

BIOGEN INC.
Form 10-Q
October 21, 2015

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

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

For the quarterly period ended September 30, 2015
OR

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

Commission File Number 0-19311

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

225 Binney Street, Cambridge, MA 02142

(617) 679-2000

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

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

90 days: Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(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 ☐ No ☒

The number of shares of the issuer's Common Stock, \$0.0005 par value, outstanding as of October 16, 2015, was 222,903,109 shares.

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 For the Quarterly Period Ended September 30, 2015
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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the “Act”) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the Act. These forward-looking statements may be accompanied by such words as “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 expenses, amortization of intangible assets, foreign currency exchange risk, estimated fair value of assets and liabilities, and impairment assessments;
- expectations and plans relating to sales, pricing, growth, launch and prospects of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete;
- 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;
- the costs and timing of potential trials, filing and approvals, and the potential therapeutic scope of the development and commercialization of our and our collaborators’ pipeline products;
- our intent to commit resources for research and development opportunities, and expectations relating to selling, general and administrative expense;
- the drivers for growing our business, including our plans relating to business development opportunities and research and development programs;
- the anticipated benefits, cost savings, and charges related to our corporate restructuring initiatives;
- the expected timing of completion of our 2015 share repurchase program;
- the expected timing of the closing our proposed collaboration with Mitsubishi Tanabe Pharma Corporation; our manufacturing capacity, use of third party contract manufacturing and our plans and timing relating to the expansion of our manufacturing capabilities, including anticipated investments and activities in Solothurn, Switzerland and Research Triangle Park, North Carolina;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact of healthcare reform in the U.S., implementation of provisions of the Patient Protection and Affordable Care Act (also known as the Affordable Care Act or PPACA), and measures being taken worldwide designed to reduce healthcare costs to constrain the overall level of government expenditures, including the impact of pricing actions in Europe and elsewhere, and reduced reimbursement for our products;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- expectations relating to the timing and execution of our stock repurchase programs;
- 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. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Throughout this report, “Biogen,” the “Company,” “we,” “us” and “our” refer to Biogen Inc. (formerly Biogen Idec 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), and “ANGIOMAX” refers to both ANGIOMAX (the trade name for bivalirudin in the U.S., Canada and Latin America) and ANGIOX (the trade name for bivalirudin in Europe).

NOTE REGARDING TRADEMARKS

ALPROLIX[®], AVONEX[®], ELOCTATE[®], PLEGRIDY[®], RITUXAN[®], TECFIDERA[®] and TYSABRI[®] are registered trademarks of Biogen. BENEPALI[™], ELOCTA[™], FLIXABI[™], FUMADERM[™] and ZINBRYTA[™] are trademarks of Biogen. The following are trademarks of the respective companies listed: ANGIOMAX[®] and ANGIOX[®] — The Medicines Company; BETASERON[®] — Bayer Pharma AG; BRENZYS[®] — Merck Sharp & Dohme Corp.; EXTAVIA[®] — Novartis AG; FAMPYRA[™] — Acorda Therapeutics, Inc.; GAZYVA[®] — Genentech, Inc.; and REBIF[®] — Ares Trading S.A.

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PART I FINANCIAL INFORMATION

BIOGEN INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited, in thousands, except per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product, net	\$2,391,717	\$2,117,366	\$6,762,605	\$5,916,423
Unconsolidated joint business	337,181	290,678	1,005,302	890,859
Other	48,961	103,402	156,557	255,367
Total revenues	2,777,859	2,511,446	7,924,464	7,062,649
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	310,028	302,639	908,579	873,771
Research and development	519,863	417,174	1,471,140	1,393,331
Selling, general and administrative	477,827	570,436	1,530,083	1,658,732
Amortization of acquired intangible assets	98,065	122,431	285,972	382,515
(Gain) loss on fair value remeasurement of contingent consideration	244	(49,433)	) 5,887	(46,213)
Total cost and expenses	1,406,027	1,363,247	4,201,661	4,262,136
Gain on sale of rights	—	4,379	—	12,138
Income from operations	1,371,832	1,152,578	3,722,803	2,812,651
Other income (expense), net	(15,413)	) (16,290)	) (41,288)	) (17,030)
Income before income tax expense and equity in loss of investee, net of tax	1,356,419	1,136,288	3,681,515	2,795,621
Income tax expense	330,093	274,774	904,475	721,709
Equity in loss of investee, net of tax	6,833	5,394	12,548	14,932
Net income	1,019,493	856,120	2,764,492	2,058,980
Net income (loss) attributable to noncontrolling interests, net of tax	53,871	(738)	) 49,053	7,660
Net income attributable to Biogen Inc.	\$965,622	\$856,858	\$2,715,439	\$2,051,320
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$4.16	\$3.63	\$11.60	\$8.67
Diluted earnings per share attributable to Biogen Inc.	\$4.15	\$3.62	\$11.57	\$8.64
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	232,191	236,217	234,134	236,641
Diluted earnings per share attributable to Biogen Inc.	232,612	236,972	234,659	237,449

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(unaudited, in thousands)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income attributable to Biogen Inc.	\$965,622	\$856,858	\$2,715,439	\$2,051,320
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax of \$(1,320) and \$(6) for the three months ended September 30, 2015 and 2014, respectively; and \$(699) and \$(3,021) for the nine months ended September 30, 2015 and 2014, respectively	(2,239	) 12	(1,154	) (5,127
Unrealized gains (losses) on cash flow hedges, net of tax of \$(187) and \$302 for the three months ended September 30, 2015 and 2014, respectively; and \$(229) and \$307 for the nine months ended September 30, 2015 and 2014, respectively	(31,171	) 48,242	(40,084	) 64,793
Unrealized gains (losses) on pension benefit obligation	523	691	4,632	1,338
Currency translation adjustment	(23,504	) (60,254	) (61,322	) (71,246
Total other comprehensive income (loss), net of tax	(56,391	) (11,309	) (97,928	) (10,242
Comprehensive income attributable to Biogen Inc.	909,231	845,549	2,617,511	2,041,078
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	53,586	(738	) 49,053	7,660
Comprehensive income	\$962,817	\$844,811	\$2,666,564	\$2,048,738

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	As of September 30, 2015	As of December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$4,089,003	\$1,204,924
Marketable securities	1,753,499	640,460
Accounts receivable, net	1,327,780	1,292,445
Due from unconsolidated joint business, net	319,788	283,360
Inventory	918,921	804,022
Other current assets	861,882	446,943
Total current assets	9,270,873	4,672,154
Marketable securities	1,947,354	1,470,652
Property, plant and equipment, net	2,027,821	1,765,683
Intangible assets, net	4,181,245	4,028,507
Goodwill	2,408,854	1,760,249
Investments and other assets	892,221	617,536
Total assets	\$20,728,368	\$14,314,781
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable and other financing arrangements	\$5,171	\$3,136
Taxes payable	458,672	168,058
Accounts payable	251,228	229,178
Accrued expenses and other	1,918,897	1,819,334
Total current liabilities	2,633,968	2,219,706
Notes payable and other financing arrangements	6,529,275	580,283
Long-term deferred tax liability	136,761	50,656
Other long-term liabilities	861,421	650,096
Total liabilities	10,161,425	3,500,741
Commitments and contingencies		
Equity:		
Biogen Inc. shareholders' equity		
Preferred stock, par value \$0.001 per share	—	—
Common stock, par value \$0.0005 per share	124	129
Additional paid-in capital	1,342,373	4,196,156
Accumulated other comprehensive loss	(157,416)	(59,488)
Retained earnings	11,999,358	9,283,919
Treasury stock, at cost	(2,611,713)	(2,611,706)
Total Biogen Inc. shareholders' equity	10,572,726	10,809,010
Noncontrolling interests	(5,783)	5,030
Total equity	10,566,943	10,814,040
Total liabilities and equity	\$20,728,368	\$14,314,781

