BIOGEN INC.
Form 10-Q
October 26, 2016

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, 2016
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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check One):

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

(Do not check if a smaller reporting company)

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

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of October 21, 2016, was 217,574,479 shares.

Table of Contents

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2016
TABLE OF CONTENTS

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Table of Contents

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Throughout this report, “Biogen,” the “Company,” “we,” “us” and “our” refer to Biogen Inc. and its consolidated subsidiaries. References to “RITUXAN” refer to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan). References to "ELOCTATE" refer 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

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

Table of Contents

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,	
	2016	2015	2016	2015
Revenues:				
Product, net	$2,539.6	$2,391.7	$7,315.0	$6,762.6
Revenues from anti-CD20 therapeutic programs	317.6	337.2	996.3	1,005.3
Other	98.6	49.0	265.5	156.6
Total revenues	2,955.8	2,777.9	8,576.8	7,924.5
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	416.9	310.0	1,100.2	908.6
Research and development	529.0	519.9	1,439.4	1,471.1
Selling, general and administrative	462.7	477.8	1,452.4	1,530.1
Amortization of acquired intangible assets	99.7	98.1	281.4	286.0
Restructuring charges	11.6	—	21.3	—
(Gain) loss on fair value remeasurement of contingent consideration	5.9	0.2	18.8	5.9
Collaboration profit (loss) sharing	4.7	—	(0.9)	—
Total cost and expenses	1,530.5	1,406.0	4,312.6	4,201.7
Income from operations	1,425.3	1,371.8	4,264.2	3,722.8
Other income (expense), net	(58.1)	(15.4)	(169.4)	(41.3)
Income before income tax expense and equity in loss of investee, net of tax	1,367.2	1,356.4	4,094.8	3,681.5
Income tax expense	337.0	330.1	1,047.0	904.5
Equity in loss of investee, net of tax	—	6.8	—	12.5
Net income	1,030.2	1,019.5	3,047.8	2,764.5
Net income (loss) attributable to noncontrolling interests, net of tax	(2.7)	53.9	(5.8)	49.1
Net income attributable to Biogen Inc.	$1,032.9	$965.6	$3,053.6	$2,715.4
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$4.72	$4.16	$13.95	$11.60
Diluted earnings per share attributable to Biogen Inc.	$4.71	$4.15	$13.92	$11.57
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	218.9	232.2	219.0	234.1
Diluted earnings per share attributable to Biogen Inc.	219.4	232.6	219.4	234.7

See accompanying notes to these unaudited condensed consolidated financial statements.

5

Table of Contents

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,	
	2016	2015	2016	2015
Net income attributable to Biogen Inc.	$1,032.9	$965.6	$3,053.6	$2,715.4
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	(5.4)	(2.2)	1.6	(1.2)
Unrealized gains (losses) on cash flow hedges, net of tax	1.3	(31.2)	(17.0)	(40.1)
Unrealized gains (losses) on pension benefit obligation	0.4	0.5	1.3	4.6
Currency translation adjustment	(14.4)	(23.5)	(62.8)	(61.3)
Total other comprehensive income (loss), net of tax	(18.1)	(56.4)	(76.9)	(97.9)
Comprehensive income attributable to Biogen Inc.	1,014.8	909.2	2,976.7	2,617.5
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	(2.6)	53.6	(5.7)	49.1
Comprehensive income	$1,012.2	$962.8	$2,971.0	$2,666.6

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	As of September 30, 2016	As of December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$2,084.8	$1,308.0
Marketable securities	2,231.2	2,120.5
Accounts receivable, net	1,467.8	1,227.0
Due from anti-CD20 therapeutic programs	305.2	314.5
Inventory	1,009.7	893.4
Other current assets	993.1	836.9
Total current assets	8,091.8	6,700.3
Marketable securities	3,096.9	2,760.4
Property, plant and equipment, net	2,387.0	2,187.6
Intangible assets, net	3,869.9	4,085.1
Goodwill	3,419.7	2,663.8
Investments and other assets	1,239.6	1,107.6
Total assets	$22,104.9	$19,504.8
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable and other financing arrangements	$4.9	$4.8
Taxes payable	208.8	208.7
Accounts payable	274.0	267.4
Accrued expenses and other	2,012.0	2,096.8
Total current liabilities	2,499.7	2,577.7
Notes payable and other financing arrangements	6,529.6	6,521.5
Long-term deferred tax liability	98.7	124.9
Other long-term liabilities	862.1	905.8
Total liabilities	9,990.1	10,129.9
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	—	—
Accumulated other comprehensive loss	(300.9)	(224.0)
Retained earnings	15,030.0	12,208.4
Treasury stock, at cost	(2,611.7)	(2,611.7)
Total Biogen Inc. shareholders' equity	12,117.5	9,372.8
Noncontrolling interests	(2.7)	2.1
Total equity	12,114.8	9,374.9
Total liabilities and equity	$22,104.9	$19,504.8

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	For the Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net income	$3,047.8	$2,764.5
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	505.3	444.1
Share-based compensation	117.8	131.5
Deferred income taxes	(56.8)	(185.8)
Other	33.4	31.6
Changes in operating assets and liabilities, net:		
Accounts receivable	(238.1)	(63.6)
Inventory	(155.1)	(150.4)
Accrued expenses and other current liabilities	(223.2)	(174.5)
Changes in other tax assets and liabilities, net	(147.4)	(1.2)
Other changes in operating assets and liabilities, net	62.1	(120.5)
Net cash flows provided by operating activities	2,945.8	2,675.7
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	5,185.8	3,363.4
Purchases of marketable securities	(5,631.7)	(4,870.1)
Contingent consideration related to Fumapharm AG acquisition	(900.0)	(550.0)
Purchases of property, plant and equipment	(434.0)	(456.9)
Acquisitions of intangible assets	(110.4)	(6.3)
Acquisitions of business, net of cash acquired	—	(198.8)
Other	(12.8)	(27.4)
Net cash flows used in investing activities	(1,903.1)	(2,746.1)
Cash flows from financing activities:		
Purchase of treasury stock	(348.9)	(2,998.2)
Proceeds from issuance of stock for share-based compensation arrangements	35.2	45.5
Proceeds from borrowings	—	5,930.9
Repayment of borrowings	(2.7)	(2.1)
Excess tax benefit from share-based awards	11.9	70.8
Other	37.9	(62.1)
Net cash flows (used in) provided by financing activities	(266.6)	2,984.8
Net increase in cash and cash equivalents	776.1	2,914.4
Effect of exchange rate changes on cash and cash equivalents	0.7	(30.3)
Cash and cash equivalents, beginning of the period	1,308.0	1,204.9
Cash and cash equivalents, end of the period	$2,084.8	$4,089.0

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents
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 patients for the treatment of neurological diseases, autoimmune disorders and rare diseases.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), ELOCTATE for hemophilia A and ALPROLIX for hemophilia B and FUMADERM for the treatment of severe plaque psoriasis. We also have a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, which entitles us to certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma.

In addition to our innovative drug development efforts, we aim to leverage our manufacturing and commercial capabilities and scientific expertise through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics) that develops, manufactures and markets biosimilars as well as through other strategic contract manufacturing partners. Under our commercial agreement with Samsung Bioepis, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the E.U.

In May 2016, we announced our intention to spin off our hemophilia business as an independent, publicly traded company. The company, named Bioverativ Inc. (Bioverativ), will focus on the discovery, development and commercialization of therapies for the treatment of hemophilia and other blood disorders, including our existing marketed products ELOCTATE and ALPROLIX. The transaction is expected to be completed in early 2017, subject to the satisfaction of certain conditions, including, among others, final approval of our Board of Directors, receipt of a favorable opinion with respect to the tax-free nature of the transaction and the effectiveness of a Form 10 registration statement filed with the Securities and Exchange Commission. The results of Bioverativ will be included in our condensed consolidated financial statements until the transaction is completed.

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, 2015 (2015 Form 10-K). Our accounting policies are described in the “Notes to Consolidated Financial Statements” in our 2015 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, 2016, 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, which is discovering, developing, manufacturing and delivering therapies to patients for the treatment of neurological diseases, autoimmune disorders and rare diseases.

Consolidation

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

9

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

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.

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. We are currently evaluating the method of adoption and the potential impact that these standards may have on our financial position and results of operations.

During 2015, the FASB issued the following new standards, which we adopted on January 1, 2016:

- ASU No. 2015-05, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement.
- ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory.
- ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments.

The adoption of these standards did not have an impact on our financial position or results of operations. 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 2015 Form 10-K.

10

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

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 our 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. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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 the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The adoption of this standard is not expected to have a material impact on our net financial position, but will impact the amount of our assets and liabilities. We are currently evaluating the potential impact that this standard may have on our results of operations.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments. The new standard simplifies the embedded derivative analysis for debt instruments containing contingent call or put options by removing the requirement to assess whether a contingent event is related to interest rates or credit risks. The new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In March 2016, the FASB issued ASU No. 2016-07, Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting. The new standard eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an adjustment must be made to the investment, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect during all previous periods that the investment had been held. The new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard requires recognition of the income tax effects of vested or settled awards in the income statement and involves several other aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have a material impact on our financial position, results of operations or statements of cash flows upon adoption.

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 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.

11

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

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.

2. Restructuring, Business Transformation and Other Cost Saving Initiatives

2015 Cost Saving Initiatives

2015 Restructuring Charges

On October 21, 2015, we announced a corporate restructuring, which included the termination of certain pipeline programs and an 11% reduction in workforce. Under this restructuring, cash payments were estimated to total approximately $120 million, of which $15.9 million were related to previously accrued 2015 incentive compensation, resulting in expected net restructuring charges totaling approximately $105 million. These amounts are expected to be substantially paid by the end of 2016.

For the three months ended September 30, 2016, we recognized an adjustment to our previous estimates, which resulted in a negative restructuring charge of $1.6 million. For the nine months ended September 30, 2016, we recognized total net restructuring charges of $8.1 million. We previously recognized $93.4 million of restructuring charges in our consolidated statements of income during the fourth quarter of 2015. Our restructuring reserve is included in accrued expenses and other in our condensed consolidated balance sheets.

The following table summarizes the charges and spending related to our 2015 restructuring efforts during the nine months ended September 30, 2016:

(In millions)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2015	$ 33.7	$ 3.6	$37.3
Expense	4.9	5.4	10.3
Payments	(29.6)	(7.5)	(37.1)
Adjustments to previous estimates, net	(5.1)	2.9	(2.2)
Restructuring reserve as of September 30, 2016	$ 3.9	$ 4.4	$8.3

2016 Organizational Changes and Cost Saving Initiatives

2016 Restructuring Charges

During the third quarter of 2016, we initiated additional cost saving measures which are primarily intended to realign our organizational structure in anticipation of the changes in roles and workforce resulting from our decision to spin off our hemophilia business, and to achieve further targeted cost reductions. For the three and nine months ended September 30, 2016, we recognized charges totaling $13.2 million related to this effort, which are in addition to, and separate from, the 2015 corporate restructuring described above. These charges are reflected in restructuring charges in our condensed consolidated statements of income.

Under this initiative, we expect to incur restructuring charges totaling approximately $20.0 million. These amounts are primarily related to severance and are expected to be substantially incurred and paid by the end of 2016.

12

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

Cambridge, MA Manufacturing Facility

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

We are currently considering alternatives for the facility, which may include a sale of our rights to, lease of, or other form of disposition of, the facility and related assets. In the event we are unsuccessful with a sale, lease or other disposition, we will cease manufacturing by December 31, 2016. As of September 30, 2016, the carrying value of associated assets totaled approximately $29.0 million. An impairment assessment was performed related to the assets, which resulted in no impairments. Our remaining lease obligation related to these facilities totaled $25.5 million.

Our anticipated departure from these facilities has shortened the expected useful lives of certain leasehold improvements and other assets at these facilities. As a result, we recorded additional depreciation expense to reflect the assets' new shorter useful lives. During the three and nine months ended September 30, 2016, we recognized approximately $15.7 million and $31.5 million, respectively, of this additional depreciation, which was recorded as cost of sales in our condensed consolidated statements of income.

3. 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, 2015	$ 56.1	$ 548.7	$ 57.9	$ 662.7
Current provisions relating to sales in current year	385.1	1,535.5	23.4	1,944.0
Adjustments relating to prior years	(2.4)	(11.0)	(13.4)	(26.8)
Payments/credits relating to sales in current year	(334.5)	(1,129.6)	(2.3)	(1,466.4)
Payments/credits relating to sales in prior years	(48.4)	(510.6)	(16.1)	(575.1)
Balance, as of September 30, 2016	$ 55.9	$ 433.0	$ 49.5	$ 538.4

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

(In millions)	As of September 30, 2016	As of December 31, 2015
Reduction of accounts receivable	$ 155.4	$ 144.6
Component of accrued expenses and other	383.0	518.1
Total reserves	$ 538.4	$ 662.7

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

4. Inventory

The components of inventory are summarized as follows:

(In millions)	As of September 30, 2016	As of December 31, 2015
Raw materials	$ 166.4	$ 213.0
Work in process	712.0	577.6
Finished goods	171.1	143.0
Total inventory	$ 1,049.5	$ 933.6
Balance Sheet Classification:		
Inventory	$ 1,009.7	$ 893.4
Investments and other assets	39.8	40.2
Total inventory	$ 1,049.5	$ 933.6

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

As of December 31, 2015, our inventory included $24.7 million associated with our ZINBRYTA program, $24.2 million associated with the FLIXABI program and $18.4 million associated with the BENEPALI program, which had been capitalized in advance of regulatory approval. The European Commission (EC) approved the marketing authorization applications for BENEPALI and FLIXABI, two anti-tumor necrosis factor (TNF) biosimilars, for marketing in the E.U. in January 2016 and May 2016, respectively. In addition, the U.S. Food and Drug Administration (FDA) approved ZINBRYTA for the treatment of relapsing forms of MS in the U.S. in May 2016, and the EC approved ZINBRYTA for the treatment of relapsing forms of MS in the E.U. in July 2016.

