—	11.6	(100.0)%	—	21.3	(100.0)%
Total cost and expenses	$1,424.3	$1,530.5	(6.9)%	$5,088.5	$4,312.6	18.0 %

** Percentage not meaningful.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Product Cost of Sales

For the three months ended September 30, 2017, compared to the same period in 2016, the decrease in product cost of sales was primarily driven by lower contract manufacturing, the impact from the spin-off of our hemophilia business on February 1, 2017 and the accelerated depreciation recorded in the third quarter of 2016 as a result of our decision to cease manufacturing in Cambridge, MA. These decreases were partially offset by higher unit sales volume related to our biosimilar product shipments and an increase in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons.

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in product cost of sales was primarily driven by higher unit sales volume related to our biosimilar product shipments and an increase in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons. These increases were partially offset by the impact from the spin-off of our hemophilia business on February 1, 2017, lower contract manufacturing shipments and the accelerated depreciation recorded in the second and third quarters of 2016 as a result of our decision to cease manufacturing in Cambridge, MA.

For additional information related to our Cambridge, MA manufacturing facility, please read Note 3, Restructuring, Business Transformation and Other Cost Saving Initiatives, to our consolidated financial statements included in our 2016 Form 10-K.

Royalty Cost of Sales

For the three months ended September 30, 2017, compared to the same period in 2016, the decrease in royalty cost of sales was primarily driven by lower royalties on sales of TYSABRI resulting from the expiration of certain third-party royalties and the elimination of royalties payable on sales of hemophilia product resulting from the spin-off of our hemophilia business on February 1, 2017. These decreases were partially offset by the recognition of royalties payable to Ionis on sales of SPINRAZA.

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For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in royalty cost of sales was primarily driven by the recognition of royalties payable to Ionis on sales of SPINRAZA and higher royalties on sales of AVONEX and PLEGRIDY in the U.S., as described below. These increases were partially offset by lower royalties on sales of TYSABRI resulting from the expiration of certain third-party royalties and the elimination of royalties payable on sales of hemophilia product resulting from the spin-off of our hemophilia business on February 1, 2017.

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

Research and Development

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We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities, particularly within areas of our scientific, manufacturing and technical capabilities.

A significant amount of our research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as management costs, as well as depreciation, information technology and facility-based expenses. These costs are considered other research and development costs in the table above and are not allocated to a specific program or stage.

Research and development expense incurred in support of our marketed products includes costs associated with product lifecycle management activities including, if applicable, costs associated with the development of new indications for existing products. Late stage programs are programs in Phase 3 development or in registration stage. Early stage

programs are programs in Phase 1 or Phase 2 development. Research and discovery represents costs incurred to support our discovery research and translational science efforts. Costs are reflected in the development stage based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same year. For several of our programs, the research and development activities are part of our collaborative and other relationships. Our costs reflect our share of the total costs incurred.

For the three months ended September 30, 2017, compared to the same period in 2016, the decrease in research and development expense was primarily related to a decrease in milestone and upfront expenses and decreased costs incurred in connection with our marketed products and our late stage and research and discovery programs.

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in research and development expense was primarily related to milestone and upfront expenses, partially offset by decreased costs incurred in connection with our marketed products and our late stage and research and discovery programs.

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

Milestone and Upfront Expenses

The decrease in milestone and upfront expenses for the three months ended September 30, 2017, compared to the same period in 2016, was primarily due to the $75.0 million license fee paid to Ionis in the third quarter of 2016 upon the exercise of our option to develop and commercialize SPINRAZA.

The increase in milestone and upfront expenses for the nine months ended September 30, 2017, compared to the same period in 2016, was primarily due to a $300.0 million upfront payment to Bristol-Myers Squibb Company (BMS) upon the closing of our agreement to exclusively license BMS-986168 (now known as BIIB092) and a $60.0 million developmental milestone that became payable to the former stockholders of iPierian, Inc. upon dosing of the first patient in the Phase 2 progressive supranuclear palsy (PSP) study for BIIB092. These amounts were partially offset by the prior year license fee paid to Ionis upon the exercise of our option to develop and commercialize SPINRAZA discussed above and the $20.0 million upfront milestone paid to the University of Pennsylvania upon entering into a collaboration and alliance agreement in May 2016.

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For additional information related to our agreements with BMS and Ionis, please read Note 18, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report.

Marketed Products

The decrease in spending associated with our marketed products for the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily due to a reduction in spending resulting from the spin-off of our hemophilia business on February 1, 2017, and a reduction in spending related to TECFIDERA, partially offset by increased spending related to SPINRAZA following its approval in the U.S. in the fourth quarter of 2016.