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	For the Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net income	\$2,764,492	\$2,058,980
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	444,100	530,508
Share-based compensation	131,537	119,508
Deferred income taxes	(185,802)	(229,273)
Other	31,564	(95,711)
Changes in operating assets and liabilities, net:		
Accounts receivable	(63,608)	(297,057)
Inventory	(150,387)	(119,890)
Accrued expenses and other current liabilities	(174,532)	19,283
Other changes in operating assets and liabilities, net	(121,659)	22,904
Net cash flows provided by operating activities	2,675,705	2,009,252
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	3,363,374	1,942,871
Purchases of marketable securities	(4,870,142)	(2,738,584)
Acquisitions of business, net of cash acquired	(198,798)	—
Purchases of property, plant and equipment	(456,885)	(180,854)
Contingent consideration related to Fumapharm AG acquisition	(550,000)	(175,000)
Other	(33,620)	(13,131)
Net cash flows used in investing activities	(2,746,071)	(1,164,698)
Cash flows from financing activities:		
Purchase of treasury stock	(2,998,190)	(359,981)
Proceeds from issuance of stock for share-based compensation arrangements	45,509	44,960
Proceeds from borrowings	5,930,936	—
Repayment of borrowings	(2,083)	(2,674)
Excess tax benefit from stock options	70,778	90,423
Other	(62,147)	(15,336)
Net cash flows provided by (used in) financing activities	2,984,803	(242,608)
Net increase in cash and cash equivalents	2,914,437	601,946
Effect of exchange rate changes on cash and cash equivalents	(30,358)	(18,227)
Cash and cash equivalents, beginning of the period	1,204,924	602,562
Cash and cash equivalents, end of the period	\$4,089,003	\$1,186,281

See accompanying notes to these unaudited condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Summary of Significant Accounting Policies

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing, manufacturing and delivering therapies for neurological, autoimmune and hematologic disorders. Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, and FAMPYRA for the treatment of multiple sclerosis (MS), ALPROLIX for the treatment of hemophilia B, ELOCTATE for the treatment of hemophilia A and FUMADERM for the treatment of severe plaque psoriasis. We also generate revenue from our collaboration with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, and share profits and losses with Genentech for GAZYVA, which is approved for the treatment of CLL.

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, 2014 (2014 Form 10-K). Our accounting policies are described in the "Notes to Consolidated Financial Statements" in our 2014 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, 2015, are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

Consolidation

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

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

We operate as one operating segment, which is focused on discovering, developing, manufacturing and delivering therapies for neurological, autoimmune and hematologic disorders.

Use of Estimates

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

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Accounts Receivable

Our accounts receivable primarily arise from product sales in the U.S. and Europe and mainly represent amounts due from our wholesale distributors, public hospitals and other government entities. Concentrations of credit risk with respect to our accounts receivable, which are typically unsecured, are limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. The majority of our accounts receivable require payment within 30 to 90 days. We monitor the financial performance and credit worthiness of our customers so that we can properly assess and respond to changes in their credit profile. We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. To date, our historical reserves and write-offs of accounts receivable have not been significant.

In countries where we have experienced a pattern of payments extending beyond our contractual payment term and we expect to collect receivables greater than one year after the time of sale, we discount our receivables and reduce related revenues over the period of time that we estimate those amounts will be paid using the country's market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets. We accrete interest income on these receivables, which is recognized as a component of other income (expense), net in our condensed consolidated statement of income. To date, our historical discounts of receivables have not been significant.

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 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. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-11, Transfers and Servicing (Topic 860): Repurchase-to-Maturity Transactions, Repurchase Financings, and Disclosure. The new standard expanded secured borrowing accounting to include repurchase-to-maturity transactions and repurchase financings and set forth new disclosure requirements for repurchase agreements, securities lending transactions, and repurchase-to-maturity transactions that are accounted for as secured borrowings. We adopted this standard on April 1, 2015 and expanded our disclosures presented in Note 7, Financial Instruments to these condensed consolidated financial statements. The adoption of this standard did not have an impact on our financial position or results of operations.

In April 2015, the FASB issued ASU No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, Interest - Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements, which clarified that debt issuance costs related to line-of-credit arrangements can be presented in the balance sheet as an asset and amortized over the term of the line-of-credit arrangement. We adopted these standards as of September 30, 2015 with retroactive application. The adoption of these standards did not have a significant impact on our financial position or results of operations. For additional information, please read Note 6, Fair Value

Measurements to these condensed consolidated financial statements.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

In April 2015, the FASB issued 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. Under this standard, if a cloud computing arrangement includes a software license, the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. The new standard will be effective for us on January 1, 2016. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In May 2015, the FASB issued ASU No. 2015-07, Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent). The new standard removes the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share practical expedient. The new standard will be effective for us on January 1, 2016. Early application is permitted. We maintain investments in certain venture capital funds which primarily invest in small, privately-owned, venture-backed biotechnology companies. The value of our investments in these venture capital funds is estimated using the net asset value of the fund and has been included in the fair value hierarchy disclosure as a Level 3 measurement. These venture capital investments are not material to our financial position or results of operations. We adopted this standard as of June 30, 2015 and our investments in venture capital funds are no longer included in our disclosures reflected in Note 6, Fair Value Measurements to these condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. 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 September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and sets forth new disclosure requirements related to the adjustments. The new standard will be effective for us on January 1, 2016. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

2. Acquisitions

Convergence Pharmaceuticals

On February 12, 2015, we completed our acquisition of all of the outstanding stock of Convergence Pharmaceuticals (Convergence), a clinical-stage biopharmaceutical company with a focus on developing product candidates for neuropathic pain. Convergence's lead candidate is its Phase 2 clinical candidate Raxatrigine (CNV1014802), which has demonstrated clinical activity in proof-of-concept studies for trigeminal neuralgia (TGN), a chronic orphan disease. Additionally, Raxatrigine has potential applicability in several other neuropathic pain states.

The purchase price consisted of a \$200.1 million cash payment at closing, plus contingent consideration in the form of development and approval milestones up to a maximum of \$450.0 million, of which \$350.0 million is associated with the development and approval of Raxatrigine for the treatment of TGN. The acquisition was funded from our existing cash on hand and has been accounted for as the acquisition of a business. In addition to obtaining the rights to Raxatrigine and additional product candidates in preclinical development, we retained the services of key employees of Convergence.

In connection with our acquisition of Convergence, we recorded a liability of \$274.5 million representing the fair value of the contingent consideration. This amount was estimated through a valuation model that incorporates

industry-based probability adjusted assumptions relating to the achievement of these milestones and thus the likelihood of making the contingent payments. This fair value measurement is based upon significant inputs not observable in the market and therefore represents a Level 3 measurement.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

The purchase price, as adjusted, consisted of the following:

(In millions)

Cash portion of consideration	\$200.1
Contingent consideration	274.5
Total purchase price	\$474.6

Subsequent changes in the fair value of the contingent consideration obligation will be recognized as adjustments to contingent consideration and reflected in our condensed consolidated statements of income. For additional information related to the fair value of this obligation, please read Note 6, Fair Value Measurements to these condensed consolidated financial statements.

During the second quarter of 2015, we adjusted our preliminary estimate of the fair value of the assets acquired and contingent consideration as of the date of acquisition to reflect revised estimates to our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. The primary effects of these revised estimates resulted in an increase in the value of our estimated contingent consideration and goodwill by \$36.0 million, respectively. Our revised purchase price allocation is reflected in the chart below. Our purchase price allocation is substantially complete.

The following table summarizes the estimated fair values of the separately identifiable assets acquired and liabilities assumed as of February 12, 2015, as adjusted:

(In millions)

In-process research and development	\$424.6	
Other intangible assets	7.6	
Goodwill	128.3	
Deferred tax liability	(84.9	)
Other, net	(1.0	)
Total purchase price	\$474.6	

Our estimate of the fair value of the in-process research and development (IPR&D) programs acquired was determined through a probability adjusted discounted cash flow analysis utilizing a discount rate of 11%. This valuation was primarily driven by the value associated with the lead candidate, Raxatrigine, which is in development for the treatment of TGN and is expected to be completed no earlier than 2020, at a remaining cost of approximately \$145.0 million. The fair value associated with Raxatrigine for the treatment of TGN was \$200.0 million. We have recorded additional IPR&D assets related to the use of Raxatrigine in two additional neuropathic pain indications, with a total estimated value of \$220.0 million. The remaining cost of development for these two indications is approximately \$415.0 million, with an expected completion date of no earlier than 2021. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

We have attributed the goodwill recognized to the Convergence workforce's expertise in chronic pain research and clinical development and to establishing a deferred tax liability for the acquired IPR&D intangible assets which have no tax basis. The goodwill is not tax deductible.