5. Intangible Assets and Goodwill

Intangible Assets

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

		As of September 30, 2016			As of December 31, 2015		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	$543.3	$ (519.4)	$23.9	$543.3	$ (506.0)	$37.3
Developed technology	15-23 years	3,005.3	(2,619.8)	385.5	3,005.3	(2,552.9)	452.4
In-process research and development	Indefinite until commercialization	679.7	—	679.7	730.5	—	730.5
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	6-18 years	3,420.2	(703.4)	2,716.8	3,303.2	(502.3)	2,800.9
Total intangible assets		$7,712.5	$ (3,842.6)	$3,869.9	$7,646.3	$ (3,561.2)	$4,085.1

For the three and nine months ended September 30, 2016, amortization of acquired intangible assets totaled $99.7 million and $281.4 million, respectively, as compared to $98.1 million and $286.0 million, respectively, in the prior year comparative periods. In-process research and development balances include adjustments related to foreign exchange rate fluctuations.

14

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

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, 2016 was $377.8 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 (Elan). The net book value of this asset as of September 30, 2016 was $2,559.9 million.

The increase in acquired and in-licensed rights and patents during the nine months ended September 30, 2016, primarily reflects:

- $50.0 million in total milestone payments due to Samsung Bioepis, which became payable upon the approval of BENEPALI and FLIXABI in the E.U. in January 2016 and May 2016, respectively;
- $32.0 million in total milestone payments due to AbbVie, Inc. (AbbVie), which became payable upon the regulatory approval of ZINBRYTA in the U.S. in May 2016 and the E.U. in July 2016; and
- $26.5 million upon the approval of ALPROLIX in the E.U. in May 2016, which is comprised of a $20.0 million contingent payment due to the former owners of Syntonix Pharmaceuticals, Inc. (Syntonix) and $6.5 million related to the establishment of a corresponding deferred tax liability.

For additional information on our relationship with Samsung Bioepis and AbbVie, please read Note 17, Collaborative and Other Relationships to these condensed consolidated financial statements. For additional information on our obligation to the former shareholders of Syntonix, please read Note 21, Commitments and Contingencies to our consolidated financial statements included in our 2015 Form 10-K.

Estimated Future Amortization of Intangible Assets

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

Our most recent long range planning cycle was completed in the third quarter of 2016. Based upon this analysis, the estimated future amortization of acquired intangible assets for the next five years is expected to be as follows:

(In millions)	As of September 30, 2016
2016 (remaining three months)	$ 92.8
2017	347.8
2018	321.4
2019	301.9
2020	265.6
2021	247.7

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

Goodwill

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

(In millions)	As of September 30, 2016
Goodwill, beginning of period	$ 2,663.8
Increase to goodwill	771.3
Other	(15.4)
Goodwill, end of period	$ 3,419.7

The increase in goodwill during the nine months ended September 30, 2016 was related to $900.0 million in contingent milestones achieved (exclusive of $128.7 million in tax benefits) and payable to the former shareholders of Fumapharm AG or holders of their rights. Other includes changes in foreign 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 19, Commitments and Contingencies to these condensed consolidated financial statements. As of September 30, 2016, we had no accumulated impairment losses related to goodwill.

6. 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, 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	$ 1,736.4	$ —	$ 1,736.4	$ —
Marketable debt securities:				
Corporate debt securities	2,632.1	—	2,632.1	—
Government securities	2,038.2	—	2,038.2	—
Mortgage and other asset backed securities	657.8	—	657.8	—
Marketable equity securities	29.0	29.0	—	—
Derivative contracts	20.3	—	20.3	—
Plan assets for deferred compensation	34.1	—	34.1	—
Total	$ 7,147.9	$ 29.0	$ 7,118.9	$ —
Liabilities:				
Derivative contracts	$ 14.0	$ —	$ 14.0	$ —
Contingent consideration obligations	521.6	—	—	521.6
Total	$ 535.6	$ —	$ 14.0	$ 521.6

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

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

There have been no material impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2016. 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, 2016. 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, refer to Note 1, Summary of Significant Accounting Policies: Fair Value Measurements to our consolidated financial statements included in our 2015 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, 2016		As of December 31, 2015	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
Notes payable to Fumedica	$6.5	$6.3	$9.4	$9.0
6.875% Senior Notes due March 1, 2018	591.9	560.2	602.6	565.3
2.900% Senior Notes due September 15, 2020	1,558.1	1,500.6	1,497.5	1,485.5
3.625% Senior Notes due September 15, 2022	1,070.8	993.0	1,014.2	992.2
4.050% Senior Notes due September 15, 2025	1,908.3	1,734.5	1,764.6	1,733.4
5.200% Senior Notes due September 15, 2045	2,070.5	1,721.4	1,757.6	1,721.1
Total	$7,206.1	$6,516.0	$6,645.9	$6,506.5

The fair value of our notes payable to Fumedica was estimated using market observable inputs, including current interest and foreign currency exchange rates. The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. For additional information related to our debt instruments, please read Note 11, Indebtedness to our consolidated financial statements included in our 2015 Form 10-K.

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2016	2015	2016	2015
Fair value, beginning of period	$515.7	$495.7	$506.0	$215.5
Additions	—	—	—	274.5
Changes in fair value	5.9	0.2	18.8	5.9
Payments	—	(14.5)	(3.2)	(14.5)
Fair value, end of period	$521.6	$481.4	$521.6	$481.4

As of September 30, 2016 and December 31, 2015, approximately $251.1 million and $301.3 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.

7. 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 sheet:

(In millions)	As of September 30, 2016	As of December 31, 2015
Commercial paper	$ 84.2	$ 21.9
Overnight reverse repurchase agreements	42.1	134.7
Money market funds	1,600.1	673.8
Short-term debt securities	10.0	79.1
Total	$ 1,736.4	$ 909.5

The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and our short-term debt securities approximate fair value due to their short-term maturities. Our overnight reverse repurchase agreements are collateralized with agency-guaranteed mortgage-backed securities and represent approximately 0.2% and 0.7% of total assets as of September 30, 2016 and December 31, 2015, respectively.

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

As of September 30, 2016 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	$1,293.2	$ 0.2	$ (0.3)	$ 1,293.3
Non-current	1,338.9	4.5	(0.7)	1,335.1
Government securities				
Current	938.0	0.6	(0.1)	937.5
Non-current	1,100.2	1.6	(0.5)	1,099.1
Mortgage and other asset backed securities				
Current	—	—	—	—

Non-current	657.8	1.3	(0.8)	657.3
Total marketable debt securities	$5,328.1	$ 8.2	$ (2.4)	$ 5,322.3
Marketable equity securities, non-current	$29.0	$ 3.8	$ (8.3)	$ 33.5

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

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

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, 2016		As of December 31, 2015	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$2,231.2	$ 2,230.8	$2,120.5	$ 2,122.0
Due after one year through five years	2,815.5	2,810.2	2,575.9	2,583.9
Due after five years	281.4	281.3	184.5	185.3
Total available-for-sale securities	$5,328.1	$ 5,322.3	$4,880.9	$ 4,891.2

The average maturity of our marketable debt securities available-for-sale as of September 30, 2016 and December 31, 2015 was approximately 14 months and 16 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)	2016	2015	2016	2015
Proceeds from maturities and sales	$2,362.2	$2,387.9	$5,185.8	$3,363.4
Realized gains	$1.1	$0.7	$2.1	$1.3
Realized losses	$(1.1)	$(2.0)	$(2.7)	$(2.9)

Strategic Investments

As of September 30, 2016 and December 31, 2015, our strategic investment portfolio was comprised of investments totaling $94.8 million and $96.0 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.

19

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

8. 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, 2016 and December 31, 2015 had durations of 1 to 15 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, beginning in the fourth quarter 2015, in operating expenses when the expense in the currency being hedged is recorded. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net.

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

	Notional Amount	
Foreign Currency: (In millions)	As of September 30, 2016	As of December 31, 2015
Euro	$980.6	$ 945.5
Swiss francs	23.9	80.8
Canadian dollar	20.3	76.7
Total foreign currency forward contracts	$1,024.8	$ 1,103.0

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 $15.0 million and net gains of $1.8 million as of September 30, 2016 and December 31, 2015, respectively. We expect all contracts outstanding as of September 30, 2016 to be settled over the next 15 months and any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of September 30, 2016 and December 31, 2015, 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	2016	2015	Location	2016	2015
Revenue	$(5.2)	$43.9	Other income (expense)	$(0.6)	$2.0
Operating expenses	$(0.2)	$—	Other income (expense)	$—	$—

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

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	2016	2015	Location	2016	2015
Revenue	$(0.7)	$119.3	Other income (expense)	$3.4	$5.4
Operating expenses	$(0.4)	$—	Other income (expense)	$(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, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in the 2.90% Senior Notes attributable to changes in interest rates. Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recorded as a component of the 2.90% Senior Notes with no net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recognized as a component of interest expense in our 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 $668.6 million and $721.0 million as of September 30, 2016 and December 31, 2015, respectively. Net losses of $0.4 million and $16.6 million related to these contracts were recognized as a component of other income (expense), net, for three and nine months ended September 30, 2016, respectively, as compared to net losses of $8.1 million and $4.2 million, respectively, in the prior year comparative periods.

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

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, 2016
Hedging Instruments:		
Asset derivatives	Other current assets	$ 2.9
	Investments and other assets	$ 12.1
Liability derivatives	Accrued expenses and other	$ 11.4
	Other long-term liabilities	$ —
Other Derivatives:		
Asset derivatives	Other current assets	$ 5.3
Liability derivatives	Accrued expenses and other	$ 2.6

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

9. 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 $1,528.4 million and $1,330.1 million as of September 30, 2016 and December 31, 2015, respectively.

Solothurn, Switzerland Facility

On December 1, 2015, we purchased land in Solothurn, Switzerland for 64.4 million Swiss Francs (approximately $62.5 million). We are building a biologics manufacturing facility on this land in the Commune of Luterbach over the next several years. As of September 30, 2016 and December 31, 2015, we had approximately $350.8 million and $99.0 million, respectively, capitalized as construction in progress related to the construction of this facility.

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

10. Equity

Total equity as of September 30, 2016 increased $2,739.9 million compared to December 31, 2015. This increase was primarily driven by net income attributable to Biogen Inc. of $3,053.6 million, partially offset by share repurchases of $348.9 million, as described below.

Share Repurchases

In July 2016, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. The 2016 Share Repurchase Program is in addition to the approximately 1.3 million shares remaining under our February 2011 Share Repurchase Program (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under our share-based compensation plans. 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 under our 2016 Share Repurchase Program. During the nine months ended September 30, 2016 and 2015, we did not repurchase any shares of common stock under our 2011 Share Repurchase Program.

In May 2015, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2015 Share Repurchase Program), which was completed as of December 31, 2015. During the three and nine months ended September 30, 2015, we repurchased and retired 9.7 million shares of common stock at a cost of $2,998.2 million under our 2015 Share Repurchase Program.

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)	2016	2015	2016	2015
NCI, beginning of period	$(0.1)	$0.4	$2.1	$5.0
Net income (loss) attributable to NCI, net of tax	(2.7)	53.9	(5.8)	49.1
Fair value of net assets and liabilities acquired and assigned to NCI	—	0.2	0.9	0.1
Distribution to NCI	—	(60.0)	—	(60.0)
Translation adjustment and other	0.1	(0.3)	0.1	—
NCI, end of period	$(2.7)	$(5.8)	$(2.7)	$(5.8)

For the three and nine months ended September 30, 2015, net income (loss) attributable to NCI, net of tax, was related to a $60.0 million milestone payment made to Neurimmune SubOne AG. For additional information, please read Note 16, Investments in Variable Interest Entities to these condensed consolidated financial statements.