Late Stage Programs

The decrease in spending associated with our late stage programs for the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily related to the approval of SPINRAZA in the fourth quarter of 2016. These decreases were partially offset by increased costs associated with the development of aducanumab and costs incurred associated with the development of E2609, a BACE inhibitor that was advanced to a late stage program in the fourth quarter of 2016.

Early Stage Programs

The increase in spending associated with early stage programs for the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily related to spending associated with the development of BIIB092 in AD and PSP pursuant to our June 2017 agreement with BMS, BIIB074 in trigeminal neuralgia (TGN) and BIIB076 in AD. These increases were partially offset by a reduction in costs resulting from our discontinuance of development of amiselimod in the third quarter of 2016.

Selling, General and Administrative

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decreases in selling, general and administrative expenses were primarily due to a reduction in operational spending resulting from the spin-off of our hemophilia business on February 1, 2017, and the execution of targeted cost reduction initiatives, partially offset by an increase in commercialization costs associated with SPINRAZA.

The comparative decrease in selling, general and administrative expenses for the nine month comparative periods also reflects the discontinuance of our TECFIDERA television advertising campaign in the second quarter of 2016, partially offset by an increase in corporate giving throughout 2017.

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Amortization of Acquired Intangible Assets

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

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

We monitor events and expectations regarding product performance. If new information indicates that the assumptions underlying our most recent analysis are substantially different than those utilized in our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenues of the relevant process. The occurrence of an adverse event could substantially increase the amount of amortization expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

Amortization of acquired intangible assets for the three and nine months ended September 30, 2017, includes $30.4 million and $413.4 million, respectively, of amortization and impairment charges associated with our U.S. and rest of world licenses to Forward Pharma A/S' (Forward Pharma) intellectual property related to TECFIDERA acquired in the first quarter of 2017, as discussed below.

TECFIDERA License Rights

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

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the E.U., concerning intellectual property related to TECFIDERA. In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma appealed to the U.S. Court of Appeals for the Federal Circuit and the appeal is pending. For additional information related to these disputes, please read Note 19, Litigation, to our condensed consolidated financial statements included in this report.

As we prevailed in the U.S. proceeding in March 2017, we evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded an impairment charge 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. We also 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.

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

Overall, the value of our acquired IPR&D assets is dependent upon a number of variables, including estimates of future revenues and the effects of competition, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from a clinical trial phase to the next. We are continually reevaluating our estimates concerning these variables and evaluating industry data regarding the productivity of clinical research and the development process. Changes in our estimates of items may result in a significant change to our valuation of these assets.

We review amounts capitalized as acquired IPR&D for impairment at least annually, as of October 31, and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable. Our most recent impairment assessment as of October 31, 2016 resulted in no impairments. Changes to clinical development plans, regulatory feedback received, life cycle management strategies and changes in program economics, including foreign currency exchange rates, are evaluated regularly. The field of developing treatments for forms of neuropathic pain, such as TGN and idiopathic pulmonary fibrosis (IPF) are highly competitive and can be affected by changes to expected market candidates and changes in timing and the clinical development of our product candidates. There can be no assurance that we will be able to successfully develop BIIB074 for the treatment of TGN or STX-100 for the treatment of IPF or other indications, including our ability to confirm safety and efficacy based on data from clinical trials, or that a successfully developed therapy will be able to secure sufficient pricing in a competitive market. Changes in events and circumstances for these programs may have a material impact on the value of our related IPR&D.

For additional information related to the amortization of acquired intangible assets and our TECFIDERA settlement and license agreement please read Note 6, Intangible Assets and Goodwill, to our condensed consolidated financial statements included in this report.

Acquired In-Process Research and Development

On May 15, 2017, we completed an asset purchase of the Phase 3 candidate, CIRARA (now known as BIIB093), from Remedy Pharmaceuticals Inc. (Remedy). Upon closing of the transaction, we made a $120.0 million upfront payment to Remedy, which was recorded as acquired in-process research and development in our condensed consolidated statements of income during the second quarter of 2017 as BIIB093 had not yet reached technological feasibility. For additional information related to this transaction, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report.

Collaboration Profit (Loss) Sharing

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

We began to recognize revenues on sales of biosimilars in the first quarter of 2016. For the three and nine months ended September 30, 2017, we shared collaboration profits and therefore recognized net expense of $34.5 million and $80.5 million, respectively, as compared to net expense of $7.4 million and $1.8 million, respectively, in the prior year comparative periods. The increase in profit sharing expense for the comparative periods was primarily due to increased collaboration profits resulting from increased biosimilar product sales.