Pro forma results of operations would not be materially different as a result of the acquisition of Convergence and therefore are not presented. Subsequent to the acquisition date, our results of operations include the results of operations of Convergence.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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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, 2014	\$47.6	\$387.1	\$49.1	\$483.8
Current provisions relating to sales in current year	332.0	1,278.0	26.4	1,636.4
Adjustments relating to prior years	(1.3)	(20.9)	(14.8)	(37.0)
Payments/credits relating to sales in current year	(277.9)	(871.8)	(1.6)	(1,151.3)
Payments/credits relating to sales in prior years	(40.7)	(271.6)	(8.9)	(321.2)
Balance, as of September 30, 2015	\$59.7	\$500.8	\$50.2	\$610.7

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

(In millions)	As of September 30, 2015	As of December 31, 2014
Reduction of accounts receivable	\$148.0	\$124.6
Component of accrued expenses and other	462.7	359.2
Total reserves	\$610.7	\$483.8

4. Inventory

The components of inventory are summarized as follows:

(In millions)	As of September 30, 2015	As of December 31, 2014
Raw materials	\$221.5	\$128.3
Work in process	537.7	511.5
Finished goods	159.7	164.2
Total inventory	\$918.9	\$804.0

As of September 30, 2015, our inventory included \$54.3 million associated with our ZINBRYTA, FLIXABI and BENEPALI programs, which have been capitalized in advance of regulatory approval. As of December 31, 2014, our inventory included \$6.3 million associated with our ZINBRYTA program, which had been capitalized in advance of regulatory approval.

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5. Intangible Assets and Goodwill

Intangible Assets

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

(In millions)	Estimated Life	As of September 30, 2015			As of December 31, 2014		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	\$543.3	\$ (499.9)	\$43.4	\$543.3	\$ (481.7)	\$61.6
Developed technology	15-23 years	3,005.3	(2,523.8)	481.5	3,005.3	(2,396.8)	608.5
In-process research and development	Indefinite until commercialization	735.6	—	735.6	314.1	—	314.1
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	3-17 years	3,297.6	(440.9)	2,856.7	3,280.4	(300.1)	2,980.3
Total intangible assets		\$7,645.8	\$ (3,464.6)	\$4,181.2	\$7,207.1	\$ (3,178.6)	\$4,028.5

For the three and nine months ended September 30, 2015, amortization of acquired intangible assets totaled \$98.1 million and \$286.0 million, respectively, as compared to \$122.4 million and \$382.5 million, respectively, in the prior year comparative periods.

For the three months ended September 30, 2015, compared to the same period in 2014, the decrease in amortization of acquired intangible assets was primarily driven by higher expected lifetime revenues of AVONEX, partially offset by lower expected lifetime revenues of TYSABRI. Amortization of acquired intangible assets during the three months ended September 30, 2014 included a \$16.2 million impairment loss related to one of our IPR&D intangible assets. For the nine months ended September 30, 2015, compared to the same period in 2014, the decrease in amortization of acquired intangible assets was primarily driven by a decrease in AVONEX revenues during the comparative periods. Amortization of acquired intangible assets during the nine months ended September 30, 2014 included total impairment charges of \$50.9 million related to one of our out-licensed patents and one of our IPR&D intangible assets.

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, 2015 was \$472.9 million.

IPR&D

IPR&D represents the fair value assigned to research and development assets that we acquire that have not reached technological feasibility at the date of acquisition. Upon commercialization, we will determine the estimated useful life. In connection with our acquisition of Convergence in February 2015, we acquired IPR&D programs with an estimated fair value of \$424.6 million. This amount will be adjusted for foreign exchange rate fluctuations. For a more detailed description of this transaction, please read Note 2, Acquisitions to these condensed consolidated financial statements.

Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of the TYSABRI rights from Elan Corporation plc (Elan). Elan was acquired by Perrigo Company plc (Perrigo) in December 2013. The net book value of this asset as of September 30, 2015 was \$2,797.5 million.

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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 updated in the third quarter of 2015. Based upon this analysis, there was not a significant change in our expected rate of amortization for acquired intangible assets and the estimated future amortization is expected to be as follows:

(In millions)	As of September 30, 2015
2015 (remaining three months)	\$94.3
2016	348.8
2017	318.6
2018	291.0
2019	275.1
2020	269.1
Total	\$1,596.9

Goodwill

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

(In millions)	
Balance, as of December 31, 2014	\$1,760.2
Increase to goodwill	649.4
Other	(0.7)
Balance, as of September 30, 2015	\$2,408.9

The increase in goodwill during the nine months ended September 30, 2015 was related to \$600.0 million in contingent payments achieved (exclusive of a \$78.9 million tax benefit) to former shareholders of Fumapharm AG or holders of their rights and our acquisition of Convergence. Other includes changes related to foreign exchange rate fluctuations. For additional information related to future contingent payments to the former shareholders of Fumapharm AG or holders of their rights, please read Note 20, Commitments and Contingencies to these condensed consolidated financial statements. For additional information related to our acquisition of Convergence, please read Note 2, Acquisitions to these condensed consolidated financial statements.

As of September 30, 2015, we had no accumulated impairment losses related to goodwill.

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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, 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	\$3,804.2	\$—	\$ 3,804.2	\$—
Marketable debt securities:				
Corporate debt securities	1,039.9	—	1,039.9	—
Government securities	2,411.1	—	2,411.1	—
Mortgage and other asset backed securities	249.9	—	249.9	—
Marketable equity securities	25.7	25.7	—	—
Derivative contracts	61.4	—	61.4	—
Plan assets for deferred compensation	38.6	—	38.6	—
Total	\$7,630.8	\$25.7	\$ 7,605.1	\$—
Liabilities:				
Derivative contracts	\$31.3	\$—	\$ 31.3	\$—
Contingent consideration obligations	481.4	—	—	481.4
Total	\$512.7	\$—	\$ 31.3	\$481.4
As of December 31, 2014 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$716.3	\$—	\$ 716.3	\$—
Marketable debt securities:				
Corporate debt securities	1,063.0	—	1,063.0	—
Government securities	849.8	—	849.8	—
Mortgage and other asset backed securities	198.3	—	198.3	—
Marketable equity securities	6.9	6.9	—	—
Derivative contracts	72.7	—	72.7	—
Plan assets for deferred compensation	36.9	—	36.9	—
Total	\$2,943.9	\$6.9	\$ 2,937.0	\$—
Liabilities:				
Derivative contracts	\$5.4	\$—	\$ 5.4	\$—
Contingent consideration obligations	215.5	—	—	215.5
Total	\$220.9	\$—	\$ 5.4	\$215.5

There have been no material impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2015. 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, 2015. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities was 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 2014 Form 10-K. For additional information

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related to our decision to no longer reflect our investments in venture capital funds within the fair value hierarchy, refer to Note 1, Summary of Significant Accounting Policies: New Accounting Pronouncements, to these condensed consolidated financial statements.

Debt Instruments

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

(In millions)	As of September 30, 2015		As of December 31, 2014	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Notes payable to Fumedica	\$9.5	\$9.1	\$12.6	\$11.7
6.875% Senior Notes due March 1, 2018	614.0	566.9	634.6	571.7
2.900% Senior Notes due September 15, 2020	1,514.1	1,492.3	—	—
3.625% Senior Notes due September 15, 2022	1,008.4	991.9	—	—
4.050% Senior Notes due September 15, 2025	1,767.1	1,733.1	—	—
5.200% Senior Notes due September 15, 2045	1,766.9	1,721.0	—	—
Total	\$6,680.0	\$6,514.3	\$647.2	\$583.4

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. In accordance with ASU No. 2015-03, during the three months ended September 30, 2015, we reclassified \$1.8 million of our debt issuance costs related to our 6.875% Senior Notes issued in 2008 from an asset to a reduction to the carrying amount of the 6.875% Senior Notes. For additional information related to our notes payable to Fumedica and our 6.875% Senior Notes, please read Note 12, Indebtedness to our consolidated financial statements included in our 2014 Form 10-K. For additional information related to our Senior Notes issued on September 15, 2015, please read Note 10, Indebtedness, to these condensed consolidated financial statements.