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

11. Accumulated Other Comprehensive Income (Loss)

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

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	Unrealized Gains (Losses) on Cash Flow Hedges	Unfunded Status of Postretirement Benefit Plans	Translation Adjustments	Total
Balance, 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)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	Unrealized Gains (Losses) on Cash Flow Hedges	Unfunded Status of Postretirement Benefit Plans	Translation Adjustments	Total
Balance, as of December 31, 2014	$ (0.4)	$ 71.7	$ (31.6)	$ (99.2)	$(59.5)
Other comprehensive income (loss) before reclassifications	(2.2)	78.6	4.6	(61.3)	19.7
Amounts reclassified from accumulated other comprehensive income (loss)	1.0	(118.7)	—	—	(117.7)
Net current period other comprehensive income (loss)	(1.2)	(40.1)	4.6	(61.3)	(97.9)
Balance, as of September 30, 2015	$ (1.6)	$ 31.6	$ (27.0)	$ (160.5)	$(157.4)

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

(In millions)	Income Statement Location	Amounts Reclassified from Accumulated Other Comprehensive Income			
		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
		2016	2015	2016	2015
Gains (losses) on securities available for sale	Other income (expense)	$—	$(1.3)	$(0.6)	$(1.6)
	Income tax benefit (expense)	—	0.5	0.2	0.6
Gains (losses) on cash flow hedges	Revenues	(5.2)	43.9	(0.7)	119.3
	Operating expenses	(0.2)	—	(0.4)	—
	Other income (expense)	0.1	—	0.2	—
	Income tax benefit (expense)	—	(0.2)	—	(0.6)

Total reclassifications, net of tax	$(5.3)	$42.9	$(1.3)	$117.7

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

12. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Three Months Ended September 30, 2016	2015	For the Nine Months Ended September 30, 2016	2015
Numerator:				
Net income attributable to Biogen Inc.	$1,032.9	$965.6	$3,053.6	$2,715.4
Denominator:				
Weighted average number of common shares outstanding	218.9	232.2	219.0	234.1
Effect of dilutive securities:				
Stock options and employee stock purchase plan	0.1	0.1	0.1	0.1
Time-vested restricted stock units	0.2	0.2	0.2	0.3
Market stock units	0.2	0.1	0.1	0.2
Dilutive potential common shares	0.5	0.4	0.4	0.6
Shares used in calculating diluted earnings per share	219.4	232.6	219.4	234.7

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

13. Share-based Payments

Share-based Compensation Expense

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

(In millions)	For the Three Months Ended September 30, 2016	2015	For the Nine Months Ended September 30, 2016	2015
Research and development	$22.7	$10.8	$65.6	$68.3
Selling, general and administrative	31.2	17.5	94.6	99.3
Restructuring charges	—	—	(1.8)	—
Subtotal	53.9	28.3	158.4	167.6
Capitalized share-based compensation costs	(3.2)	(2.8)	(10.7)	(8.4)
Share-based compensation expense included in total cost and expenses	50.7	25.5	147.7	159.2
Income tax effect	(14.6)	(6.4)	(42.5)	(46.0)
Share-based compensation expense included in net income attributable to Biogen Inc.	$36.1	$19.1	$105.2	$113.2

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2016	2015	2016	2015
Market stock units	$5.7	$7.3	$27.0	$33.4
Time-vested restricted stock units	28.5	30.4	92.5	94.1
Cash settled performance units	7.9	(9.5)	12.7	17.5
Performance units	9.1	(2.8)	17.3	11.6
Employee stock purchase plan	2.7	2.9	8.9	11.0
Subtotal	53.9	28.3	158.4	167.6
Capitalized share-based compensation costs	(3.2)	(2.8)	(10.7)	(8.4)
Share-based compensation expense included in total cost and expenses	$50.7	$25.5	$147.7	$159.2

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.

Grants Under Share-based Compensation Plans

The following table summarizes our equity grants to employees, officers and directors under our current stock plans:

	For the Nine Months Ended September 30,	
	2016	2015
Market stock units	166,000	181,000
Cash settled performance shares	86,000	115,000
Performance units	67,000	89,000
Time-vested restricted stock units	603,000	393,000

Employee Stock Purchase Plan (ESPP)

In June 2015, our stockholders approved the Biogen Inc. 2015 ESPP (2015 ESPP). The 2015 ESPP, which became effective on July 1, 2015, replaced the Biogen Idec Inc. 1995 ESPP (1995 ESPP), which expired on June 30, 2015. The maximum aggregate number of shares of our common stock that may be purchased under the 2015 ESPP is 6,200,000.

For the nine months ended September 30, 2016, approximately 156,000 shares were issued under our 2015 ESPP, compared to approximately 98,000 and 43,000 shares issued under our 1995 ESPP and 2015 ESPP, respectively, in the prior year comparative period.

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

14. 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,	
	2016	2015	2016	2015
Statutory rate	35.0 %	35.0 %	35.0 %	35.0 %
State taxes	1.1	1.2	1.0	0.5
Taxes on foreign earnings	(10.1)	(10.7)	(9.4)	(10.1)
Credits and net operating loss utilization	(1.4)	(1.1)	(1.3)	(0.9)
Purchased intangible assets	1.2	1.5	1.1	1.2
Manufacturing deduction	(1.8)	(2.1)	(1.7)	(2.0)
Other permanent items	0.2	0.5	0.5	0.6
Other	0.5	—	0.4	0.3
Effective tax rate	24.7 %	24.3 %	25.6 %	24.6 %

For the three months ended September 30, 2016, compared to the same period in 2015, our effective tax rate was relatively consistent.

For the nine months ended September 30, 2016, compared to the same period in 2015, our effective tax rate increased primarily due to a net state tax benefit in 2015 resulting from the remeasurement of one of our uncertain tax positions, described below, and a higher relative percentage of our earnings being attributed to the U.S., a higher tax jurisdiction.

Accounting for Uncertainty in Income Taxes

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

In March 2015, we received a final assessment from the Danish Tax Authority (SKAT) for 2009 regarding withholding taxes and the treatment of certain intercompany transactions involving a Danish affiliate and another of our affiliates. In April 2016, we received final assessments from the SKAT for 2011 and 2013 regarding withholding taxes for similar intercompany transactions. The total amount assessed for 2009, 2011 and 2013 is estimated to be $68.7 million, including interest. For the assessments related to 2011 and 2013, we have made payments to SKAT totaling $13.0 million. We continue to dispute the assessments for all of these periods and believe that the positions we have taken in our historical filings are valid.

In October 2011, in conjunction with an examination by the Internal Revenue Service (IRS), the IRS proposed a disallowance of approximately $130.0 million in deductions for tax years 2007, 2008 and 2009 related to payments for services provided by our wholly owned Danish subsidiary located in Hillerød, Denmark. We initiated a mutual agreement procedure between the IRS and SKAT for the years 2001 through 2009, to reach agreement on the issue. Over the past year, we have reached agreement with the IRS and SKAT regarding the tax treatment of these items for the years up to and including 2009. We have recorded the results of these agreements, which were not significant to our results. In addition, we applied for a bilateral advance pricing agreement for the years 2010 through 2014 to resolve similar issues for those years. In June 2016, we withdrew from the bilateral advance pricing agreement process. We believe that the positions we have taken in our historical filings are valid and supportable. Potential changes in these positions are not expected to have a significant impact on our financial position or results of operations.

During the nine months ended September 30, 2015, the net effect of adjustments to our uncertain tax positions was a net benefit of approximately $24.0 million primarily related to the state impact of a federal uncertain tax item.

27

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

It is reasonably possible that we will adjust the value of our uncertain tax positions related to our revenues from anti-CD20 therapeutic programs and certain transfer pricing issues as we receive additional information from various taxing authorities, including reaching settlements with the tax authorities. In addition, the IRS and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

15. 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)	2016	2015	2016	2015
Interest income	$16.4	$5.4	$43.0	$13.0
Interest expense	(66.0)	(15.6)	(195.2)	(28.1)
Gain (loss) on investments, net	0.8	1.1	(0.3)	(0.3)
Foreign exchange gains (losses), net	(4.9)	(4.3)	(2.6)	(18.8)
Other, net	(4.4)	(2.0)	(14.3)	(7.1)
Total other income (expense), net	$(58.1)	$(15.4)	$(169.4)	$(41.3)

Other Current Assets

Other current assets includes prepaid taxes totaling approximately $725.3 million and $550.6 million as of September 30, 2016 and December 31, 2015, respectively.

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2016	As of December 31, 2015
Current portion of contingent consideration obligations and milestones	$ 570.5	$ 504.7
Revenue-related reserves for discounts and allowances	383.0	518.1
Employee compensation and benefits	282.7	270.8
Royalties and licensing fees	209.0	167.9
Other	566.8	635.3
Total accrued expenses and other	$ 2,012.0	$ 2,096.8

Pricing of TYSABRI in Italy - AIFA

In the fourth quarter of 2011, Biogen Italia SRL, our Italian subsidiary, received a notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. In January 2012, we filed an appeal in the Regional Administrative Tribunal of Lazio (Il Tribunale Amministrativo Regionale per il Lazio) in Rome, Italy seeking a ruling that the reimbursement limit in the Price Resolution should apply as written to only "the first 24 months" of TYSABRI sales, which ended in mid-February 2009. That appeal is still pending.

In June 2014, AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. As a result, we recognized $53.5 million of TYSABRI revenues related to the periods beginning February 2013 that were previously deferred. AIFA and Biogen Italia SRL are still discussing a possible resolution for the period

from February 2009 through January 2013. We have approximately EUR75 million recorded as accrued expenses and deferred revenue included in our long-term liabilities in our condensed consolidated balance sheet for this matter as of September 30, 2016 and December 31, 2015.

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

For additional information relating to our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 17, Other Consolidated Financial Statement Detail to our consolidated financial statements included in our 2015 Form 10-K.

16. 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 Alzheimer's disease. Neurimmune conducts research to identify potential therapeutic antibodies and we are responsible for the development, manufacturing and commercialization of all products. Our anti-amyloid beta antibody, aducanumab, for the treatment of Alzheimer's disease resulted from this collaboration. Based upon our current development plans for aducanumab, we may pay Neurimmune up to $275.0 million in remaining milestone payments. We may also pay royalties in the low-to-mid-teens on sales of any resulting commercial products.

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

We are required to reimburse Neurimmune for amounts that are incurred by Neurimmune for research and development expenses in support of the collaboration. Amounts reimbursed are reflected in research and development expense in our condensed consolidated statements of income. For the three and nine months ended September 30, 2016 and 2015, these amounts were immaterial. Future milestone payments and royalties, if any, will be reflected in our condensed consolidated statements of income as a charge to noncontrolling interest, net of tax, when such milestones are achieved.

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

Other Variable Interest Entities

We also consolidate the financial results of our other variable interest entities where we are the primary beneficiary. We may pay these variable interest entities up to approximately $8.0 million in remaining milestone payments. We have provided no financing to these entities other than amounts provided for in the applicable contract.

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, 2016 and December 31, 2015, the total carrying value of our investments in biotechnology companies totaled $39.2 million and $29.2 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 variable interest entities, please read Note 18, Investments in Variable Interest Entities to our consolidated financial statements included in our 2015 Form 10-K.

29

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

17. Collaborative and Other Relationships

University of Pennsylvania

In May 2016, we entered into a collaboration and alliance with the University of Pennsylvania (Penn) to advance gene therapy and gene editing technologies. The collaboration will primarily focus on the development of therapeutic approaches that target the eye, skeletal muscle and the central nervous system. The alliance is also expected to focus on the research and validation of next-generation gene transfer technology using adeno-associated virus gene delivery vectors and exploring the expanded use of genome editing technology as a potential therapeutic platform.

During the second quarter of 2016, we paid Penn an upfront amount of $20.0 million, which was recorded as research and development expense in our condensed consolidated statements of income, and prepaid research and development expenditures of $15.0 million, which was recorded in investments and other assets in our condensed consolidated balance sheets. We also expect to fund an additional $47.5 million in the aggregate in research and development costs extending over the next three to five years in seven preclinical research and development programs, as well as the exploration of genome-editing technology.

If all of the collaboration programs are successful and we exercise all of our options under the Penn collaboration and alliance, we may be required to make future payments of over $2.0 billion in research funding, options and milestone payments, in addition to royalties payable on net sales of products.

Swedish Orphan Biovitrum AB

In January 2007, we acquired 100% of the stock of Syntonix. Syntonix, now known as Bioverativ Therapeutics Inc. (formerly Biogen Hemophilia Inc.), had previously entered into a collaboration agreement with Swedish Orphan Biovitrum AB (publ) (Sobi) to jointly develop and commercialize Factor VIII and Factor IX hemophilia products, including ELOCTATE and ALPROLIX. Under an amended and restated collaboration agreement, we have commercial rights for North America (the Biogen North America Territory) and for rest of the world markets outside of the Sobi Territory, as defined below (the Biogen Direct Territory). Following its exercise of an option right, Sobi has assumed commercialization rights for ELOCTA, the trade name for ELOCTATE, and ALPROLIX, in substantially all of Europe, Northern Africa, Russia and certain countries in the Middle East (the Sobi Territory). For additional information on our collaboration agreement with Sobi, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in our 2015 Form 10-K.

Sobi had its first commercial sale of ELOCTA in January 2016. In March 2016, the EC approved the transfer of the marketing authorization for ELOCTA in the E.U. from Biogen to Sobi, making Sobi the marketing authorization holder of ELOCTA in the E.U. As the marketing authorization holder, Sobi assumes full legal responsibility for ELOCTA, from a regulatory perspective, during its entire life cycle in the E.U. As of September 30, 2016, approximately $151.0 million in expenditures for ELOCTA, net of the $10.0 million escrow payment and other royalty adjustments as described in the table and its footnote (3) below, are reimbursable to us by Sobi under our collaboration agreement due to Sobi's election to assume final development and commercialization of ELOCTA in the Sobi Territory, which is the Opt-In Consideration for ELOCTA. This reimbursement will be recognized by us as royalty revenue in proportion to collaboration revenues, over a ten year period, consistent with the initial patent term of the product.