We began to recognize revenues on sales of ZINBRYTA in the E.U. in the third quarter of 2016. For the three and nine months ended September 30, 2017, we recognized net expense of $0.7 million and $2.0 million, respectively, to reflect AbbVie's 50% sharing of the net collaboration profits in the E.U. and Canada as compared to net income recognized of $2.7 million in both of the prior year comparative periods, to reflect AbbVie's 50% sharing of the net collaboration losses in the E.U. and Canada.

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

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

Consideration payable for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular factor or factors. We record an obligation for such contingent consideration payments at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in our condensed consolidated statements of income.

The change in fair value remeasurement of contingent consideration for the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily due to the increase in the probability of achieving certain developmental milestones based upon the progression of the underlying clinical programs.

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Other Income (Expense), Net

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the change in other income (expense), net was primarily due to an increase in foreign currency exchange gains, an increase in interest income and a decrease in interest expense, partially offset by other than temporary impairments recorded on strategic investments during the year.

Income Tax Provision

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

For the three and nine months ended September 30, 2017, compared to the same periods in 2016, the decrease in our effective tax rate was primarily due to a lower relative percentage of our earnings being recognized in the U.S., a high tax jurisdiction, along with a higher deduction for U.S. manufacturing activities. The geographic split of our earnings was affected by milestone and upfront payments in the current year and the spin-off of our hemophilia business, partially offset by growth from the U.S. launch of SPINRAZA and increases in our revenues from anti-CD20 therapeutic programs in the U.S. In addition, in 2017 we are earning a lower benefit from the orphan drug credit due to the FDA's approval of SPINRAZA.

For more information on our uncertain tax positions and income tax rate reconciliation for the three and nine months ended September 30, 2017 and 2016, please read Note 15, Income Taxes, to our condensed consolidated financial statements included in this report.

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Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions, except percentages)	As of September 30, 2017	As of December 31, 2016	Change	%
Financial assets:				
Cash and cash equivalents	$ 1,548.1	$ 2,326.5	(33.5	)%
Marketable securities — current	1,960.2	2,568.6	(23.7	)%
Marketable securities — non-current	3,062.0	2,829.4	8.2	%
Total cash, cash equivalents and marketable securities	$ 6,570.3	$ 7,724.5	(14.9	)%
Borrowings:				
Current portion of notes payable and other financing arrangements	$ 573.2	$ 4.7	**	
Notes payable and other financing arrangements	5,938.3	6,512.7	(8.8	)%
Total borrowings	$ 6,511.5	$ 6,517.4	(0.1	)%
Working capital:				
Current assets	$ 7,568.0	$ 8,732.2	(13.3	)%
Current liabilities	(3,448.4)	(3,419.9)	0.8	%
Total working capital	$ 4,119.6	$ 5,312.3	(22.5	)%

** Percentage not meaningful.

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 and settlement charges that were 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 intellectual property related to TECFIDERA;
- $636.8 million used for purchases of property, plant and equipment;
- $302.7 million net cash contribution made to Bioverativ; and
- $230.0 million in upfront and milestone payments made to Remedy and Ionis.

For the nine months ended September 30, 2016, certain significant cash flows were as follows:

- $3.0 billion in net cash flows provided by operating activities, net of:
  - $1.3 billion in total payments for income taxes;
- $900.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $434.0 million used for purchases of property, plant and equipment; and
- $348.9 million used for share repurchases.

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 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

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new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources should we identify a significant new opportunity.

The undistributed cumulative foreign earnings of certain of our foreign subsidiaries, exclusive of earnings that would result in little or no net income tax expense under current U.S. tax law or which has already been subject to tax under U.S. tax law, are invested indefinitely outside the U.S.

Of the total cash, cash equivalents and marketable securities at September 30, 2017, approximately $4.4 billion was generated in foreign jurisdictions and is primarily intended for use in our foreign operations or in connection with business development transactions outside the U.S. In managing our day-to-day liquidity in the U.S., we do not rely on the unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings.

For additional information related to certain risks that could negatively impact our financial position or future results of operations, please read the “Risk Factors” and “Quantitative and Qualitative Disclosures About Market Risk” sections of this report.

Share Repurchase Programs

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock. This authorization does not have an expiration date. All share repurchases under this authorization will be retired. Under this program, we repurchased and retired 3.7 million shares of common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of common stock under this program during the three months ended September 30, 2017. During the three and nine months ended September 30, 2016, we repurchased and retired 1.1 million shares of common stock at a cost of $348.9 million. As of September 30, 2017, approximately $3.0 billion remains available to repurchase shares under this authorization.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of common stock, which was completed as of March 31, 2017. During the nine months ended September 30, 2017, we repurchased 1.3 million shares of common stock at a cost of $365.4 million under this program. We did not repurchase any shares of common stock under this program during the three and nine months ended September 30, 2016.