Contingent Consideration Obligations

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Fair value, beginning of period	\$495.7	\$279.1	\$215.5	\$280.9
Additions	—	—	274.5	—
Changes in fair value	0.2	(49.4)	5.9	(46.2)
Payments	(14.5)	(16.5)	(14.5)	(21.5)
Fair value, end of period	\$481.4	\$213.2	\$481.4	\$213.2

As of September 30, 2015 and December 31, 2014, approximately \$301.9 million and \$200.0 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.

In connection with our acquisition of Convergence, we recorded a liability of \$274.5 million, representing the fair value of the contingent consideration. This valuation was based on probability weighted net cash outflow projections of \$450.0 million, discounted using a rate of 2%, which is the estimated cost of debt financing for market participants. This liability reflects the revised estimate from the date of acquisition for our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. For a more detailed description of this transaction, please read Note 2, Acquisitions to these condensed consolidated financial statements. As of September 30, 2015, approximately \$176.4 million, related to our contingent consideration obligations arising from

our acquisition of Convergence, is reflected as a component of accrued expenses and other in our condensed consolidated balance sheets.

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Acquired IPR&D

In connection with our acquisition of Convergence, we also allocated \$424.6 million of the total purchase price to acquired IPR&D, which was capitalized as an intangible asset. The amount allocated to acquired IPR&D was based on significant inputs not observable in the market and thus represented a Level 3 fair value measurement. This estimate was also adjusted from our preliminary estimate as of the date of acquisition to reflect revised estimates to our initial clinical development plans, resulting probabilities of success and the timing of certain milestone payments. These assets will be tested for impairment annually until commercialization, after which time the IPR&D will be amortized over its estimated useful life. For a more detailed description of this transaction, please read Note 2, Acquisitions to these condensed consolidated financial statements.

7. Financial Instruments

Marketable Securities

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

As of September 30, 2015 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	\$272.1	\$—	\$(0.1)	) \$272.2
Non-current	767.8	0.7	(1.3)	) 768.4
Government securities				
Current	1,481.4	0.6	—	1,480.8
Non-current	929.7	0.8	(0.3)	) 929.2
Mortgage and other asset backed securities				
Current	—	—	—	—
Non-current	249.9	0.2	(0.5)	) 250.2
Total marketable debt securities	\$3,700.9	\$2.3	\$(2.2)	) \$3,700.8
Marketable equity securities, non-current	\$25.7	\$0.9	\$(3.4)	) \$28.2
As of December 31, 2014 (In millions)	Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
Corporate debt securities				
Current	\$370.4	\$—	\$(0.2)	) \$370.6
Non-current	692.6	0.2	(1.5)	) 693.9
Government securities				
Current	269.9	—	(0.1)	) 270.0
Non-current	579.9	0.3	(0.4)	) 580.0
Mortgage and other asset backed securities				
Current	0.2	—	—	0.2
Non-current	198.1	0.2	(0.2)	) 198.1
Total marketable debt securities	\$2,111.1	\$0.7	\$(2.4)	) \$2,112.8
Marketable equity securities, non-current	\$6.9	\$1.2	\$(0.2)	) \$5.9

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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, 2015	As of December 31, 2014
Commercial paper	\$21.4	\$54.2
Overnight reverse repurchase agreements	188.3	305.0
Money market funds	3,119.1	321.2
Short-term debt securities	475.4	35.9
Total	\$3,804.2	\$716.3

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 securities and represent approximately 0.9% and 2.1% of total assets as of September 30, 2015 and December 31, 2014, respectively.

Summary of Contractual Maturities: Available-for-Sale Securities

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

(In millions)	As of September 30, 2015		As of December 31, 2014	
	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	\$1,753.5	\$1,753.0	\$640.5	\$640.8
Due after one year through five years	1,820.1	1,820.3	1,343.7	1,345.2
Due after five years	127.3	127.5	126.9	126.8
Total available-for-sale securities	\$3,700.9	\$3,700.8	\$2,111.1	\$2,112.8

The average maturity of our marketable debt securities available-for-sale as of September 30, 2015 and December 31, 2014 was approximately 13 months and 15 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:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Proceeds from maturities and sales	\$2,387.9	\$625.4	\$3,363.4	\$1,942.9
Realized gains	\$0.7	\$—	\$1.3	\$0.4
Realized losses	\$(2.0)	\$(0.1)	\$(2.9)	\$(0.3)

Strategic Investments

As of September 30, 2015 and December 31, 2014, our strategic investment portfolio was comprised of investments totaling \$68.4 million and \$47.8 million, respectively, which are included in investments and other assets in our accompanying condensed consolidated balance sheets. Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies and investments in venture capital funds where the underlying investments are in equity securities of biotechnology companies.

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8. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

Due to the global nature of our operations, portions of our revenues are earned in currencies other than the U.S. dollar. The value of revenues 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.

Foreign currency forward contracts in effect as of September 30, 2015 and December 31, 2014 had durations of 1 to 15 months. 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. 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 is summarized as follows:

Foreign Currency: (In millions)	Notional Amount	
	As of September 30, 2015	As of December 31, 2014
Euro	\$1,146.1	\$1,174.6
Canadian dollar	17.4	56.7
British pound sterling	12.0	34.5
Japanese yen	9.3	16.6
Australian dollar	5.4	19.9
Total foreign currency forward contracts	\$1,190.2	\$1,302.3

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 gains of \$23.3 million and \$72.1 million as of September 30, 2015 and December 31, 2014, respectively. We expect all contracts 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. 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, 2015 and December 31, 2014, credit risk did not change the fair value of our foreign currency forward contracts.

The following table summarizes 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	2015	2014	Location	2015	2014
Revenue	\$43.9	\$2.9	Other income (expense)	\$2.0	\$(0.5)

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	2015	2014	Location	2015	2014
Revenue	\$119.3	\$(7.1)		\$5.4	\$(1.6)

Other income
(expense)

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Interest Rate Contracts - Hedging Instruments

We may enter into interest rate lock contracts or interest rate swap contracts on certain borrowing transactions to manage our exposure to interest rate changes and to reduce our overall cost of borrowing.

Interest Rate Lock Contracts

During the three months ended September 30, 2015, we entered into treasury rate locks that were designated as cash flow hedges to hedge against changes in the 10-year and 30-year U.S. treasury interest rates that could have impacted our anticipated debt offering. In connection with the issuance of our 4.05% and 5.20% Senior Notes, as described in Note 10, Indebtedness, we settled the treasury rate locks and realized an \$8.5 million gain. As the hedging relationship was effective, the gain was recorded in AOCI and will be recognized in other income (expense), net over the life of the 4.05% and 5.20% Senior Notes.

Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes, as described in Note 10, Indebtedness, 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 one month durations, 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 \$787.2 million and \$365.2 million as of September 30, 2015 and December 31, 2014, respectively. Net losses of \$8.1 million and \$4.2 million related to these contracts were recognized as a component of other income (expense), net, for three and nine months ended September 30, 2015, respectively, as compared to net losses of \$7.7 million and \$11.5 million, respectively, in the prior year comparative periods.

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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, 2015
Hedging Instruments:		
Asset derivatives	Other current assets	\$54.1
	Investments and other assets	\$5.6
Liability derivatives	Accrued expenses and other	\$17.6
	Other long-term liabilities	\$8.5
Other Derivatives:		
Asset derivatives	Other current assets	\$1.7
Liability derivatives	Accrued expenses and other	\$5.2
Fair Value As of December 31, 2014		
(In millions)	Balance Sheet Location	
Hedging Instruments:		
Asset derivatives	Other current assets	\$69.5
	Investments and other assets	\$1.9
Other Derivatives:		
Asset derivatives	Other current assets	\$1.3
Liability derivatives	Accrued expenses and other	\$5.4

9. Property, Plant and Equipment

Property, plant and equipment are recorded at cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was \$1,320.5 million and \$1,186.4 million as of September 30, 2015 and December 31, 2014, respectively.