ALPROLIX was approved in the E.U. by the EC in May 2016 and Sobi had its first commercial sale in June 2016. In September 2016, the EC approved the transfer of the marketing authorization for ALPROLIX in the E.U. from Biogen to Sobi, making Sobi the marketing authorization holder of ALPROLIX in the E.U. As the marketing authorization holder, Sobi assumes full legal responsibility for ALPROLIX, from a regulatory perspective, during its entire life cycle in the E.U. As of September 30, 2016, approximately $129.0 million in expenditures for ALPROLIX, net of the $10.0 million escrow payment and other royalty adjustments as described in the table and its footnote (3) below, are reimbursable to us by Sobi under our collaboration agreement due to Sobi's election to assume final development and commercialization of ALPROLIX in the Sobi Territory, which is the Opt-In Consideration for ALPROLIX. This reimbursement will be recognized by us as royalty revenue in proportion to collaboration revenues, over a ten year

period, consistent with the initial patent term of the product.

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

The Opt-In Consideration for each product will be paid by Sobi using a cross-royalty cash payment structure for sales in each company's respective territories as an adjustment to the Base Rate in the table below. Under the collaboration agreement, cash payments are as follows:

		Rates post Sobi Opt-In[3]	
Royalty and Net Revenue Share Rates:	Method	Base Rate following 1st commercial sale in the Sobi Territory:	Rate during the Reimbursement Period:
Sobi rate to Biogen on net sales in the Sobi Territory	Royalty	12%	Base Rate plus 5%
Biogen rate to Sobi on net sales in the Biogen North America Territory	Royalty	12%	Base Rate less 5%
Biogen rate to Sobi on net sales in the Biogen Direct Territory	Royalty	17%	Base Rate less 5%
Biogen rate to Sobi on net revenue[1] from the Biogen Distributor Territory[2]	Net Revenue Share	50%	Base Rate less 15%

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

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

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

We are recording revenue at the effective royalty rate expected over the term of the agreement of approximately 14% and recording cost of sales at the effective royalty rate expected over the term of the agreement of approximately 11%. If the reimbursement of the Opt-in Consideration has not been achieved within six years of the first commercial sale of such product, we maintain the right to require Sobi to pay any remaining balances due to us within 90 days of the six year anniversary date of the first commercial sale.

Following the anticipated spin-off of our hemophilia business, we expect our collaboration agreement with Sobi to continue with Bioverativ, an independent, publicly traded company. For additional information about the proposed spin off, please see Note 1, Summary of Significant Accounting Policies.

AbbVie

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

During the nine months ended September 30, 2016, we made milestone payments to AbbVie of $32.0 million related to the regulatory approval of ZINBRYTA, of which $20.0 million was due for regulatory approval in the U.S. and $12.0 million for approval in the E.U. These payments were recorded as intangible assets in our condensed consolidated balance sheets.

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

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 total revenues in our condensed consolidated statements of income. The collaboration began selling ZINBRYTA in the U.S. in the third quarter of 2016. For the three and nine months ended September 30, 2016, we recognized a net reduction in revenue of $13.5 million to reflect our share of an overall net loss within the collaboration.

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

In the E.U. and Canada, we recognize revenues on sales to third parties in product revenues, net in our condensed consolidated statements of income. We also record the related cost of revenues and sales and marketing expenses to their respective line items in our condensed consolidated statements of income as these costs are incurred. We reimburse AbbVie for their 50% share of the co-promotion profits or losses in the E.U. and Canada. This reimbursement 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, 2016, we recognized income of $2.7 million to reflect AbbVie's 50% sharing of net collaboration losses in the E.U. and Canada.

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

Ionis Pharmaceuticals, Inc.

Nusinersen

In January 2012, we entered into an exclusive, worldwide option and collaboration agreement with Ionis Pharmaceuticals, Inc. (Ionis) under which both companies will develop and commercialize the antisense investigational candidate nusinersen for the treatment of spinal muscular atrophy (SMA). Under the terms of this agreement, we paid Ionis $29.0 million as an upfront payment. During 2014, we amended the agreement to adjust the amount of potential additional payments and terms of the exercise of our opt-in right to license nusinersen, which included providing for additional opt-in scenarios, based on the filing or acceptance of a new drug application (NDA) or marketing authorization application with the FDA or European Medicines Agency (EMA). Consistent with the initial agreement, Ionis remained responsible for conducting the pivotal/Phase 3 trials and we provided input on the clinical trial design and regulatory strategy for the development of nusinersen.

In August 2016, we and Ionis announced that nusinersen met the primary endpoint for the interim analysis of the Phase 3 trial evaluating nusinersen in infantile-onset SMA. As a result, during the three months ended September 30, 2016, we exercised our option to develop and commercialize nusinersen and paid Ionis a $75.0 million license fee in connection with the option exercised. This fee was recognized as research and development expense in our condensed consolidated statements of income during the three months ended September 30, 2016.

During the three and nine months ended September 30, 2016, we recognized research and development expenses of $25.7 million and $58.9 million, respectively, for clinical trial payments related to the advancement of the program, as compared to $10.6 million and $23.9 million, respectively, in the prior year comparative periods. We may pay Ionis up to approximately $150.0 million in additional milestone payments upon the achievement of certain regulatory milestones as well as a royalty rate in the mid-teens on future sales of nusinersen.

Samsung Bioepis

Joint Venture Agreement

In February 2012, we entered into a joint venture agreement with Samsung BioLogics Co. Ltd. (Samsung Biologics), establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar pharmaceuticals. Samsung Biologics contributed 280.5 billion South Korean won (approximately $250.0 million) for an 85% stake in Samsung Bioepis and we contributed approximately 49.5 billion South Korean won (approximately $45.0 million) for the remaining 15% ownership interest. Under the joint venture agreement, we have no obligation to provide any additional funding and our ownership interest may be diluted due to financings in which we do not participate. As of September 30, 2016, our ownership interest is approximately 9%, 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 and is based on paying for 49.9% of the total investment made by Samsung Biologics into Samsung Bioepis in excess of what we have already contributed under the agreement plus a rate that will represent their return on capital.

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

Based on our level of influence over Samsung Bioepis, we account for this investment under the equity method of accounting and 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 the three and nine months ended September 30, 2015, we recognized a loss on our investment of $6.8 million and $12.5 million, respectively. 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

In December 2013, pursuant to our rights under the joint venture agreement with Samsung Biologics, we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, three anti-TNF biosimilar product candidates in Europe and in the case of one anti-TNF biosimilar, Japan. Under the terms of this agreement, we have made total upfront and clinical development milestone payments of $46.0 million, all of which have been recorded as a research and development expense in our condensed consolidated statements of income as the programs they relate to had not achieved regulatory approval. We also agreed to make an additional milestone payments of $25.0 million upon regulatory approval in the E.U. for each of the three anti-TNF biosimilar product candidates. During the nine months ended September 30, 2016, we paid $50.0 million in milestone payments, which have been capitalized in intangible assets, net in our condensed consolidated balance sheet as BENEPALI received regulatory approval in the E.U. in January 2016 and FLIXABI received regulatory approval in the E.U. in May 2016. In July 2016, the EMA accepted Samsung Bioepis' marketing authorisation application (MAA) for SB5, an adalimumab biosimilar candidate referencing HUMIRA.

We began to recognize revenue on sales of BENEPALI in the E.U. in the first quarter of 2016 and FLIXABI in the E.U. in the third quarter of 2016. 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. We share 50% of the profit or loss related to our commercial agreement with Samsung Bioepis. This profit share with Samsung Bioepis is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income. For the three and nine months ended September 30, 2016, we recognized a net expense of $7.4 million and $1.8 million, respectively, related to the collaboration profit share.

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, 2016, we recognized $0.4 million and $17.3 million, respectively, in relation to these services as other revenues in our condensed consolidated statements of income, as compared to $10.9 million and $47.0 million, respectively, in the prior year comparative periods.

For additional information related to our other significant collaboration arrangements, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in our 2015 Form 10-K.

18. 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 2015 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

Forward Pharma German Patent Litigation

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

ALPROLIX Patent Licensing Matter

Biogen has received communications from Pfizer Inc. (Pfizer) regarding its proposal that we take a license to Pfizer's U.S. Patent No. 8,603,777 (Expression of Factor VII and IX Activities in Mammalian Cells) and pay royalties on past and future sales of ALPROLIX. There is no pending litigation regarding this matter and an estimate of the possible loss or range of loss cannot be made at this time.

Italian National Medicines Agency

In the fourth quarter of 2011, Biogen Italia SRL received notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. On January 12, 2012, we filed an appeal in the Regional Administrative Tribunal of Lazio (Il Tribunale Amministrativo Regionale per il Lazio) in Rome, Italy seeking a ruling that the reimbursement limit in the Price Resolution should apply as written to only “the first 24 months” of TYSABRI sales, which ended in mid-February 2009. The appeal is still pending. In June 2014, AIFA approved a resolution affirming that there is no reimbursement limit from and after February 2013. AIFA and Biogen Italia SRL are discussing a possible resolution for the period from February 2009 through January 2013.

For additional information regarding this matter, please read Note 15, Other Consolidated Financial Statement Detail to these condensed consolidated financial statements.

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 In re Biogen Inc. Securities Litigation, filed by a shareholder on August 18, 2015 in the U.S. District Court for the District of Massachusetts. The amended complaint alleges violations of federal securities laws under 15 U.S.C. §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5. The lead plaintiff sought a declaration of the action as a class action, certification as a representative of the class and its counsel as class counsel, and an award of damages, interest and attorneys' fees. On July 1, 2016 the U.S. District Court dismissed the case and in September 2016 denied the plaintiff's motion to vacate the order of dismissal. The plaintiff has filed a notice of appeal. An estimate of the possible loss or range of loss cannot be made at this time.

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

We and certain current and former officers are also defendants in an action filed by another shareholder on October 20, 2016 in the U.S. District Court for the District of Massachusetts, designated as related to the matter described above and assigned to the same judge. The complaint alleges violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeks 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

Interference Proceeding with Forward Pharma

In April 2015, the U.S. Patent and Trademark Office (USPTO) declared an interference between Forward Pharma's pending U.S. Patent Application No. 11/576,871 and our U.S. Patent No. 8,399,514 (the '514 patent). The '514 patent includes claims covering the treatment of multiple sclerosis with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. A hearing has been scheduled for November 2016.

Inter Partes Review Petitions and Proceeding

On March 22, 2016, the USPTO instituted inter partes review of the '514 patent on the petition of the Coalition for Affordable Drugs V LLC, an entity associated with a hedge fund. A hearing has been scheduled for November 2016.

On April 18, 2016, Swiss Pharma International AG filed petitions in the USPTO for inter partes review of U.S. Patent Nos. 8,349,321 and, 8,900,577, relating to specific formulations of natalizumab (TYSABRI), and U.S. Patent No. 8,815,236, relating to methods for treating MS and Crohn's disease using specific formulations of natalizumab (TYSABRI). In October 2016, the USPTO declined to institute proceedings under all three petitions.

European Patent Office Oppositions

In June 2016, the European Patent Office 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.

Patent Revocation Matter

In December 2015, Swiss Pharma International AG brought an action in the Patents Court of the United Kingdom to revoke the UK counterpart of our European Patent Number 1 485 127 ("Administration of agents to treat inflammation") (the '127 patent), which was issued in June 2011 and concerns administration of natalizumab (TYSABRI) to treat MS. The patent expires in February 2023. Subsequently, the same entity brought 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 the '127 patent. In September 2016 we resolved the UK action by agreeing to revocation of the UK patent. A hearing has been scheduled in the Dutch action for early 2017 and 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. (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

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

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 September 2017.

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.

On March 4, 2016, we received a subpoena from the federal government for documents relating to our relationship with non-profit organizations that provide assistance to patients taking drugs sold by Biogen. 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 Average Manufacturer Prices in connection with the Medicaid Drug Rebate Program. 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.

19. Commitments and Contingencies

Fumapharm AG

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

During the nine months ended September 30, 2016, we paid $900.0 million in contingent payments as we reached the $7.0 billion, $8.0 billion and $9.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2015, first quarter of 2016 and second quarter of 2016, respectively, and accrued $300.0 million upon reaching $10.0 billion in total cumulative sales of Fumapharm Products in the third quarter of 2016.

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 will be accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm. Any portion of the payment which is tax deductible will be recorded as a reduction to goodwill. Payments are due within 60 days following the end of the quarter in which the applicable cumulative sales level has been reached.

Solothurn, Switzerland Facility

On December 1, 2015, we purchased land in Solothurn, Switzerland where we are building a biologics manufacturing facility over the next several years. As of September 30, 2016, we had contractual commitments of approximately $100.0 million for the construction of this facility.

Table of Contents

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, 2015 (2015 Form 10-K). Certain totals may not sum due to rounding.

Executive Summary

Introduction

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

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, ZINBRYTA and FAMPYRA for multiple sclerosis (MS), ELOCTATE for hemophilia A and ALPROLIX for hemophilia B and FUMADERM for the treatment of severe plaque psoriasis. We also have a collaboration agreement with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, which entitles us to certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, GAZYVA indicated for the treatment of CLL and follicular lymphoma.