Cash, Cash Equivalents and Marketable Securities

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

The net decrease in cash, cash equivalents and marketable securities at September 30, 2017 from December 31, 2016, was primarily due to cash used for share repurchases, the payment made to Forward Pharma in connection with our January 2017 settlement and license agreement, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, net purchases of property, plant and equipment, upfront and milestone payments made to BMS, Remedy and Ionis and the net cash contribution made to Bioverativ. These cash outflows were partially offset by cash flows related to operations.

Borrowings

The following is a summary of our principal indebtedness:

- $550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018;
- $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020;
- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022;
- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025; and
- $1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045.

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

We expect to redeem our $550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 during the fourth quarter of 2017. As a result, we expect to recognize an insignificant loss on the extinguishment of debt in other income (expense), net in our condensed consolidated statements of income. For additional information on our 6.875% Senior Notes due March 1, 2018 and related interest rate swap contracts, please read Note

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11, Indebtedness, to our consolidated financial statements included in our 2016 Form 10-K.

During the third quarter of 2015, we entered into a $1.0 billion, 5-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of September 30, 2017, we had no outstanding borrowings and were in compliance with all covenants under this facility.

For a summary of the fair and carrying values of our outstanding borrowings as of September 30, 2017 and December 31, 2016, 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, 2017 from December 31, 2016, reflects a decrease in total current assets of approximately $1.2 billion and an increase in total current liabilities of $28.5 million.

The decrease in total current assets was driven by a decrease in net cash, cash equivalents and marketable securities, as described above.

The increase in current liabilities was driven by the reclassification to current liabilities of $550.0 million of our 6.875% Senior Notes due March 1, 2018, as these notes are due within one year, partially offset by a reduction in accrued expenses primarily due to the payment of the $454.8 million charge that was accrued as of December 31, 2016 in relation to our settlement and license agreement with Forward Pharma.

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Cash Flows

The following table summarizes our cash flow activity:

	For the Nine Months Ended September 30,		
(In millions, except percentages)	2017	2016	% Change
Net cash flows provided by operating activities	$3,032.7	$3,005.3	0.9 %
Net cash flows used in investing activities	$(2,193.6)	$(1,903.1)	15.3 %
Net cash flows used in financing activities	$(1,671.9)	$(326.1)	**

** Percentage not meaningful.

Operating Activities

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

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

- Non-cash operating items such as depreciation and amortization, impairment charges, acquired in-process research and development and share-based compensation;
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- Changes associated with the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in net cash flows provided by operating activities was primarily due to a decrease in income tax payments in the U.S., partially offset by the $454.8 million payment that was accrued as of December 31, 2016 and paid in the first quarter of 2017, in relation to our settlement and license agreement with Forward Pharma.

Investing Activities

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in net cash flows used in investing activities was primarily due to the $795.2 million payment made to license Forward Pharma's intellectual property related to TECFIDERA in the first quarter of 2017, the $120.0 million payment made to Remedy for the purchase of BIIB093 in the second quarter of 2017, the $60.0 million and $50.0 million milestone payments made to Ionis in the first and third quarters of 2017, respectively, related to the approvals of SPINRAZA and an increase in purchases of property, plant and equipment primarily related to the construction of our Solothurn, Switzerland facility, partially offset by an increase in net proceeds of marketable securities.

Financing Activities

For the nine months ended September 30, 2017, compared to the same period in 2016, the increase in net cash flows used in financing activities was primarily due to approximately $1.4 billion of cash used for share repurchases in the first half of 2017 and the $302.7 million net cash contribution made to Bioverativ in connection with the spin-off of our hemophilia business in February 2017.

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Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, capital 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, 2016.

TYSABRI Contingent Payments

In 2013 we acquired from Elan Corporation plc (Elan) full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the terms of the acquisition agreement, we are obligated to make contingent payments to Elan of 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our 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 another third party effective January 2017.

Contingent Consideration related to Business Combinations

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

As the acquisitions of Convergence, Stromedix and BIN occurred after January 1, 2009, we record contingent consideration liabilities at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately $1.2 billion in remaining milestones related to these acquisitions.

Fumapharm AG

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

During the nine months ended September 30, 2017, we paid $900.0 million in contingent payments as we reached the $11.0 billion, $12.0 billion and $13.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2016, the first quarter of 2017 and the second quarter of 2017, respectively, and accrued $300.0 million upon reaching $14.0 billion in total cumulative sales of Fumapharm Products in the third quarter of 2017.