Research Triangle Park Facility Purchase

On August 24, 2015, we purchased from Eisai, Inc. (Eisai) its drug product manufacturing facility and supporting infrastructure in Research Triangle Park (RTP), North Carolina for \$104.8 million. The purchase price consisted of the following:

(In millions)	
Buildings	\$58.6
Machinery and equipment	25.9
Land	20.3
Total purchase price	\$104.8

On August 24, 2015, we also amended our existing 10 year lease related to Eisai's oral solid dose products manufacturing facility in RTP, North Carolina where we manufacture our and Eisai's oral solid dose products. As amended, the lease provides for a 3 year term and our agreement to purchase the facility upon expiration of the lease term and Eisai's completion of certain activities. Accordingly, we recorded the assets along with a corresponding financing obligation on our condensed consolidated balance sheet for \$20.3 million, the net present value of the future minimum lease payments. The assets were recorded as a component of buildings and machinery and equipment. We expect to complete the purchase of the oral solid products manufacturing facility at the end of the lease term in the

third quarter of 2018.

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(unaudited, continued)

10. Indebtedness

2015 Senior Notes

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion, consisting of the following:

\$1.5 billion of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;

\$1.0 billion of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;

\$1.75 billion of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and

\$1.75 billion of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

These notes are senior unsecured obligations and may be redeemed at our option at the greater of (1) 100% of the principal amount plus accrued and unpaid interest or (2) the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis at the treasury rate plus an incremental margin, plus, in either case, accrued and unpaid interest. The notes also contain a change of control provision that may require us to purchase the notes at a price equal to 101% of the principal amount plus accrued and unpaid interest to the date of purchase under certain circumstances.

The costs associated with this offering of approximately \$47.5 million have been recorded as a reduction to the carrying amount of the debt on our condensed consolidated balance sheet. These costs will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. The discounts will be amortized as additional interest expense over the period from issuance through maturity using the effective interest rate method. Interest on the notes is payable March 15 and September 15 of each year.

Additionally, in connection with this offering, we entered into interest rate swaps. The carrying value of the 2.90% Senior Notes includes approximately \$5.6 million related to changes in the fair value of the interest rate swaps. For additional information, please read Note 8, Derivative Instruments, to these condensed consolidated financial statements.

Credit Facility

In August 2015, we entered into a \$1.0 billion senior unsecured revolving credit facility, under which we are permitted to draw funds for working capital and general corporate purposes for 5 years. 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, 2015, we had no outstanding borrowings and were in compliance with all covenants under this facility.

11. Equity

Total equity as of September 30, 2015 decreased \$247.1 million compared to December 31, 2014. Significant changes were as follows:

• Additional paid in capital was reduced by share repurchases of \$2,998.2 million, as described below, and activity under our share-based compensation arrangements totaling \$144.4 million;

• Other comprehensive losses of \$97.9 million; and

• Net income attributable to Biogen Inc. of \$2,715.4 million.

Share Repurchases

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). This authorization does not have an expiration date. Repurchased shares will be retired. The 2015 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.

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During the nine months ended September 30, 2015, we repurchased and retired approximately 9.7 million shares of common stock at a cost of \$2,998.2 million under our 2015 Share Repurchase Program, which had the effect of reducing additional paid in capital by a similar amount. We did not repurchase any shares of common stock under our 2011 Share Repurchase Program. During the nine months ended September 30, 2014, we purchased approximately 1.2 million shares of common stock at a cost of \$360.0 million under our 2011 Share Repurchase Program. As of September 30, 2015, additional paid in capital totaled approximately \$1,342.4 million.

Noncontrolling Interests

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
NCI, beginning of period	\$0.4	\$3.9	\$5.0	\$0.6
Net income (loss) attributable to NCI, net of tax	53.9	(0.7	) 49.1	7.7
Fair value of net assets and liabilities acquired and assigned to NCI	0.2	—	0.1	4.0
Distribution to NCI	(60.0	) —	(60.0	) (9.1
Translation adjustment and other	(0.3	) —	—	—
NCI, end of period	\$ (5.8	) \$ 3.2	\$ (5.8	) \$ 3.2

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 17, Investments in Variable Interest Entities, to these condensed consolidated financial statements.

12. Accumulated Other Comprehensive Income (Loss)

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

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale	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

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(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, 2013	\$5.6	\$(23.7)	\$(19.6)	\$10.0	\$(27.7)
Other comprehensive income (loss) before reclassifications	1.4	57.5	1.3	(71.2)	(11.0)
Amounts reclassified from accumulated other comprehensive income (loss)	(6.5)	7.3	—	—	0.8
Net current period other comprehensive income (loss)	(5.1)	64.8	1.3	(71.2)	(10.2)
Balance, as of September 30, 2014	\$0.5	\$41.1	\$(18.3)	\$(61.2)	\$(38.0)

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

		Amounts Reclassified from Accumulated Other Comprehensive Income			
(In millions)	Income Statement Location	For the Three Months Ended September 30, 2015 2014		For the Nine Months Ended September 30, 2015 2014	
Gains (losses) on securities available for sale	Other income (expense)	\$(1.3)	\$(0.1)	\$(1.6)	\$10.1
	Income tax benefit (expense)	0.5	—	0.6	(3.6)
Gains (losses) on cash flow hedges	Revenues	43.9	2.9	119.3	(7.1)
	Other income (expense)	—	—	—	—
	Income tax benefit (expense)	(0.2)	(0.1)	(0.6)	(0.2)
Total reclassifications, net of tax		\$42.9	\$2.7	\$117.7	\$(0.8)

13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Three Months Ended September 30, 2015 2014		For the Nine Months Ended September 30, 2015 2014	
Numerator:				
Net income attributable to Biogen Inc.	\$965.6	\$856.9	\$2,715.4	\$2,051.3
Denominator:				
Weighted average number of common shares outstanding	232.2	236.2	234.1	236.6
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	0.5	0.3	0.5

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Market stock units	0.1	0.2	0.2	0.2
Dilutive potential common shares	0.4	0.8	0.6	0.8
Shares used in calculating diluted earnings per share	232.6	237.0	234.7	237.4

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Amounts excluded from the calculation of net income per diluted share because their effects were anti-dilutive were not significant.

14. Share-based Payments

Share-based Compensation Expense

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development	\$10.8	\$24.2	\$68.3	\$78.1
Selling, general and administrative	17.5	34.7	99.3	115.5
Subtotal	28.3	58.9	167.6	193.6
Capitalized share-based compensation costs	(2.8	) (2.3	) (8.4	) (7.5
Share-based compensation expense included in total cost and expenses	25.5	56.6	159.2	186.1
Income tax effect	(6.4	) (16.6	) (46.0	) (55.4
Share-based compensation expense included in net income attributable to Biogen Inc.	\$19.1	\$40.0	\$113.2	\$130.7

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Market stock units	\$7.3	\$7.1	\$33.4	30.2
Time-vested restricted stock units	30.4	28.2	94.1	86.6
Cash settled performance units	(9.5	) 15.2	17.5	50.6
Performance units	(2.8	) 5.7	11.6	16.0
Employee stock purchase plan	2.9	2.7	11.0	10.2
Subtotal	28.3	58.9	167.6	193.6
Capitalized share-based compensation costs	(2.8	) (2.3	) (8.4	) (7.5
Share-based compensation expense included in total cost and expenses	\$25.5	\$56.6	\$159.2	\$186.1

We estimate the fair value of our obligations associated with our performance 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,	
	2015	2014
Market stock units	181,000	236,000
Cash settled performance shares	115,000	182,000
Performance units	89,000	57,000
Time-vested restricted stock units	393,000	437,000

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Employee Stock Purchase Plan (ESPP)

In June 2015, our stockholders approved the Biogen Inc. 2015 Employee Stock Purchase Plan (ESPP). The 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 ESPP is 6,200,000.

For the nine months ended September 30, 2015, approximately 98,000 and 43,000 shares were issued under our 1995 ESPP and 2015 ESPP, respectively, compared to approximately 150,000 shares issued under our 1995 ESPP in the prior year comparative period.