In May 2016, we announced our intention to spin off our hemophilia business as an independent, publicly traded company. The company, named Bioverativ Inc. (Bioverativ), will focus on the discovery, development and commercialization of therapies for the treatment of hemophilia and other blood disorders, including our existing marketed products ELOCTATE and ALPROLIX. The transaction is expected to be completed in early 2017, subject to the satisfaction of certain conditions, including, among others, final approval of our Board of Directors, receipt of a favorable opinion with respect to the tax-free nature of the transaction and the effectiveness of a Form 10 registration statement filed with the Securities and Exchange Commission. The results of Bioverativ will be included in our condensed consolidated financial statements until the transaction is completed.

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. Further, if the proposed spin-off of Bioverativ is completed, our revenues will be further reliant and concentrated on sales of our MS products in an increasingly competitive market.

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. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products in disease areas for which there are inadequate treatments and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

In addition to our innovative drug development efforts, we aim to leverage our manufacturing capabilities and scientific expertise through Samsung Bioepis, our joint venture with Samsung BioLogics Co. Ltd. (Samsung Biologics) that develops, manufactures and markets biosimilars as well as through other strategic contract manufacturing partners. Under our commercial agreement with Samsung Bioepis, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the European Union (E.U.).

Table of Contents

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were $4.71 for the three months ended September 30, 2016, representing an increase of 13.5% over the same period in 2015.

Our income from operations for the three months ended September 30, 2016 reflects the following:

- Total revenues were $2,955.8 million for the third quarter of 2016, representing an increase of 6.4% over the same period in 2015.
- Product revenues, net totaled $2,539.6 million for the third quarter of 2016, representing an increase of 6.2% over the same period in 2015. This increase was driven by an 10.3% increase in worldwide TECFIDERA revenues, a 7.5% increase in worldwide TYSABRI revenues and revenues from ELOCTATE, ALPROLIX and BENEPALI. These increases were partially offset by a 9.8% decrease in worldwide Interferon revenues. Product revenues, net for the third quarter of 2016, compared to the same period in 2015, were also negatively impacted by a $49.1 million change in hedge results under our hedging program in the comparative periods.
- Revenues from anti-CD20 therapeutic programs totaled $317.6 million for the third quarter of 2016, representing a decrease of 5.8% over the same period in 2015.
- Other revenues totaled $98.6 million for the third quarter of 2016, representing an increase of 101.2% over the same period in 2015. This increase was primarily driven by an increase in other corporate revenue.
- Total cost and expenses totaled $1,530.5 million for the third quarter of 2016, representing an increase of 8.9% compared to the same period in 2015. This increase was driven by a 34.5% increase in cost of sales, a 1.8% increase in research and development expense and the recognition of an $11.6 million charge related to our restructuring programs. This increase was partially offset by a 3.2% decrease in selling, general and administrative expenses.
- We generated $2,945.8 million of net cash flows from operations for the nine months ended September 30, 2016, which were primarily driven by earnings. Cash, cash equivalents and marketable securities totaled approximately $7,412.9 million as of September 30, 2016.

Business Environment

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing. In addition, the commercialization of certain of our own approved MS products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing MS products. Our products may also face increased competitive pressures from the introduction of generic versions, prodrugs of existing therapeutics or biosimilars of existing products and other technologies, such as gene therapies and bispecific antibodies.

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

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.

Table of Contents

Key Pipeline and Product Developments

TYSABRI

In June 2016, the European Commission (EC) approved a variation to the marketing authorization of TYSABRI, which extended its indication to include relapsing-remitting MS patients with highly active disease activity despite a full and adequate course of treatment with at least one disease modifying therapy. TYSABRI was previously only indicated for patients who had failed to respond to beta-interferon or glatiramer acetate in the E.U.

ZINBRYTA

In May 2016, the U.S. Food and Drug Administration (FDA) approved ZINBRYTA for the treatment of relapsing forms of MS and in July 2016, the EC approved ZINBRYTA for the treatment of relapsing forms of MS. Sales of ZINBRYTA began during the third quarter of 2016 in the U.S. and E.U. Under our collaboration agreement with AbbVie, Inc. (AbbVie), we and AbbVie conduct co-promotion activities in the E.U., U.S. and Canadian Territories, where development and commercialization costs and profits are shared equally.

Hemophilia

In March 2016, the EC approved the transfer of the marketing authorization for ELOCTA in the E.U. to Swedish Orphan Biovitrum AB (publ) (Sobi). As the marketing authorization holder, Sobi assumes full legal responsibility for ELOCTA, from a regulatory perspective, during its entire life cycle in the E.U.

In May 2016, the EC approved ALPROLIX in the E.U. for the treatment of hemophilia B. In September 2016, the EC approved the transfer of the marketing authorization for ALPROLIX in the E.U. to Sobi. As the marketing authorization holder, Sobi assumes full legal responsibility for ALPROLIX, from a regulatory perspective, during its entire life cycle in the E.U.

Biosimilars

The EC approved Samsung Bioepis' marketing authorisation applications (MAAs) for BENEPALI and FLIXABI, two anti-tumor necrosis factor (TNF) biosimilars, for marketing in the E.U. in January 2016 and May 2016, respectively. Under our agreement with Samsung Bioepis, we manufacture and commercialize BENEPALI and FLIXABI in specified E.U. countries.

In July 2016, the European Medicine Agency (EMA) accepted Samsung Bioepis' MAA for SB5, an adalimumab biosimilar candidate referencing HUMIRA.

GAZYVA

In February 2016, the Roche Group announced that the FDA approved GAZYVA plus bendamustine chemotherapy followed by GAZYVA alone as a new treatment for people with follicular lymphoma who did not respond to a RITUXAN-containing regimen, or whose follicular lymphoma returned after such treatment. Follicular lymphoma is the most common type of indolent non-Hodgkin’s lymphoma.

In May 2016, the Roche Group announced positive results from the Phase 3 GALLIUM study, which investigated the efficacy and safety of GAZYVA in combination with chemotherapy followed by maintenance with GAZYVA alone, compared to RITUXAN in combination with chemotherapy followed by maintenance with RITUXAN alone in previously untreated patients with follicular lymphoma. Results from a pre-planned interim analysis showed that GAZYVA-based treatment significantly reduced the risk of disease worsening or death compared to RITUXAN-based treatment.

In July 2016, the Roche Group announced that the Phase 3 GOYA study evaluating GAZYVA plus CHOP chemotherapy in people with previously untreated diffuse large B-cell lymphoma did not meet its primary endpoint of significantly reducing the risk of disease worsening or death compared to RITUXAN plus CHOP chemotherapy. Adverse events with GAZYVA and RITUXAN were consistent with those seen in previous clinical trials when each was combined with various chemotherapies.

For additional information related to our relationship with Genentech (Roche Group), please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in our 2015 Form 10-K.

OCREVUS (Ocrelizumab)

In June 2016, the Roche Group announced that the EMA validated its MAA of OCREVUS for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS) in the E.U. The FDA has also

accepted for review its Biologics License Application for OCREVUS for the treatment of RMS and PPMS, and has granted the application Priority Review Designation with a targeted action date of December 28, 2016.

Under our agreement with Genentech, if OCREVUS is approved, we will receive tiered royalty payments on sales of OCREVUS in the U.S. For additional information related to our relationship with Genentech, please read Note 19, Collaborative and Other Relationships to our consolidated financial statements included in our 2015 Form 10-K.

Table of Contents

While we have a financial interest in OCREVUS, future sales of our MS products may be adversely affected by the commercialization of OCREVUS.

Nusinersen

In August 2016, we and Ionis Pharmaceuticals, Inc. (Ionis) announced that nusinersen met the primary endpoint for the interim analysis of the Phase 3 trial evaluating nusinersen in infantile-onset spinal muscular atrophy (SMA). As a result, during the three months ended September 30, 2016, we exercised our option to develop and commercialize nusinersen and paid Ionis a $75.0 million license fee in connection with the option exercise. In addition, we committed to opening an Expanded Access Program (EAP) in order to provide patient access to nusinersen. In October 2016, we dosed our first patient in our infantile-onset SMA EAP.

In September 2016, we and Ionis announced that we completed the rolling submission of a New Drug Application (NDA) to the FDA for the approval of nusinersen. We have also applied for Priority Review which, if granted, would shorten the review period of nusinersen following the FDA's acceptance of the NDA. Nusinersen has received an Orphan Drug designation in both the U.S. and the E.U. In October 2016, we filed an MAA with the EMA, which had already granted Accelerated Assessment status to nusinersen.

Aducanumab

In June 2016, we announced that aducanumab, our investigational treatment for early Alzheimer’s disease, was accepted into the EMA's Priority Medicines (PRIME) program. PRIME aims to bring treatments to patients more quickly by enhancing the EMA’s support for the development of investigational medicines for diseases without available treatments or in need of better treatment options. Aducanumab was accepted into PRIME based on results from a Phase 1b placebo-controlled study of aducanumab in patients with prodromal or mild Alzheimer’s disease. Through the PRIME program, we will have access to enhanced support from EMA, including advice at key development milestones and the potential for accelerated assessment status of a MAA.

In September 2016, we announced that aducanumab was granted Fast Track designation by the FDA. The FDA’s Fast Track program supports the development of new treatments for serious conditions with an unmet medical need such as Alzheimer’s disease. We also announced that in a recently completed interim analysis from our Phase 1b study of aducanumab in early Alzheimer's disease, efficacy and safety data were consistent with results previously reported.

Anti-LINGO

In June 2016, we reported top-line results from SYNERGY our Phase 2 trial evaluating anti-LINGO in people with relapsing forms of MS. Anti-LINGO did not meet the primary endpoint of the SYNERGY trial as well as its secondary efficacy endpoint. However, based on these results, there was a subset of patients within the study that we believe that have the potential to benefit from treatment and we are therefore planning to perform additional clinical trials related to anti-LINGO in the future.

Amiselimod

In October 2016, we announced we discontinued development of amiselimod (MT-1303).

Table of Contents

Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2016		2015		For the Nine Months Ended September 30, 2016		2015	
Product revenues:								
United States	$1,828.6	61.9 %	$1,721.5	62.0 %	$5,269.4	61.4 %	$4,820.6	60.8 %
Rest of world	711.0	24.1 %	670.2	24.1 %	2,045.6	23.9 %	1,942.0	24.5 %
Total product revenues	2,539.6	86.0 %	2,391.7	86.1 %	7,315.0	85.3 %	6,762.6	85.3 %
Revenues from anti-CD20 therapeutic programs	317.6	10.7 %	337.2	12.1 %	996.3	11.6 %	1,005.3	12.7 %
Other revenues	98.6	3.3 %	49.0	1.8 %	265.5	3.1 %	156.6	2.0 %
Total revenues	$2,955.8	100.0%	$2,777.9	100.0%	$8,576.8	100.0%	$7,924.5	100.0%

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2016		2015		For the Nine Months Ended September 30, 2016		2015	
Multiple Sclerosis:								
TECFIDERA	$1,033.7	40.7 %	$937.4	39.2 %	$2,966.1	40.5 %	$2,645.6	39.1 %
Interferon*	708.3	27.9 %	784.8	32.8 %	2,107.0	28.8 %	2,229.0	33.0 %
TYSABRI	515.5	20.3 %	479.7	20.1 %	1,489.9	20.4 %	1,405.4	20.8 %
FAMPYRA	21.1	0.8 %	21.0	0.9 %	62.9	0.9 %	62.1	0.9 %
ZINBRYTA	1.9	0.1 %	—	— %	1.9	— %	—	— %
Hemophilia:								
ELOCTATE	131.8	5.2 %	90.6	3.8 %	364.2	5.0 %	218.5	3.2 %
ALPROLIX	85.2	3.4 %	65.7	2.7 %	240.5	3.2 %	163.2	2.4 %
Other product revenues:								
FUMADERM	11.3	0.4 %	12.5	0.5 %	34.5	0.5 %	38.8	0.6 %
BENEPALI	30.7	1.2 %	—	— %	47.9	0.7 %	—	— %
FLIXABI	0.1	— %	—	— %	0.1	— %	—	— %
Total product revenues	$2,539.6	100.0%	$2,391.7	100.0%	$7,315.0	100.0%	$6,762.6	100.0%

*Interferon includes AVONEX and PLEGRIDY.

Table of Contents

Multiple Sclerosis (MS)

TECFIDERA

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in U.S. TECFIDERA revenues was primarily due to price increases, partially offset by higher discounts and allowances.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volumes of 24% and 37%, respectively, including sales in existing markets and new markets where we continue to launch the product and expand our presence around the world, partially offset by pricing reductions in certain European countries. Rest of world TECFIDERA revenues for the three and nine months ended September 30, 2016, compared to the same periods in 2015, were also negatively impacted by a $14.6 million and $34.5 million change in hedge results under our hedging program in the comparative periods, respectively.

Interferon

AVONEX and PLEGRIDY

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the decrease in U.S. Interferon revenues was primarily due to an overall decrease in Interferon unit sales volume attributable to a decrease in AVONEX unit sales volume primarily due to patients transitioning to other oral MS therapies, partially offset by price increases.

For the three and nine months ended September 30, 2016, U.S. AVONEX revenues totaled $421.8 million and $1,264.0 million, respectively, as compared to $467.1 million and $1,350.5 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2016, U.S. PLEGRIDY revenues totaled $83.9 million and $228.2 million, respectively, as compared to $70.6 million and $160.5 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the decrease in rest of world Interferon revenues was primarily due to pricing reductions in certain European countries and an overall decrease in AVONEX unit sales volume due primarily to patients transitioning to other oral MS therapies, including TECFIDERA. Rest of world Interferon revenues for the three and nine months ended September 30, 2016, compared to the same periods in 2015, were also negatively impacted by a $19.1 million and $48.4 million change in hedge results under our hedging program in the comparative periods, respectively.