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

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of September 30, 2017, we could make potential future milestone payments to third parties of up to approximately $3.1 billion, including approximately $0.6 billion in development milestones, approximately $0.9 billion in regulatory milestones and approximately $1.6 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 had not occurred as of September 30, 2017, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not

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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 $25.0 million of milestone payments during the remainder of 2017 in addition to the $40.0 million due to Ionis for the regulatory approval of SPINRAZA in Japan and the $25.0 million due to Samsung Bioepis for the marketing authorization of IMRALDI in the E.U.

Other Funding Commitments

As of September 30, 2017, we have several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). Our contracts with CROs are generally cancellable, with notice, at our option. We recorded accrued expenses of approximately $35.0 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2017. We have approximately $455.0 million in cancellable future commitments based on existing CRO contracts as of September 30, 2017.

Tax Related Obligations

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of September 30, 2017, we have approximately $80.0 million of liabilities associated with uncertain tax positions.

Other Off-Balance Sheet Arrangements

We do not have any relationships with entities often referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We consolidate variable interest entities if we are the primary beneficiary.

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.

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 ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

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” of our 2016 Form 10-K. There have been no material changes to these critical accounting estimates since our 2016 Form 10-K.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market Risk

We are subject to certain risks that may affect our results of operations, cash flows and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements, pricing pressures worldwide and weak economic conditions in the foreign markets in which we operate. We manage the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. We do not enter into financial instruments for trading or speculative purposes. The counterparties to these contracts are major financial institutions, and there is no significant concentration of exposure with any one counterparty.

Foreign Currency Exchange Risk

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. We have operations or maintain distribution relationships in the U.S., Europe, Canada, Asia, and Central and South America. In addition, we recognize our share of pre-tax co-promotion profits on RITUXAN in Canada. As a result, our 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. revenue will decline when reported in U.S. dollars. The impact to net income as a result of a strengthening U.S. dollar will be partially mitigated by the value of non-U.S. expense, which will also decline when reported in U.S. dollars. As the U.S. dollar weakens versus other currencies, the value of the non-U.S. revenue and expenses will increase when reported in U.S. dollars. We have established revenue and operating expense hedging and balance sheet risk management programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign currency exchange rates.

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

Revenue and Operating Expense Hedging Program

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues and operating expenses. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 21 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 9, Derivative Instruments, to our condensed consolidated financial statements included in this report.

Our ability to mitigate the impact of exchange rate changes on revenues and net income diminishes as significant exchange rate fluctuations are sustained over extended periods of time. In particular, devaluation or significant deterioration of foreign currency exchange rates are difficult to mitigate and likely to negatively impact earnings. The cash flows from these contracts are reported as operating activities in our condensed consolidated statements of cash flows.

Balance Sheet Risk Management Hedging Program

We also use forward contracts to mitigate the foreign currency exposure related to certain balance sheet items. The primary objective of our balance sheet risk management program is to mitigate the exposure of foreign currency denominated net monetary assets and liabilities of foreign affiliates. In these instances, we principally utilize currency forward contracts. We have not elected hedge accounting for the balance sheet related items. The cash flows from these contracts are reported as operating activities in our condensed consolidated statement of cash flows.

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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, 2017 and December 31, 2016, a hypothetical adverse 10% movement in foreign currency rates compared to the U.S. dollar across all maturities would result in a hypothetical decrease in the fair value of forward contracts of approximately $210.0 million and $172.0 million, respectively. The estimated fair value change was determined by measuring the impact of the hypothetical exchange rate movement on outstanding forward contracts. Our use of this methodology to quantify the market risk of such instruments is subject to assumptions and actual impact could be significantly different. The quantitative information about market risk is limited because it does not take into account all foreign currency operating transactions.

Interest Rate Risk

Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of September 30, 2017 and December 31, 2016, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $53.0 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, 2017 and December 31, 2016, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately $6.8 million.

Pricing Pressure

Governments in some international markets in which we operate have implemented measures aimed at reducing healthcare costs to limit the overall level of government expenditures. These implemented measures vary by country and include, among other things, mandatory rebates and discounts, prospective and possible retroactive price reductions and suspensions on price increases of pharmaceuticals.

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

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

Our products are also susceptible to increasing competition from generics and biosimilars in many markets. Generic versions of drugs and biosimilars are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of generic or biosimilar versions of our marketed products, as well as lower-priced competing products, likely would significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may have an adverse impact on our results of operations.

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

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Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We operate in certain countries where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

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

We believe that our allowance for doubtful accounts was adequate as of September 30, 2017 and December 31, 2016. However, if significant changes occur in the availability of government funding or the reimbursement practices of these or other governments, we may not be able to collect on amounts due to us from customers in such countries and our results of operations could be adversely affected.

Item 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, 2017. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the 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, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Part II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

We are substantially dependent on revenues from our principal products.