15. Income Taxes

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,			
	2015	2014	2015	2014		
Statutory rate	35.0	% 35.0	% 35.0	% 35.0	%	%
State taxes	1.2	1.2	0.5	1.2		
Taxes on foreign earnings	(10.7)	) (9.3	) (10.1	) (8.9	)	)
Credits and net operating loss utilization	(1.1)	) (0.6	) (0.9	) (0.8	)	)
Purchased intangible assets	1.5	0.7	1.2	1.1		
Manufacturing deduction	(2.1)	) (2.0	) (2.0	) (1.9	)	)
Other permanent items	0.5	0.4	0.6	0.4		
Other	—	(1.2	) 0.3	(0.3	)	)
Effective tax rate	24.3	% 24.2	% 24.6	% 25.8	%	%

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, our effective tax rate benefited from lower anticipated taxes on foreign earnings. Our effective tax rate for the comparative nine month periods also reflects a benefit, described below, resulting from the remeasurement of one of our uncertain tax positions.

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 fiscal 2009, regarding withholding taxes and the treatment of certain intercompany transactions involving our Danish affiliate and another of our affiliates. The audits of our tax filings for 2010 through 2013 are not completed but have been prepared in a manner consistent with prior filings, with similar transactions, which may result in an assessment for those years. The total amount assessed for 2009 is \$49.3 million, including interest. For all periods potentially under dispute, we believe that positions taken in our tax filings are valid and we are contesting the assessment vigorously.

Federal Uncertain Tax Positions

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. It is reasonably possible that we will adjust the value of our uncertain tax positions related to our unconsolidated joint business and certain transfer pricing issues as we receive additional information from various taxing authorities, including reaching settlements with the authorities. In addition, the Internal Revenue Service (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.

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In October 2011, in conjunction with our examination, 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 believe that these items represent valid deductible business expenses and are vigorously defending our position. We have initiated a mutual agreement procedure between the IRS and SKAT for the years 2001 through 2009, in an attempt to reach agreement on the issue. In addition, we have applied for a bilateral advanced pricing agreement for the years 2010 through 2014 to resolve similar issues for the subsequent years.

16. Other Consolidated Financial Statement Detail

Other Income (Expense), Net

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

(In millions)	For the Three Months		For the Nine Months	
	Ended September 30,		Ended September 30,	
	2015	2014	2015	2014
Interest income	\$5.4	\$3.6	\$13.0	\$8.7
Interest expense	(15.6)	(7.4)	(28.1)	(22.1)
Gain (loss) on investments, net	1.1	(3.1)	(0.3)	13.5
Foreign exchange gains (losses), net	(4.3)	(4.8)	(18.8)	(9.5)
Other, net	(2.0)	(4.6)	(7.1)	(7.6)
Total other income (expense), net	\$(15.4)	\$(16.3)	\$(41.3)	\$(17.0)

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2015	As of December 31, 2014
Current portion of contingent consideration obligations	\$479.5	\$265.5
Revenue-related rebates	462.7	359.2
Employee compensation and benefits	214.2	393.8
Royalties and licensing fees	154.9	172.4
Deferred revenue	58.4	120.9
Other	549.2	507.5
Total accrued expenses and other	\$1,918.9	\$1,819.3

Other Long-Term Liabilities

Other long-term liabilities consist of the following:

(In millions)	As of September 30, 2015	As of December 31, 2014
Contingent consideration obligations	\$301.9	\$200.0
Employee compensation and benefits	218.4	200.7
Other	341.1	249.4
Total other long-term liabilities	\$861.4	\$650.1

Pricing of TYSABRI in Italy - AIFA

In the fourth quarter of 2011, Biogen Italia SRL (formerly Biogen Idec Italia SRL), our Italian subsidiary, 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 granted by AIFA in December 2006. In December 2011, we filed an appeal against AIFA in administrative court in Rome, Italy seeking a ruling that the reimbursement limit is unenforceable. That appeal is pending.

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In June 2014, AIFA eliminated the reimbursement limit from February 2013 going forward. As a result, in June 2014, we recognized \$53.5 million of TYSABRI revenues related to the periods beginning February 2013 that were previously deferred. AIFA and Biogen Italia SRL continue to discuss a possible resolution for the period between February 2009 and January 2013. We have approximately EUR75 million recorded as accrued expenses and deferred revenue in our long-term liabilities in our condensed consolidated balance sheets for this matter.

For additional information relating to our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 4, Accounts Receivable to our consolidated financial statements included in our 2014 Form 10-K.

17. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

In 2007, we entered into a collaboration agreement with Neurimmune SubOne AG (Neurimmune), a subsidiary of Neurimmune AG, for the development and commercialization of antibodies for the treatment of 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 (BIIB037), for the treatment of Alzheimer's disease resulted from this collaboration. In September 2015, we announced that the first patient had been enrolled in a Phase 3 trial for aducanumab, which triggered a \$60.0 million milestone payment due to Neurimmune. As we consolidate the financial results of Neurimmune, we recognized this payment as a charge to noncontrolling interest in the third quarter of 2015. Based upon our current development plans, 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.

Amounts that are incurred by Neurimmune for research and development expenses in support of the collaboration that we reimburse are reflected in research and development expense in our condensed consolidated statements of income. Future milestone payments, 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.

For the three and nine months ended September 30, 2015, the collaboration incurred expenses totaling \$39.7 million and \$87.5 million, respectively, which is included in total costs and expenses in our condensed consolidated statements of income, as compared to \$7.4 million and \$29.1 million, respectively, in the prior year comparative periods.

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 contractually required amounts.

Unconsolidated Variable Interest Entities

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

As of September 30, 2015 and December 31, 2014, the total carrying value of our investments in biotechnology companies totaled \$10.7 million and \$7.9 million, respectively. Our maximum exposure to losses related to these variable interest entities is limited to the carrying value of our investments.

We have 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 19, Investments in Variable Interest Entities to our consolidated financial statements included in our 2014 Form 10-K.

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18. Collaborative and Other Relationships

Mitsubishi Tanabe Pharma Corporation

On September 9, 2015, we announced an agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) to exclusively license MT-1303, a late stage experimental medicine with potential in multiple autoimmune indications. MT-1303 is an oral compound that targets the sphingosine 1-phosphate (S1P) receptor. Under the terms of the agreement, we will receive worldwide rights to MT-1303, excluding Asia. We will be responsible for global commercialization and development costs except for costs related to the Asian territories, which are the responsibility of MTPC. The transaction is subject to customary closing conditions, including the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the United States, and is expected to close in the fourth quarter of 2015.

Upon closing, we will pay MTPC an upfront payment of \$60.0 million and in the future may pay up to approximately \$484.0 million in milestone payments for multiple indications and territories, along with average royalties in the mid-teen to high-teen percentages of annual net sales. We will record the \$60.0 million upfront payment as research and development expense in our condensed consolidated statements of income when the agreement closes. MTPC has the right to participate in our global clinical trials related to MT-1303 and has an option to co-promote non-MS indications in the U.S.

Applied Genetic Technologies Corporation

On July 2, 2015, we announced a collaboration and license agreement to develop gene-based therapies for multiple ophthalmic diseases with Applied Genetic Technologies Corporation (AGTC). The collaboration will focus on the development of a portfolio of AGTC's therapeutic programs, including both a clinical stage candidate for X-linked Retinoschisis (XLRS) and a pre-clinical candidate for the treatment of X-Linked Retinitis Pigmentosa (XLRP). The agreement also includes options for early stage discovery programs in two ophthalmic diseases and one non-ophthalmic condition, as well as an equity investment in AGTC.

During the third quarter of 2015, the collaboration became effective and we made an upfront payment of \$124.0 million, which included a \$30.0 million equity investment in AGTC, prepaid research and development expenditures of \$58.4 million and total licensing and other fees of \$35.6 million. The \$58.4 million of prepaid research and development expenditures were recorded in investments and other assets in our condensed consolidated balance sheets and will be expensed as the services are provided. During the three months ended September 30, 2015, we recorded \$56.8 million as research and development expense associated with AGTC in our condensed consolidated statements of income, including the \$35.6 million total licensing and other fees, \$8.7 million in research and development services, a \$7.5 million premium on our equity investment and a \$5.0 million clinical development milestones related to XLRS.