Table of Contents

For the three and nine months ended September 30, 2016, rest of world AVONEX revenues totaled $158.3 million and $485.8 million, respectively, as compared to $218.0 million and $642.5 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2016, rest of world PLEGRIDY revenues totaled $44.3 million and $129.0 million, respectively, as compared to $29.1 million and $75.5 million, respectively, in the prior year comparative periods.

We expect that overall Interferon revenues will continue to decline as a result of competition from our other products, including TECFIDERA, as well as other MS therapies.

TYSABRI

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in U.S. TYSABRI revenues was primarily due to increases in unit sales volume of 4% and 3%, respectively, and price increases, partially offset by higher discounts and allowances.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in rest of world TYSABRI revenues was due to an increase in unit sales volume of 11% and 10%, respectively, primarily in Europe, and a favorable adjustment of approximately $20.0 million to previous reserve estimates related to a government price reimbursement program included in our discounts and allowances, partially offset by pricing reductions in certain European countries. Rest of world TYSABRI revenues for the three and nine months ended September 30, 2016, compared to the same periods in 2015, were also negatively impacted by a $13.9 million and $33.2 million change in hedge results under our hedging program in the comparative periods, respectively.

In the fourth quarter of 2011, Biogen Italia SRL, our Italian subsidiary, received a notice from the Italian National Medicines Agency (Agenzia Italiana del Farmaco or AIFA) that sales of TYSABRI after mid-February 2009 exceeded a reimbursement limit established pursuant to a Price Determination Resolution (Price Resolution) granted by AIFA in December 2006. AIFA and Biogen Italia SRL are still discussing a possible resolution for the period from February 2009 through January 2013. If our most recent settlement offer is accepted, we could recognize approximately EUR40 million in revenue upon resolution of this matter. For information regarding our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 17, Other Consolidated Financial Statement Detail to our consolidated financial statements included in our 2015 Form 10-K.

We expect that TYSABRI revenues will continue to face competition from additional treatments for MS, including ZINBRYTA, and other MS product candidates, including OCREVUS.

Table of Contents

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 17, Collaborative and Other Relationships to our condensed consolidated financial statements included in this report.

Hemophilia

ELOCTATE

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in U.S. ELOCTATE revenues was primarily due to an increase in unit sales volume of 26% and 52%, respectively.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in rest of world ELOCTATE revenues was primarily due to an increase in unit sales volume primarily in Japan.

Table of Contents

ALPROLIX

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in U.S. ALPROLIX revenues was primarily due to an increase in unit sales volume of 13% and 31%, respectively.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in rest of world ALPROLIX revenues was primarily due to an increase in unit sales volume primarily in Japan.

We expect continued growth of ELOCTATE as there remains a portion of the patient population that we believe can benefit from long-acting therapies. We also expect continued growth for ELOCTATE and ALPROLIX as we and Sobi expand into additional markets.

Biosimilars

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 quarter of 2016 and third quarter of 2016, respectively.

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

Table of Contents

Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN and GAZYVA operating profits 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)	2016	2015
Product revenues, net	$961.8	$959.1
Cost and expenses	191.7	161.5
Pre-tax profits in the U.S.	770.1	797.6
Biogen's share of pre-tax profits	$301.0	$319.9

	For the Nine Months Ended September 30,	
(In millions)	2016	2015
Product revenues, net	$2,969.3	$2,901.1
Cost and expenses	544.9	516.8
Pre-tax profits in the U.S.	2,424.4	2,384.3
Biogen's share of pre-tax profits	$947.6	$952.7

For the three months ended September 30, 2016, compared to the same period in 2015, the increase in U.S. product revenues was primarily due to an increase in GAZYVA unit sales volume of 32% and price increases, partially offset by a decrease in RITUXAN unit sales volume of 2% and higher RITUXAN discounts and allowances.

For the nine months ended September 30, 2016, compared to the same period in 2015, the increase in U.S. product revenues was primarily due to price increases and an increase in GAZYVA unit sales volume of 48%, partially offset by higher RITUXAN discounts and allowances.

The increase in collaboration costs and expenses for the three and nine months ended September 30, 2016, compared to the same periods in 2015, was primarily due to an increase in RITUXAN product cost of sales.

Our share of RITUXAN pre-tax profits in the U.S. decreased to 39% from 40% as GAZYVA was approved by the FDA in follicular lymphoma in February 2016.

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 2015 Form 10-K.

Revenue on Sales in the Rest of World for RITUXAN

Revenue on sales in the rest of world for RITUXAN consists of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenues on sales outside the U.S. and Canada. For the three and nine months ended September 30, 2016, compared to the same periods in 2015, revenues on sales in the rest of world for RITUXAN decreased as a result of lower pre-tax co-promotion revenues on RITUXAN in Canada and patent expirations.

Table of Contents

Other Revenues

Other revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2016		2015		For the Nine Months Ended September 30, 2016		2015	
Revenues from collaborative and other relationships	$(0.9)	(0.9)%	$15.3	31.2 %	$30.2	11.4 %	$51.4	32.8 %
Other royalty and corporate revenues	99.5	100.9 %	33.7	68.8 %	235.3	88.6 %	105.2	67.2 %
Total other revenues	$98.6	100.0 %	$49.0	100.0%	$265.5	100.0%	$156.6	100.0%

Revenues from Collaborative and Other Relationships

Revenues from collaborative and other relationships include revenues earned under our manufacturing services agreement with Sobi on shipments of ELOCTA and ALPROLIX to Sobi, royalties from Sobi on sales of ELOCTA and ALPROLIX in their territory, which includes substantially all of Europe, Northern Africa, Russia and certain markets in the Middle East (Sobi Territory), 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.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the decrease in revenues from collaborative and other relationships is primarily due to a net overall loss in the collaboration with AbbVie of $13.5 million and lower revenues earned under our manufacturing services agreement with Samsung Bioepis, partially offset by an increase in ELOCTA shipments made under our manufacturing services agreement with Sobi.

For additional information on our collaborative and other relationships, please read Note 17, Collaborative and Other Relationships to our condensed consolidated financial statements included in this report.

Other Royalty and Corporate Revenues

Royalty Revenues

We receive royalties from net sales on products related to patents that we have out-licensed.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, royalty revenues were relatively consistent.

Other Corporate Revenues

Our other corporate revenues include amounts earned under contract manufacturing agreements.

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in other corporate revenues was primarily due to higher contract manufacturing revenues related to drug substance manufacturing provided to a strategic partner.

Table of Contents

Reserves for Discounts and Allowances

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

Reserves established for these discounts and allowances are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which will have an effect on earnings in the same period. To date, such adjustments have not been significant.

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

For the three and nine months ended September 30, 2016, reserves for discounts and allowances as a percentage of gross product revenues were 20.8%, as compared to 18.5% and 19.1%, respectively, in the prior year comparative periods. The increase in percentage of gross product sales was primarily driven by higher contractual adjustments, as further described below.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three months ended September 30, 2016, compared to the same period in 2015, discounts were relatively consistent.

For the nine months ended September 30, 2016, compared to the same period in 2015, the increase in discounts was primarily driven by increases in gross selling price and contractual discount rates.

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, 2016, compared to the same periods in 2015, the increase in contractual adjustments was primarily due to higher Medicaid and other governmental rebates and allowances in the U.S., and managed care rebates primarily as a result of an increase in gross selling prices.

Returns

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

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, return provisions decreased primarily due to a reduction in return rates based on recent experiences of returned products.

For additional information related to our reserves, please read Note 3, Reserves for Discounts and Allowances to our condensed consolidated financial statements included in this report.

Table of Contents

Cost and Expenses

A summary of total cost and expenses is as follows:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
(In millions, except percentages)	2016	2015	Change %	2016	2015	Change %
Cost of sales, excluding amortization of acquired intangible assets	$416.9	$310.0	34.5 %	$1,100.2	$908.6	21.1 %
Research and development	529.0	519.9	1.8 %	1,439.4	1,471.1	(2.2)%
Selling, general and administrative	462.7	477.8	(3.2)%	1,452.4	1,530.1	(5.1)%
Amortization of acquired intangible assets	99.7	98.1	1.6 %	281.4	286.0	(1.6)%
Restructuring charges	11.6	—	**	21.3	—	**
(Gain) loss on fair value remeasurement of contingent consideration	5.9	0.2	**	18.8	5.9	218.6 %
Collaboration profit (loss) sharing	4.7	—	**	(0.9)	—	**
Total cost and expenses	$1,530.5	$1,406.0	8.9 %	$4,312.6	$4,201.7	2.6 %

** Percentage not meaningful.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Product Cost of Sales

For the three and nine months ended September 30, 2016 compared to the same periods in 2015, the increase in product cost of sales was primarily driven by increased contract manufacturing shipments and higher unit sales volume related to our biosimilars, PLEGRIDY and ELOCTATE products, partially offset by favorable production costs and mix of products.

Product cost of sales for the three and nine months ended September 30, 2016 also reflects the recognition of $15.7 million and $31.5 million of accelerated depreciation as a result of the determination that we intend to cease manufacturing in Cambridge, MA and vacate our biologics manufacturing facility in Cambridge, MA and warehouse space in Somerville, MA by the end of 2016.

Royalty Cost of Sales

For the three and nine months ended September 30, 2016, compared to the same periods in 2015, the increase in royalty cost of sales was primarily driven by royalties due on sales of AVONEX and PLEGRIDY in the U.S., the increase in royalty rates payable to Sobi and increased sales of TYSABRI and our hemophilia products.

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, US Patent No. 9,376,478, expires in June 2033. This patent was issued following an interference proceeding among JFCR and us. This patent is relevant to AVONEX and PLEGRIDY, and we will pay royalties in the mid single digits in relation to this patent during the life of the patent.

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

Table of Contents

Research and Development

Research and development expense incurred in support of our marketed products includes costs associated with product lifecycle management activities including, if applicable, costs associated with the development of new indications for existing products. Late stage programs are programs in Phase 3 development or in registration stage. Early stage programs are programs in Phase 1 or Phase 2 development. Research and discovery represents costs incurred to support our discovery research and translational science efforts. Other research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as management costs as well as depreciation and other facility-based expenses. Costs are reflected in the development stage based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same year. For several of our programs, the research and development activities are part of our collaborative and other relationships. Our costs reflect our share of the total costs incurred.

Table of Contents

For the three months ended September 30, 2016, compared to the same period in 2015, the increase in research and development expense was primarily related to increased costs incurred in connection with our late stage programs and milestone and upfront expenses, partially offset by decreases in costs incurred in connection with our marketed products, early stage programs and other research and development costs.

For the nine months ended September 30, 2016, compared to the same period in 2015, the decrease in research and development expense was primarily related to decreases in costs incurred in connection with our early stage programs, marketed products and other research and development costs. These decreases were partially offset by increased costs incurred in connection with our late stage programs and milestone and upfront expenses.

The decrease in spending associated with our early stage programs for the three months ended September 30, 2016, compared to the same period in 2015, was primarily due to the discontinuance of development of anti-TWEAK in lupus nephritis and decreased costs incurred in connection with anti-LINGO in MS, partially offset by increased costs associated with our discontinuance of development of amiselimod in the third quarter of 2016.

The decrease in spending associated with our early stage programs for the nine months ended September 30, 2016, compared to the same period in 2015, was primarily due to the advancement of our aducanumab program for Alzheimer's disease to a late stage program in the third quarter of 2015, the discontinuance of developments of anti-TWEAK in lupus nephritis and Neublastin in neuropathic pain and decreased costs incurred in connection with anti-LINGO in MS. These decreases were partially offset by increased costs of BIIB074 (formerly known as Raxatrigine) in trigeminal neuralgia (TGN) and increased costs associated with our discontinuance of development of amiselimod in the third quarter of 2016.

The decrease in spending associated with our marketed products for the three and nine months ended September 30, 2016, compared to the same periods in 2015, was primarily due to the discontinuance of development of TECFIDERA and TYSABRI in SPMS in the third and fourth quarters of 2015, respectively, and decreased costs incurred in connection with our hemophilia products. These decreases were partially offset by the approval of ZINBRYTA in the third quarter of 2016.

The increase in spending associated with our late stage programs for the three and nine months ended September 30, 2016, compared to the same periods in 2015, was primarily driven by costs incurred to advance our aducanumab program for Alzheimer's disease and the nusinersen program for the treatment of SMA, partially offset by the approval of ZINBRYTA in the third quarter of 2016.

The increase in spending associated with milestone and upfront expenses for the three months ended September 30, 2016, compared to the same period in 2015, was primarily due to a $75.0 million license fee paid to Ionis in the third quarter of 2016 as we exercised our option to develop and commercialize nusinersen from Ionis, partially offset by upfront charges recognized upon entering into the collaboration with Applied Genetic Technology Corporation (AGTC) in July 2015.