Our current revenues depend upon continued sales of our principal products, and, unless we develop or acquire rights to new products and technologies, we will be substantially dependent on sales from our principal products for many years. Further, following the completion of the spin-off of our hemophilia business, our revenues are further reliant and concentrated on sales of our MS products in an increasingly competitive market, and revenues from sales of our product for SMA. Any of the following negative developments relating to any of our principal products may adversely affect our revenues and results of operations or could cause a decline in our stock price:

- safety or efficacy issues;
- the introduction or greater acceptance of competing products, including lower-priced competing products;
- constraints and additional pressures on product pricing or price increases, including those resulting from governmental or regulatory requirements, increased competition, or changes in, or implementation of, reimbursement policies and practices of payors and other third parties; or
- adverse legal, administrative, regulatory or legislative developments.

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

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

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

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

Our products are also susceptible to increasing competition from generics and biosimilars in many markets. Generic versions of drugs and biosimilars are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of generic or biosimilar versions of our marketed products, as well as lower-priced competing products, likely would significantly reduce both the price that we receive for such marketed products and the volume of products that we sell, which may have an adverse impact on our results of operations.

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

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

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

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

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

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs; and
- consolidation and increasing assertiveness of payors, including managed care organizations, health insurers, pharmacy benefit managers, government health administration authorities, private health insurers and other organizations, seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value; and
- our value-based contracting pilot program pursuant to which we aim to tie the pricing of our products to their clinical values by either aligning price to patient outcomes or adjusting price for patients who discontinue therapy for any reason including efficacy or tolerability concerns.

Our ability to set the price for our products varies significantly from country to country and as a result so can the price of our products. Certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the revenue from our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third-party cross-border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

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

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Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. In addition, competition from current and future competitors may negatively impact our ability to maintain pricing and our market share. New products or treatments brought to market by our competitors could cause revenues for our products to decrease due to potential price reductions and lower sales volumes. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility and our results of operations may be adversely impacted.

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

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals and enactments to reform health care insurance programs could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the Patient Protection and Affordable Care Act (PPACA) have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. These changes have had and are expected to continue to have a significant impact on our business.

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

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

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

In the E.U. and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures to reduce health care costs to constrain their overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries to higher-cost countries. These measures have negatively impacted our revenues, and may continue to adversely affect our revenues and results of operations in the future.

Adverse safety events or restrictions on use and safety warnings for our products can negatively affect our business, product sales and stock price.

Adverse safety events involving our marketed products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition

of fines or criminal penalties. Adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

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Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales or stock price to decline or experience periods of volatility. Restrictions on use or significant safety warnings that may be required to be included in the label of our products, such as the risk of developing progressive multifocal leukoencephalopathy, a serious brain infection, or liver injury, in the label for certain of our products, may significantly reduce expected revenues for those products and require significant expense and management time.

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

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

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

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

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

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

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

Successful preclinical work or early stage clinical trials does not ensure success in later stage trials, regulatory approval or commercial viability of a product.

Positive results in a trial may not be replicated in subsequent or confirmatory trials. Additionally, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful or that regulatory approval will be obtained. In addition, even if later stage clinical trials are successful, regulatory authorities may delay or decline approval of our product candidates. Regulatory authorities may disagree with our view of the data, require additional studies or disagree with our trial design or endpoints. Regulatory authorities may also fail to approve the facilities or the processes used to manufacture a product candidate, our dosing or delivery methods or companion devices. Regulatory authorities may grant marketing approval that is more restricted than anticipated. These restrictions may include limiting indications to narrow patient populations and the imposition of safety monitoring, educational requirements and risk evaluation and mitigation strategies. The occurrence of any of these events could result in significant costs and expenses, have an adverse effect on our business, financial condition and results of operations, and cause our stock price to decline or experience periods of volatility.

Even if we are able to successfully develop new products or indications, sales of new products or products with additional indications may not meet investor expectations. We may also make a strategic decision to discontinue development of a product or indication if, for example, we believe commercialization will be difficult relative to the standard of care or other opportunities in our pipeline.

Clinical trials and the development of biopharmaceutical products is a lengthy and complex process. If we fail to adequately manage our clinical activities, our clinical trials or potential regulatory approvals may be delayed or denied.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete clinical trials in a timely fashion depends in large part on a number of key factors. These factors include protocol design, regulatory and institutional review board approval, patient enrollment rates and compliance with current Good Clinical Practices. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful.

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

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 most recently 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

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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.

Manufacturing issues could substantially increase our costs, limit supply of our products and reduce our revenues.