AGTC is eligible to receive milestone payments aggregating in excess of \$1.0 billion, which includes up to \$472.5 million collectively for the two lead programs and up to up to \$592.5 million across the discovery programs. AGTC is also eligible to receive royalties in the mid-single digit to mid-teen percentages of annual net sales.

We were granted worldwide commercialization rights for the XLRS and XLRP programs. AGTC has an option to share development costs and profits after the initial clinical trial data are available, and an option to co-promote the second of these products to be approved in the U.S. AGTC will lead the clinical development programs of XLRS through product approval and of XLRP through the completion of first-in-human trials. We will support the clinical development costs, subject to certain conditions, following the first-in-human study for XLRS and IND-enabling studies for XLRP. Under the manufacturing license, we have received an exclusive license to use AGTC's proprietary technology platform to make AAV vectors for up to six genes, three of which are in AGTC's discretion, in exchange for payment of milestones and royalties.

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Swedish Orphan Biovitrum AB

On July 16, 2015, Swedish Orphan Biovitrum AB (Sobi) exercised its option to assume development and commercialization of ALPROLIX in Europe, Russia, Turkey and certain markets in the Middle East and paid us \$10.0 million, which will be held in escrow pending E.U. regulatory approval.

We collaborate with Sobi to jointly develop and commercialize Factor VIII and Factor IX hemophilia products, including ELOCTATE and ALPROLIX. For more information about our agreement with Sobi, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in our 2014 Form 10-K.

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, 2015, our ownership interest is approximately 10%, which reflects our additional contribution of 6.3 billion South Korean won (approximately \$5.7 million) in the first quarter of 2015 and 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. As of September 30, 2015 and December 31, 2014, the carrying value of our investment in Samsung Bioepis totaled 0.0 billion and 9.1 billion South Korean won (approximately \$0.0 million and \$8.6 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets. 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, as compared to \$5.4 million and \$14.9 million, respectively, in the prior year comparative periods. During the three months ended September 30, 2015, our share of losses exceeded the carrying value of our investment. We will suspend recognizing additional losses.

Commercial Agreement

On December 17, 2013, pursuant to our rights under the joint venture agreement with Samsung Biologics, we entered into an agreement with Samsung Bioepis to commercialize anti-tumor necrosis factor (TNF) biosimilar product candidates in Europe and, in the case of one anti-TNF biosimilar candidate, Japan. Under the terms of this agreement, we have paid \$46.0 million, which has been recorded as a research and development expense in our condensed consolidated statements of income as the programs they relate to have not achieved regulatory approval. Samsung Bioepis is eligible to receive an additional \$75.0 million in additional milestones related to regulatory approval of the product candidates. Upon commercialization, there will be a 50% profit share with Samsung Bioepis.

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, 2015, we recognized \$10.9 million and \$47.0 million, respectively, in other revenues in relation to these services, as compared to \$21.3 million and \$57.8 million, respectively, in the prior year comparative periods.

For additional information related to our other significant collaboration arrangements, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in our 2014 Form 10-K.

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19. Litigation

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

Bayer, Pfizer, Novartis and EMD Serono have all filed counterclaims in the Consolidated '755 Patent Actions seeking declaratory judgments of patent invalidity and non-infringement, and seeking monetary relief in the form of costs and attorneys' fees, and EMD Serono and Bayer have each filed a counterclaim seeking a declaratory judgment that the '755 Patent is unenforceable based on alleged inequitable conduct. Bayer has also amended its complaint to seek such a declaration. No trial date has been set.

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 December 23, 2011, 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 mid-February 2009 through January 2013.

Government Matters

We have learned that state and federal governmental authorities are investigating our sales and promotional practices and have received related subpoenas. We have also received a subpoena from the federal government for documents relating to our relationship with certain pharmacy benefit managers. We are cooperating with the government in these matters.

Qui Tam Litigation

On July 6, 2015, four qui tam actions filed against us by relators suing on behalf of the United States and certain states were unsealed by the U.S. District Court for the District of Massachusetts. The actions, which have been administratively consolidated, allege sales and promotional activities in violation of the federal False Claims Act and state law counterparts, and seek single and treble damages, civil penalties, interest, attorneys' fees and costs. The United States has declined to intervene in two of the actions and has not made an intervention decision in the other two actions. We have not been served with any of the complaints. We have not formed an opinion that an unfavorable outcome in any of the actions is either "probable" or "remote" and are unable to estimate the magnitude or range of any potential loss.

Forward Pharma 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, which was issued in April 2014 and expires 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. Forward Pharma seeks declarations of infringement and damages. A hearing has been scheduled for early 2016. We have not formed an opinion that an unfavorable outcome is either “probable” or “remote” and are unable to estimate the magnitude or range of any potential loss.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Securities Litigation

On August 18, 2015, Nicole Tehrani filed an action in the U.S. District Court for the District of Massachusetts against Biogen, our Chief Executive Officer, George A. Scangos, and our Chief Financial Officer, Paul J. Clancy, alleging federal securities law violations under 15 U.S.C. §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5. The plaintiff seeks declaration of the action as a class action, certification of the plaintiff as a representative of the class and her counsel as class counsel, and an award to the plaintiff and the class of damages, interest, and attorneys' fees. We have not formed an opinion that an unfavorable outcome is either "probable" or "remote" and are unable to estimate the magnitude or range of any potential loss.

Patent Matter relating to ALPROLIX

In September 2015, Pfizer proposed that we discuss taking a license to its U.S. Patent No. 8,603,777 (Expression of Factor VII and IX Activities in Mammalian Cells) and pay royalties on sales of ALPROLIX. We have not formed an opinion that an unfavorable outcome is either "probable" or "remote" and are unable to estimate the magnitude or range of any potential loss.

Product Liability and Other Legal Proceedings

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

20. 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 the 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 U.S. Food and Drug Administration (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, as defined in the acquisition agreement.

During the nine months ended September 30, 2015, we paid \$550.0 million in contingent payments as we reached the \$4.0 billion and \$5.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2014 and second quarter of 2015, respectively, and accrued \$300.0 million upon reaching \$6.0 billion in total cumulative sales of Fumapharm Products in the third quarter of 2015.

We will owe an additional \$300.0 million contingent payment for every additional \$1.0 billion in cumulative sales level of Fumapharm Products reached if the prior 12 months sales of the Fumapharm Products exceed \$3.0 billion, until such time as the cumulative sales level reaches \$20.0 billion, at which time no further contingent payments shall be due. 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 June 30, 2015, we signed an agreement to purchase land in Solothurn, Switzerland for 65.1 million Swiss Francs. The contract also includes certain environmental remediation costs. Our obligation to purchase the land is subject to customary closing conditions and a condition that no material adverse changes in our business, such as a decision to discontinue our aducanumab program, have occurred during the period.

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BIOGEN INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

21. Subsequent Events

Restructuring

On October 21, 2015, we announced a corporate restructuring, which includes the termination of a number of pipeline programs and an 11% reduction in workforce.

We expect to incur a charge related to these restructuring activities in the range of \$85 million to \$95 million. We anticipate making cash payments in the range of \$115 million to \$120 million, which includes amounts related to previously accrued incentive compensation. Substantially all of these amounts will be incurred and paid by the end of 2015.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and accompanying notes beginning on page 5 of this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2014 (2014 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 for neurological, autoimmune and hematologic disorders. Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI, and FAMPYRA for the treatment of multiple sclerosis (MS), ALPROLIX for the treatment of hemophilia B, ELOCTATE for the treatment of hemophilia A and FUMADERM for the treatment of severe plaque psoriasis. We also generate revenue from our collaboration with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group, with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, and share profits and losses with Genentech for GAZYVA, which is approved for the treatment of CLL.

Our current revenues depend upon continued sales of our principal products. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales and growth of TECFIDERA as we continue to expand into additional markets. 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 and 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 and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

Restructuring

On October 21, 2015, we announced a corporate restructuring, which includes the termination of a number of pipeline programs and an 11% reduction in workforce. These changes are expected to reduce the current annual run rate of operating expenses by approximately \$250 million.