The increase in spending associated with milestone and upfront expenses for the nine months ended September 30, 2016, compared to the same period in 2015, was primarily due to a $75.0 million license fee paid to Ionis in the third quarter of 2016 as we exercised our option to develop and commercialize nusinersen from Ionis and a $20.0 million upfront milestone paid to the University of Pennsylvania upon entering into a collaboration and alliance. This increase was partially offset by upfront charges recognized upon entering into the collaboration with AGTC in July 2015 and prior year milestones paid to AbbVie for the development of ZINBRYTA as a result of filing with the FDA and EMA in 2015.

We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where the drug candidate has the potential to be highly differentiated. Specifically, we intend to continue to invest in our MS pipeline, our aducanumab program, the BAN2401 and E2609 programs and our BIIB074 program.

Table of Contents

Selling, General and Administrative

For the three months ended September 30, 2016, compared to the same period in 2015, the decrease in selling, general and administrative expenses reflects cost savings in connection with our corporate restructuring initiatives, which are described below under the heading "Restructuring Charges" and a decrease in corporate giving, partially offset by costs associated with developing commercial capabilities for the anticipated product launch of nusinersen and an increase in incentive compensation.

For the nine months ended September 30, 2016, compared to the same period in 2015, the decrease in selling, general and administrative expenses reflects cost savings in connection with our corporate restructuring, which are described below under the heading "Restructuring Charges," partially offset by an increase in corporate giving and costs associated with developing commercial capabilities for ZINBRYTA and the anticipated product launch of nusinersen.

Amortization of Acquired Intangible Assets

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

Our most recent long range planning cycle was updated in the third quarter of 2016. Based upon this analysis, there was not a significant net change in our expected rate of amortization for acquired intangible assets.

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

For additional information related to the amortization of acquired intangible assets, please read Note 5, Intangible Assets and Goodwill to our condensed consolidated financial statements included in this report.

Table of Contents

In Process Research & Development (IPR&D)

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

The field of developing treatments for idiopathic pulmonary fibrosis (IPF) and forms of neuropathic pain, such as TGN, are highly competitive and can be affected by rapid changes to expected market candidates. There can be no assurance that we will be able to successfully develop STX-100 for the treatment of IPF or BIIB074 for the treatment of TGN or other indications or that a successfully developed therapy will be able to secure sufficient pricing in a competitive market. Changes to clinical development plans or life cycle management strategies are evaluated regularly. We review amounts capitalized as acquired IPR&D for impairment at least annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Our most recent impairment assessment as of October 31, 2015 resulted in no impairments.

Restructuring, Business Transformation and Other Cost Saving Initiatives

2015 Cost Saving Initiatives

2015 Restructuring Charges

On October 21, 2015, we announced a corporate restructuring, which included the termination of certain pipeline programs and an 11% reduction in workforce. As a result of these initiatives, we reduced our annual run rate of operating expenses by $250 million and reinvested these savings to support the advancement of our high potential pipeline candidates and key commercial activities.

Under this restructuring, cash payments were estimated to total approximately $120 million, of which $15.9 million were related to previously accrued 2015 incentive compensation, resulting in expected net restructuring charges totaling approximately $105 million. These amounts are expected to be substantially paid by the end of 2016.

For the three months ended September 30, 2016, we recognized an adjustment to our previous estimates, which resulted in a negative restructuring charge of $1.6 million. For the nine months ended September 30, 2016, we recognized total net restructuring charges of $8.1 million. We previously recognized $93.4 million of restructuring charges in our consolidated statements of income during the fourth quarter of 2015.

Table of Contents

The following table summarizes the charges and spending related to our 2015 restructuring efforts during the nine months ended September 30, 2016:

(In millions)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2015	$ 33.7	$ 3.6	$37.3
Expense	4.9	5.4	10.3
Payments	(29.6)	(7.5)	(37.1)
Adjustments to previous estimates, net	(5.1)	2.9	(2.2)
Restructuring reserve as of September 30, 2016	$ 3.9	$ 4.4	$8.3

2016 Organizational Changes and Cost Saving Initiatives

2016 Restructuring Charges

During the third quarter of 2016, we initiated additional cost saving measures which are primarily intended to realign our organizational structure in anticipation of the changes in roles and workforce resulting from our decision to spin off our hemophilia business, and to achieve further targeted cost reductions. For the three and nine months ended September 30, 2016, we recognized charges totaling $13.2 million related to this effort, which are in addition to, and separate from, the 2015 corporate restructuring described above. These charges are reflected in restructuring charges in our condensed consolidated statements of income.

Under this initiative, we expect to incur restructuring charges totaling approximately $20.0 million. These amounts are primarily related to severance and are expected to be substantially incurred and paid by the end of 2016.

Cambridge, MA Manufacturing Facility

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

We are currently considering alternatives for the facility, which may include a sale of our rights to, lease of, or other form of disposition of, the facility and related assets. In the event we are unsuccessful with a sale, lease or other disposition, we will cease manufacturing by December 31, 2016. As of September 30, 2016, the carrying value of associated assets totaled approximately $29.0 million. An impairment assessment was performed related to the assets, which resulted in no impairments. Our remaining lease obligation related to these facilities totaled $25.5 million. Our anticipated departure from these facilities has shortened the expected useful lives of certain leasehold improvements and other assets at these facilities. As a result, we recorded additional depreciation expense to reflect the assets' new shorter useful lives. During the three and nine months ended September 30, 2016, we recognized approximately $15.7 million and $31.5 million, respectively, of this additional depreciation, which was recorded as cost of sales in our condensed consolidated statements of income.

Table of Contents

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

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

The change in fair value remeasurement of contingent consideration for the three months ended September 30, 2016, compared to the same period in 2015, was primarily due to changes in the discount rate.

The change in fair value remeasurement of contingent consideration for the nine months ended September 30, 2016, compared to the same period in 2015, was primarily due to changes in the probabilities of success related to the achievement of certain developmental milestones and changes in the discount rate.

Collaboration Profit (Loss) Sharing

Collaboration profit (loss) sharing includes our 50% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis and our 50% share of the co-promotion profits or losses in the E.U. and Canada related to our collaboration agreement with AbbVie. 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, 2016, we recognized a net expense of $7.4 million and $1.8 million, respectively, related to our biosimilars commercial agreement with Samsung.

For the three and nine months ended September 30, 2016, we also recognized income of $2.7 million to reflect AbbVie's 50% share of net collaboration losses in the E.U. and Canada.

For additional information related to these arrangements, please read Note 17, Collaborative and Other Relationships to our condensed consolidated financial statements included in this report.

Table of Contents

Other Income (Expense), Net

For the three months ended September 30, 2016 compared to the same period in 2015, the change in other income (expense), net was primarily due to an increase in interest expense as a result of our issuance of our senior unsecured notes in the third quarter of 2015, partially offset by an increase in interest income due to higher cash, cash equivalents and marketable securities balances.

For the nine months ended September 30, 2016, compared to the same period in 2015, the change in other income (expense), net was primarily due to an increase in interest expense as a result of our issuance of our senior unsecured notes in the third quarter of 2015, partially offset by an increase in interest income due to higher cash, cash equivalents and marketable securities balances as well as a decrease in foreign exchange losses recognized during the nine months ended September 30, 2016 compared to the prior year comparative period.

Income Tax Provision

Our effective tax rate fluctuates from year to year due to the global nature of our operations. The factors that most significantly impact our effective tax rate include 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 months ended September 30, 2016, compared to the same period in 2015, our effective tax rate was relatively consistent.

For the nine months ended September 30, 2016, compared to the same period in 2015, our effective tax rate increased primarily due to a net state tax benefit in 2015 resulting from the remeasurement of one of our uncertain tax positions and a higher relative percentage of our earnings being attributed to the U.S., a higher tax jurisdiction.

For more information on our uncertain tax positions and income tax rate reconciliation for the three and nine months ended September 30, 2016 and 2015, please read Note 14, Income Taxes to our condensed consolidated financial statements included in this report.

Table of Contents

Equity in Loss of Investee, Net of Tax

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

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

For additional information related to this transaction, please read Note 17, Collaborative and Other Relationships to our condensed consolidated financial statements included in this report.

Noncontrolling Interest

For the three and nine months ended September 30, 2015, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily related to a $60.0 million milestone payment made to Neurimmune SubOne AG. For additional information, please read Note 16, Investments in Variable Interest Entities to our condensed consolidated financial statements included in this report.

Table of Contents

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions, except percentages)	As of September 30, 2016	As of December 31, 2015	Change	%
Financial assets:				
Cash and cash equivalents	$ 2,084.8	$ 1,308.0	59.4	%
Marketable securities — current	2,231.2	2,120.5	5.2	%
Marketable securities — non-current	3,096.9	2,760.4	12.2	%
Total cash, cash equivalents and marketable securities	$ 7,412.9	$ 6,188.9	19.8	%
Borrowings:				
Current portion of notes payable and other financing arrangements	$ 4.9	$ 4.8	2.1	%
Notes payable and other financing arrangements	6,529.6	6,521.5	0.1	%
Total borrowings	$ 6,534.5	$ 6,526.3	0.1	%
Working capital:				
Current assets	$ 8,091.8	$ 6,700.3	20.8	%
Current liabilities	(2,499.7)	(2,577.7)	(3.0)	%
Total working capital	$ 5,592.1	$ 4,122.6	35.6	%

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

- $2.9 billion in net cash flows provided by operating activities;
- $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.

For the nine months ended September 30, 2015, certain significant cash flows were as follows:

- $5.9 billion in proceeds from the issuance of our senior unsecured notes;
- $2.7 billion in net cash flows provided by operating activities;
- $3.0 billion used for share repurchases;
- $1.0 billion in total payments for income taxes;
- $550.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $456.9 million used for purchases of property, plant and equipment;
- $198.8 million net cash paid for the acquisition of Convergence Pharmaceuticals (Convergence); and
- $124.0 million used for an upfront payment made to AGTC.

Table of Contents

Overview

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

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, 2016, approximately $4.5 billion was generated in foreign jurisdictions and is primarily intended for use in our foreign operations or in connection with business development transactions outside of the U.S. In managing our day-to-day liquidity in the U.S., we do not rely on the unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings.

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

Share Repurchase Programs

In July 2016, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. The 2016 Share Repurchase Program is in addition to the approximately 1.3 million shares remaining under our February 2011 Share Repurchase Program (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under

our share-based compensation plans. 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 under our 2016 Share Repurchase Program. During the nine months ended September 30, 2016 and 2015, we did not repurchase any shares of common stock under our 2011 Share Repurchase Program.

In May 2015, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2015 Share Repurchase Program), which was completed as of December 31, 2015. During the three and nine months ended September 30, 2015, we repurchased and retired 9.7 million shares of common stock at a cost of $2,998.2 million under our 2015 Share Repurchase Program.

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 increase in cash, cash equivalents and marketable securities at September 30, 2016 from December 31, 2015, is primarily due to net cash flows provided by operating activities, partially offset by contingent payments made to former shareholders of Fumapharm AG and holders of their rights, net purchases of property, plant and equipment and purchases of our common stock.

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.

Table of Contents

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

During the third quarter of 2015, we entered into a $1.0 billion, 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, 2016, 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, 2016 and December 31, 2015, please read Note 6, 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 increase in working capital at September 30, 2016 from December 31, 2015 reflects an increase in total current assets of $1,391.5 million as well as a decrease in current liabilities of $78.0 million. The increase in total current assets was primarily driven by cash, cash equivalents and marketable securities due to net cash flows provided by operating activities. The decrease in current liabilities was primarily due to a decrease in interest payable.

Cash Flows

The following table summarizes our cash flow activity:

	For the Nine Months Ended September 30,		
(In millions, except percentages)	2016	2015	% Change
Net cash flows provided by operating activities	$2,945.8	$2,675.7	10.1 %
Net cash flows used in investing activities	$(1,903.1)	$(2,746.1)	(30.7)%
Net cash flows (used in) provided by financing activities	$(266.6)	$2,984.8	(108.9)%

Operating Activities

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

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

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

For the nine months ended September 30, 2016, compared to the same period in 2015, the increase in net cash flows provided by operating activities is primarily driven by higher net income, partially offset by a decrease in changes in other tax assets and liabilities, net and accounts receivable.

Investing Activities

For the nine months ended September 30, 2016, compared to the same period in 2015, the decrease in net cash flows used in investing activities is primarily due to a decrease in net purchases of marketable securities and cash paid for the acquisition of Convergence in February 2015, partially offset by an increase in the contingent consideration related to the Fumapharm AG acquisition.

Financing Activities

For the nine months ended September 30, 2016, compared to the same period in 2015, the decrease in net cash flows provided by financing activities is primarily due to the issuance of our senior unsecured notes in the third quarter of 2015, partially offset by the decrease in purchases of our common stock.

60

Table of Contents

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.

On December 1, 2015, we purchased land in Solothurn, Switzerland where we are building a biologics manufacturing facility over the next several years. As of September 30, 2016, we had contractual commitments of approximately $100.0 million for the construction of this facility.

There have been no other material changes in our contractual obligations since December 31, 2015.

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, 2016, we have approximately $97.4 million of liabilities associated with uncertain tax positions.

Other Funding Commitments

As of September 30, 2016, we have several on-going clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $23.5 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2016. We have approximately $487.5 million in cancellable future commitments based on existing CRO contracts as of September 30, 2016.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of September 30, 2016, we could make potential future milestone payments to third parties of up to approximately $3.1 billion, including approximately $500.0 million in development milestones, approximately $800.0 million in regulatory milestones and approximately $1.8 billion in commercial milestones as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of September 30, 2016, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones.