The process of manufacturing our products is complex, highly regulated and subject to numerous risks, including:

- Risk of Product Loss. The manufacturing process for our products is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.
- 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.

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

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

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

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

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

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

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

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

While we believe we currently have sufficient large scale manufacturing capacity to meet our near-term manufacturing requirements, it is probable that we would need additional large scale manufacturing capacity to support future clinical and commercial manufacturing requirements for product candidates in our pipeline, if such candidates are successful and approved. We are building a large scale biologics manufacturing facility in Solothurn, Switzerland. Due to the long lead times necessary for the expansion of manufacturing capacity, we expect to make significant investments to build or obtain third-party contract manufacturers with no assurance that such investment will be recouped. If we are unable to adequately and timely manufacture and supply our products and product candidates or if we do not fully utilize our manufacturing facilities, our business may be harmed.

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

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

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

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place significant restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies such as ours have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

Regulations governing the health care industry are subject to change, with possibly retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or 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;

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- requirements that provide for increased transparency of clinical trial results and quality data, such as the European Medicines Agency's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action, which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or otherwise adversely affect the market for our products.

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

Our effective tax rate fluctuates, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

As a global biopharmaceutical company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from country to country, the results of examinations and audits of our tax filings, adjustments to the value of our uncertain tax positions, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations.

In addition, our inability to secure or sustain acceptable arrangements with tax authorities and future changes in the tax laws, among other things, may result in tax obligations in excess of amounts accrued in our financial statements. In the U.S., there are several proposals under consideration to reform tax law, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, penalize certain transfer pricing structures and reduce or eliminate certain foreign or domestic tax credits or deductions. Our future reported financial results may be adversely affected by tax law changes which restrict or eliminate certain foreign tax credits or our ability to deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

In addition to U.S. tax reform proposals, the adoption of some or all of the recommendations set forth in the Organization for Economic Cooperation and Development’s project on “Base Erosion and Profit Shifting” 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 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

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- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that have less debt.

Our sales and operations are subject to the risks of doing business internationally.

We are increasing our presence in international markets, particularly emerging markets, subjecting us to many risks that could adversely affect our business and revenues, such as:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- uncertainties regarding the collectability of accounts receivable;
- fluctuations in foreign currency exchange rates, in particular the recent strength of the U.S. dollar versus foreign currencies, which has adversely impacted our revenues and net income;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- 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 prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. Failure to comply with domestic or foreign laws could result in various adverse consequences, including: possible delay in approval or refusal to approve a product; recalls, seizures or withdrawal of an approved product from the market; disruption in the supply or availability of our products or suspension of export or import privileges; the imposition of civil or criminal sanctions; the prosecution of executives overseeing our international operations; and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

Our operating results are subject to significant fluctuations.

Our quarterly revenues, expenses and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the risks described in these “Risk Factors” as well as the timing of charges and expenses that we may take. We have recorded, or may be required to record, charges that include:

- the cost of restructurings or other initiatives to streamline our operations and reallocate resources;
- impairments with respect to investments, fixed assets and long-lived assets, including in-process R&D and other intangible assets;
- inventory write-downs for failed quality specifications, charges for excess or obsolete inventory and charges for inventory write downs relating to product suspensions, expirations or recalls;
- changes in the fair value of contingent consideration;
- bad debt expenses and increased bad debt reserves;

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- outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters;
- milestone payments under license and collaboration agreements; and
- payments in connection with acquisitions and other business development activities.

Our revenues are also subject to foreign currency exchange rate fluctuations due to the global nature of our operations. Although we have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, the U.S. dollar and the currencies in which we do business will affect our operating results, often in unpredictable ways. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher than expected charges from hedge ineffectiveness or from the termination of a hedge relationship.

Our operating results during any one period do not necessarily suggest the anticipated results of future periods.

Our investment in Samsung Bioepis, and our success in commercializing biosimilars developed by Samsung Bioepis, is subject to risks and uncertainties inherent in the development, manufacture and commercialization of biosimilars.

Our investment in Samsung Bioepis, and our success in commercializing biosimilars developed by Samsung Bioepis, is subject to a number of risks, including:

- Reliance on Third Parties. We are dependent on the efforts of Samsung Bioepis and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If Samsung Bioepis or such other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;
- Regulatory Compliance. Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- Intellectual Property and Regulatory Challenges. Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years;
- Failure to Gain Market and Patient Acceptance. Market success of biosimilar products will be adversely affected if patients, physicians and/or payers do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- Ability to Provide Adequate Supply. Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet higher than anticipated demand; and
- Competitive Challenges. Biosimilar products face significant competition, including from innovator products and from biosimilar products offered by other companies. In some jurisdictions, local tendering processes may restrict biosimilar products from being marketed and sold in those jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective matter are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area.