We anticipate that we may pay approximately $55.0 million of milestone payments during the remainder of 2016, provided various development, regulatory or commercial milestones are achieved.

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 in December 2013. Following that acquisition, we began making these royalty payments to Perrigo.

Contingent Consideration related to Business Combinations

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

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

61

Table of Contents

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 twelve month period.

During the nine months ended September 30, 2016, we paid $900.0 million in contingent payments as we reached the $7.0 billion, $8.0 billion and $9.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2015, first quarter of 2016 and second quarter of 2016, respectively, and accrued $300.0 million upon reaching $10.0 billion in total cumulative sales of Fumapharm Products in the third quarter of 2016.

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 will be accounted for as an increase to goodwill as incurred, in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm. Any portion of the payment which is tax deductible will be recorded as a reduction to goodwill. Payments are due within 60 days following the end of the quarter in which the applicable cumulative sales level has been reached.

Other Off-Balance Sheet Arrangements

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

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 2015 Form 10-K. There have been no material changes to these critical accounting estimates since our 2015 Form 10-K.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market Risk

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

Foreign Currency Exchange Risk

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. We have operations or maintain distribution relationships in the U.S., Europe, Canada, 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 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 exchange rates.

In June 2016, the U.K. voted in a referendum to voluntarily depart from the E.U., known as Brexit. The macroeconomic impact on our results of operations from this vote remains unknown. To date, the foreign 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 15 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 8, 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 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.

63

Table of Contents

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, 2016 and December 31, 2015, 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 $170.0 million and $185.0 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, 2016 and December 31, 2015, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $49.0 million and $43.0 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, 2016 and December 31, 2015, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately $6.8 million, respectively.

Pricing Pressure

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

In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure favorable prices in a particular country may impair our ability to obtain acceptable prices in existing and potential new markets, 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.

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

Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale distributors, public hospitals and other government entities. We monitor the financial performance and creditworthiness of our 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.

Table of Contents

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, 2016 and December 31, 2015. 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, 2016. 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 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, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 18, 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 may be substantially dependent on sales from our principal products for many years. Further, if the proposed spin off of our hemophilia business is completed, our revenues will be further reliant and concentrated on sales of our MS products in an increasingly competitive market. Any of the following negative developments relating to any of our principal products may adversely affect our revenues and results of operations or could cause a decline in our stock price:

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

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

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

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

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

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

Table of Contents

- inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our MS products.

Similarly, the hemophilia treatment market is a highly competitive market, with current treatments marketed by companies that have substantially greater financial resources and marketing expertise. Our ability to successfully compete in the hemophilia market and gain share in this market may be adversely affected due to a number of reasons, including:

- difficulty in further penetrating this market if our therapies are not regarded by patients, healthcare providers or payers as offering significant benefits and value over current treatments;
- changes in technology, including the introduction by other companies of new technologies, such as gene therapies and bispecific antibody technology, that have the potential to transform the standard of care in hemophilia, or longer-lasting or more efficacious, safer, less expensive or more convenient treatments than our therapies; or
- our limited marketing experience within the hemophilia treatment market relative to certain of our competitors, which may impact our ability to develop relationships with the associated medical and scientific community.

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.

Our ability to set the price for our products can vary significantly from country to country and as a result so can the price of our products. Certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the 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 operation, could curtail or eliminate our ability to adequately fund research and development programs for the discovery and commercialization of new products, and could cause a decline in our stock price.

Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility and our results of operations may be adversely impacted.

Table of Contents

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

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

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

In 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 have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

We have opened clinical sites and are enrolling patients in a number of countries where our experience is more limited. In most cases, we use the services of third parties to carry out our clinical trial related activities and rely on such parties to accurately report their results. Our reliance on third parties for these activities may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for 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.

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.

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. In July 2016, we announced that our chief executive officer will be leaving our company after his successor is identified. It is possible that we may experience other personnel changes in connection with our business operations and the proposed spin off of our hemophilia business. Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition and results of operations. Further, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs.

Our success is dependent upon our ability to attract and retain qualified management and key personnel in a highly competitive environment. Qualified individuals are in high demand, and we may incur significant costs to attract them, particularly at the executive level. We may face difficulty in attracting and retaining key talent for a number of

reasons, such as management changes, the underperformance or discontinuation of one or more late stage programs or recruitment by competitors. We cannot assure 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.

Table of Contents

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 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 several raw materials and manufacturing supplies. These third parties are independent entities subject to their own unique operational and financial risks that are outside of our control. These third parties may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations, and they may be unable or unwilling to increase production capacity commensurate with demand for our existing or future products. Finding alternative providers could take a significant amount of time and involve significant expense due to the specialized nature of the services and the need to obtain regulatory approval of any significant changes to our suppliers or manufacturing methods. We cannot be certain that we could reach agreement with alternative providers or that the FDA or other regulatory authorities would approve our use of such alternatives.
- Global Bulk Supply Risks. We rely on our principal manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- Risks Relating to Compliance with cGMP. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

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

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

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

- we may be unable to control the resources our collaborator or third party devotes 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 collaborator or other third party, and the underlying contract with our collaborator or other third party may fail to provide significant protection or may fail to be effectively enforced if the collaborator or third party fails to perform;

71

Table of Contents

- the interests of our collaborator or third party may not always be aligned with our interests and such party 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 collaborator or other third party to comply with applicable laws and regulatory requirements in the marketing, sale and maintenance of the market authorization of our products or to fulfill any responsibilities our collaborator may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings.

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 future 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 requires 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.

The proposed spin off of our hemophilia business is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time and expense, which could harm our business, results of operations and financial condition.

In May 2016, we announced plans to separate our hemophilia business as an independent, publicly-traded company. The transaction is expected to be completed in early 2017, subject to satisfaction of certain conditions. Unanticipated developments could delay, prevent or otherwise adversely affect this proposed spin off, including but not limited to disruptions in general market conditions or potential problems, delays or difficulties in satisfying conditions and obtaining approvals and clearances or litigation or other legal proceedings that may arise as a result of the proposed spin off. In addition, consummation of the spin off will require final approval from our Board of Directors. Therefore, we cannot assure that we will be able to complete the spin off on the terms or on the timeline that we announced, if at all.

We will incur significant expenses in connection with the spin off, and such costs and expenses may be greater than we anticipate. In addition, completion of the spin off will require a significant amount of management time and effort which may disrupt our business or otherwise divert management’s attention from other aspects of our business operations. Any such difficulties could adversely affect our business, results of operations and financial condition.

Table of Contents

The proposed spin off may not achieve some or all of the anticipated benefits.

If the spin off is completed, there is uncertainty as to whether the anticipated operational, financial and strategic benefits of the spin off will be achieved. There can be no assurance that the combined value of the common stock of the two publicly-traded companies will be equal to or greater than what the value of our common stock would have been had the proposed separation not occurred. The combined value of the common stock of the two companies could be lower than anticipated for a variety of reasons, including, but not limited to, the inability of Bioverativ, as a new spin off company to operate and compete effectively as an independent company, and the stock price of the common stock of each of the two companies could experience periods of volatility. If we fail to achieve the anticipated benefits of the spin off, our stock price could decline.

If the spin off does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

We intend to obtain an opinion of outside counsel regarding the qualification of the distribution in the spin off, together with certain related transactions, as a transaction that is generally tax-free for U.S. federal income tax purposes. The opinion will be based on and rely on, among other things, certain facts and assumptions, as well as certain representations, statements and undertakings of Biogen and the new spin off company, including those relating to the past and future conduct of Biogen and the new spin off company. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete, or if we or the new spin off company breach any of their respective covenants in the separation documents, the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized. It is also possible that the U.S. Internal Revenue Service, or the IRS, could determine that the distribution in the spin off, together with certain related transactions, is taxable for U.S. federal income tax purposes if it determines that any of these facts, assumptions, representations, statements or undertakings are incorrect or have been violated or if it disagrees with the conclusions in the opinion of counsel. An opinion of counsel is not binding on the IRS or any court and there can be no assurance that the IRS will not challenge the conclusions reached in the opinion. If the distribution in the spin off, together with certain related transactions, is ultimately determined to be taxable, we and our stockholders that are subject to U.S. federal income tax could incur significant tax liabilities.

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 and “hacktivists.” Cyber-attacks could include the deployment of harmful malware and key loggers, 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

Table of Contents

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

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

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.

Table of Contents

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

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

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- collectability of accounts receivable;
- fluctuations in foreign currency exchange rates, in particular the recent strength of the U.S. dollar versus foreign currencies which has adversely impacted our revenues and net income;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability; and
- changes in tax laws and tariffs.

In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. Failure to comply with domestic or foreign laws could result in various adverse consequences, including: possible delay in approval or refusal to approve a product; recalls, seizures or withdrawal of an approved product from the market; disruption in the supply or availability of our products or suspension of export or import privileges; the imposition of civil or criminal sanctions; the prosecution of executives overseeing our international operations; and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

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

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

In addition, our inability to secure or sustain acceptable arrangements with tax authorities and future changes in the tax laws, among other things, may result in tax obligations in excess of amounts accrued in our financial statements. 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.

Table of Contents

In addition to U.S. tax reform proposals, the adoption of some or all of the recommendations set forth in the Organization for Economic Co-operation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities in the countries in which we operate, could negatively impact our effective tax rate. These recommendations focus on payments from affiliates in high tax jurisdictions to affiliates in lower tax jurisdictions and the activities that give rise to a taxable presence in a particular country.

Our operating results are subject to significant fluctuations.

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

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

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

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

We are pursuing opportunities to expand our large scale 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 and acquired an additional manufacturing facility in Research Triangle Park, North Carolina. Due to the long lead times necessary for the expansion of manufacturing capacity, we expect to incur significant investment to build or expand our facilities or obtain third-party contract manufacturers with no assurance that such investment will be recouped. If we are unable to adequately and timely manufacture and supply our products and product candidates or if we do not fully utilize our manufacturing facilities, our business may be harmed.

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

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

- Reliance on Third Parties. We are dependent on the efforts of Samsung Bioepis and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If Samsung Bioepis or such other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;

Table of Contents

- Regulatory Compliance. Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- Intellectual Property and Regulatory Challenges. Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years;
- Failure to Gain Market and Patient Acceptance. Market success of biosimilar products will be adversely affected if patients, physicians and payers do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies; and
- Competitive Challenges. Biosimilar products face significant competition, including from innovator products and from biosimilar products offered by other companies. In some jurisdictions, local tendering processes may restrict biosimilar products from being marketed and sold in those jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective matter are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area.

Our investments in properties may not be fully realized.

We own or lease real estate primarily consisting of buildings that contain research laboratories, office space and manufacturing operations. For strategic or other operational reasons, we may decide to further consolidate or co-locate certain aspects of our business operations or dispose of one or more of our properties, some of which may be located in markets that are experiencing high vacancy rates and decreasing property values. If we determine that the fair value of any of our owned properties is lower than their book value we may not realize the full investment in these properties and incur significant impairment charges or additional depreciation when the expected useful life of certain assets have been shortened due to the anticipated closing of facilities. If we decide to fully or partially vacate a leased property, such as we expect to do in connection with our intent to cease manufacturing at our facility in Cambridge, Massachusetts by the end of 2016, we may incur significant cost, including facility closing costs, employee separation and retention expenses, lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements and accelerated depreciation of assets. Any of these events may have an adverse impact on our results of operations.

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

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

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

From time to time our Board of Directors authorizes stock repurchase programs, including most recently a $5.0 billion stock repurchase program in July 2016. The amount and timing of stock repurchases are subject to capital availability and our determination that stock repurchases are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the repurchase of stock. Our ability to repurchase stock will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, results of operations, financial condition, and other factors beyond our control that we may deem relevant. A reduction in, or the completion or expiration of, our stock repurchase programs could have a negative effect on our stock price. We can provide no assurance that we will repurchase stock at favorable prices, if at all.

Table of Contents

We may not be able to access the capital and credit markets on terms that are favorable to us.

We may seek access to the capital markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets have experienced extreme volatility and disruption which leads to uncertainty and liquidity issues for both borrowers and investors. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on favorable terms. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our cost of financing and the market price of our securities.

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

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

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

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

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

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

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

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

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

Table of Contents

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 2016:

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 2016	—	—	—	$ 5,000
August 2016	200,859	313.36	200,859	$ 4,937
September 2016	932,299	306.68	932,299	$ 4,651
Total	1,133,158	307.86		

In July 2016, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. The 2016 Share Repurchase Program is in addition to the approximately 1.3 million shares remaining under our February 2011 Share Repurchase Program (2011 Share Repurchase Program), which has been used principally to offset common stock issuances under our share-based compensation plans. 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 under our 2016 Share Repurchase Program. During the nine months ended September 30, 2016 and 2015, we did not repurchase any shares of common stock under our 2011 Share Repurchase Program.

In May 2015, our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2015 Share Repurchase Program), which was completed as of December 31, 2015. During the nine months ended September 30, 2015, we repurchased and retired 9.7 million shares of common stock at a cost of $2,998.2 million under our 2015 Share Repurchase Program.

Item 6. Exhibits

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

Table of Contents

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/ Paul J. Clancy
Paul J. Clancy
Executive Vice President and
Chief Financial Officer
(principal financial officer)
October 26, 2016

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
31.1+	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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

81