Our investments in properties may not be fully realized.

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

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Our portfolio of marketable securities is subject to market, interest and credit risk that may reduce its value.
We maintain a portfolio of marketable securities for investment of our cash. Changes in the value of our portfolio of marketable securities could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the securities included in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.
There can be no assurance that we will continue to repurchase stock or that we will repurchase stock at favorable prices.
From time to time our Board of Directors authorizes stock repurchase programs, including most recently our 2016 Share Repurchase Program. The amount and timing of stock repurchases are subject to capital availability and our determination that stock repurchases are in the best interest of our shareholders and are in compliance with all respective laws and our agreements applicable to the repurchase of stock. Our ability to repurchase stock will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, our results of operations, our financial condition and other factors beyond our control that we may deem relevant. A reduction in, or the completion or expiration of, our stock repurchase programs could have a negative effect on our stock price. We can provide no assurance that we will repurchase stock at favorable prices, if at all.
We may not be able to access the capital and credit markets on terms that are favorable to us.
We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets have experienced extreme volatility and disruption, 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.
We may incur operational difficulties or be exposed to claims and liabilities as a result of the separation and distribution of Bioverativ.
On February 1, 2017, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen shareholders in connection with the separation of our hemophilia business. In connection with the distribution, we entered into a separation and distribution agreement and various other agreements (including a transition services agreement, a tax matters agreement, a manufacturing and supply agreement, an employee matters agreement, an intellectual property matters agreement and certain other commercial agreements). These agreements govern the separation and distribution and the relationship between us and Bioverativ going forward, including with respect to potential tax-related losses associated with the separation and distribution. They also provide for the performance of services by each company for the benefit of the other for a period of time (including under the manufacturing and supply agreement pursuant to which we will manufacture and supply certain products and materials to Bioverativ).
The spin-off of our hemophilia business as an independent public company is intended to qualify for tax-free treatment to Biogen and its shareholders under the Internal Revenue Code. Completion of the spin-off was conditioned upon, among other things, our receipt of a favorable opinion from our tax advisors with respect to the tax-free nature of the transaction. The opinion is not binding on the U.S. Internal Revenue Service (IRS), or the courts, and there can be no assurance that the IRS or the courts will not challenge the qualification of the spin-off as a tax-free transaction or that any such challenge would not prevail. If the spin-off is determined to be taxable, Biogen and its shareholders could incur significant tax liabilities, which could adversely affect our business, financial condition, or results of operations.
Bioverativ has agreed to indemnify us for certain potential liabilities that may arise, but we cannot guarantee that Bioverativ will be able to satisfy its indemnification obligations. The separation and distribution agreement provides for indemnification obligations designed to make Bioverativ financially responsible for many liabilities that may exist

relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation. It is possible that a court would disregard the allocation agreed to between us and Bioverativ and require us to assume responsibility for obligations allocated to Bioverativ. Third parties could also seek to hold us

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

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

We may not achieve some or all of the anticipated benefits of the separation of Bioverativ, which may adversely affect our business.

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

Our business involves environmental risks, which include the cost of compliance and the risk of contamination or injury.

Our business and the business of several of our strategic partners involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with state, federal and foreign standards, there will always be the risk of accidental contamination or injury. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

Manufacturing of our products and product candidates also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, including permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

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

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

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

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

events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

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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.

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

Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity under our 2016 Share Repurchase Program during the third quarter of 2017:

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 2017	—	$ —	—	$ 3,000.0
August 2017	—	$ —	—	$ 3,000.0
September 2017	—	—	—	$ 3,000.0
Total	—	$ —		

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock. This authorization does not have an expiration date. All share repurchases under this authorization will be retired. Under this program, we repurchased and retired 3.7 million shares of common stock at a cost of $1.0 billion during the nine months ended September 30, 2017. We did not repurchase any shares of common stock under this program during the three months ended September 30, 2017. During the three and nine months ended September 30, 2016, we repurchased and retired 1.1 million shares of common stock at a cost of $348.9 million. As of September 30, 2017, approximately $3.0 billion remains available to repurchase shares under this authorization.

In February 2011 our Board of Directors authorized a program to repurchase up to 20.0 million shares of common stock, which was completed as of March 31, 2017. During the nine months ended September 30, 2017, we repurchased 1.3 million shares of common stock at a cost of $365.4 million under this program. We did not repurchase any shares of common stock under this program during the three and nine months ended September 30, 2016.

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 Principal 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, 2017, 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/ Gregory F. Covino
Gregory F. Covino
Vice President, Finance
Chief Accounting Officer and
Interim Principal Financial Officer (principal financial officer)
October 24, 2017