We expect to reinvest the savings resulting from the restructuring to support key commercial activities, including TECFIDERA, and to support the advancement of our high potential pipeline candidates, including our programs in Alzheimer's disease, anti-LINGO for MS, ISIS-SMN₂ for spinal muscular atrophy (SMA), Raxatrigine (CNV1014802) for trigeminal neuralgia, and subject to the closing of our transaction with Mitsubishi Tanabe Pharma, indications for MT-1303, an oral S1P modulator. We also have discontinued several programs, including our Phase 3 program for TECFIDERA in secondary progressive MS (SPMS), the development of anti-TWEAK in lupus nephritis, and certain activities in immunology and fibrosis research.

We expect to incur a charge related to these restructuring activities in the range of \$85 million to \$95 million. We anticipate making cash payments in the range of \$115 million to \$120 million, which includes amounts related to previously accrued incentive compensation. Substantially all of these amounts will be incurred and paid by the end of 2015.

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Financial Highlights

For the three months ended September 30, 2015, diluted earnings per share attributable to Biogen Inc. was \$4.15, as compared to \$3.62 in the prior year comparative period.

As described below under “Results of Operations,” our operating results for the three months ended September 30, 2015 reflect the following:

Total revenues totaled \$2,777.9 million in the third quarter of 2015, representing an increase of 10.6% over the same period in 2014.

Product revenues, net totaled \$2,391.7 million in the third quarter of 2015, representing an increase of 13.0% over the same period in 2014. This increase was driven by a 19.1% increase in worldwide TECFIDERA revenues as well as revenue increases from PLEGRIDY, ALPROLIX and ELOCTATE, which are recent product additions, partially offset by a decrease in worldwide AVONEX and TYSABRI revenues.

Our share of RITUXAN and GAZYVA operating profits totaled \$337.2 million in the third quarter of 2015, representing an increase of 16.0% over the same period in 2014. This increase was due in part to the prior year recognition of additional Branded Pharmaceutical Drug (BPD) fee expense.

Other revenues totaled \$49.0 million in the third quarter of 2015, representing a decrease of 52.6% from the same period in 2014. This decrease was driven by an 86.6% decrease in royalty revenue primarily due to the expiration of U.S. patent rights that gave rise to royalty payments related to ANGIOMAX, partially offset by a 10.3% increase in corporate partner revenue.

Total cost and expenses totaled \$1,406.0 million in the third quarter of 2015, representing an increase of 3.1% compared to the same period in 2014. This increase was driven by a 24.6% increase in research and development expense, partially offset by a 19.9% decrease in the amortization of acquired intangible assets, a 16.2% decrease in selling, general and administrative expense and a decrease in the gain on fair value remeasurement of contingent consideration. In addition, total costs and expenses in the third quarter of 2015, compared to the same period in 2014, were lower due to foreign currency translation totaling \$40.4 million.

We generated \$2,675.7 million of net cash flows from operations for the nine months ended September 30, 2015, which were primarily driven by earnings. Cash, cash equivalents and marketable securities totaled approximately \$7,789.9 million as of September 30, 2015.

During the nine months ended September 30, 2015, we repurchased and retired approximately 9.7 million shares of common stock at a cost of \$2,998.2 million under our share repurchase programs.

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion.

Acquisitions

On February 12, 2015, we completed our acquisition of all of the outstanding stock of Convergence Pharmaceuticals (Convergence), a clinical-stage biopharmaceutical company with a focus on developing product candidates for neuropathic pain. For additional information related to this transaction, please read Note 2, Acquisitions to our condensed consolidated financial statements included in this report.

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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, related prodrug derivatives or biosimilars of existing products and other technologies, such as gene therapies. For additional information related to competition risk that could negatively impact our products, please read the “Risk Factors” section of this report.

Key Pipeline and Product Developments

ELOCTATE

In September 2015, we and Swedish Orphan Biovitrum AB (Sobi) received a positive recommendation from the EMA’s Committee for Medicinal Products for Human Use (CHMP) for the marketing authorization of ELOCTA, the approved trade name for ELOCTATE in the E.U., for the treatment of hemophilia A. The CHMP's recommendation was referred to the European Commission, which grants marketing authorizations for medicines in the E.U.

ALPROLIX

In February 2015, we and Sobi announced positive top-line results of the Kids B-LONG Phase 3 clinical study that evaluated the safety, efficacy and pharmacokinetics of ALPROLIX in children under age 12 with severe hemophilia B. This data was required as part of our Marketing Authorization Application (MAA) for ALPROLIX for the treatment of hemophilia B in the E.U., which was submitted to the European Medicines Agency (EMA). The EMA validated our MAA for ALPROLIX in June 2015.

ZINBRYTA

In March 2015, the EMA validated our MAA for ZINBRYTA for the treatment of relapsing forms of MS in the E.U. In April 2015, the U.S. Food and Drug Administration (FDA) accepted our Biologics License Application for ZINBRYTA for the treatment of relapsing forms of MS in the U.S.

We collaborate with AbbVie Biotherapeutics, Inc. (AbbVie) on the development and commercialization of ZINBRYTA. For additional information about this collaboration, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in our 2014 Form 10-K.

Aducanumab (BIIB037)

In March 2015, we announced data from a pre-specified interim analysis of PRIME, the Phase 1b study of aducanumab, in which aducanumab demonstrated an acceptable safety profile and positive results on radiologic and clinical measurements in patients with prodromal or mild Alzheimer’s disease. Based on results from our Phase 1b study, we advanced the aducanumab clinical program to Phase 3.

In July 2015, we announced new results from a pre-specified interim analysis of PRIME in patients with prodromal or mild Alzheimer’s disease. In this analysis, which included patients treated up to 54 weeks with the 6 mg/kg dose, aducanumab demonstrated acceptable safety and tolerability, and the findings reinforced the previously reported results from PRIME.

In September 2015, we enrolled our first patient in our two global Phase 3 studies, ENGAGE and EMERGE, to assess the efficacy and safety of aducanumab in people with early Alzheimer's disease and triggered a \$60.0 million milestone payment due to Neurimmune SubOne AG (Neurimmune). We also received FDA agreement on a special protocol assessment on the aducanumab Phase 3 studies.

Anti-LINGO

In January 2015, we announced positive top-line results from the Phase 2 acute optic neuritis RENEW trial in which treatment with anti-LINGO-1 showed evidence of biological repair of the visual system. Anti-LINGO-1 demonstrated an improvement in the study’s primary endpoint, recovery of optic nerve latency (time for a signal to travel from the retina to the visual cortex) relative to placebo. The study showed no effect on secondary endpoints, including change in thickness of the retinal layers (optic nerve neurons and axons) and visual function. Anti-LINGO-1 is also being studied in people with MS through a Phase 2 study, SYNERGY.

Results in our early stage trials for aducanumab and anti-LINGO-1 may not be indicative of results in later stage trials, which, in some cases, may take several years to enroll and complete and may result in the incurrence of significant costs and investment without the assurance of success. Development of biopharmaceutical products is subject to the risks and uncertainties described in our risk factors.

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GAZYVA

In February 2015, the Roche Group announced positive results from the Phase 3 GADOLIN study in non-Hodgkin's lymphoma. At a pre-planned interim analysis, an independent data monitoring committee determined that the study met its primary endpoint early, showing that people lived significantly longer without disease worsening or death (progression-free survival) when treated with GAZYVA plus bendamustine followed by GAZYVA alone, compared to bendamustine alone.

Ocrelizumab

In June 2015, the Roche Group announced positive results from two Phase 3 studies evaluating ocrelizumab compared with interferon beta-1a in people with relapsing forms of MS. Treatment with ocrelizumab compared with interferon beta-1a significantly reduced the annualized relapse rate over a two-year period; significantly reduced the progression of clinical disability; and led to a significant reduction in the number of lesions in the brain as measured by MRI.

In September 2015, the Roche Group announced positive results from a Phase 3 study evaluating ocrelizumab in people with primary progressive MS. Treatment with ocrelizumab significantly reduced the progression of clinical disability compared with placebo, as measured by the Expanded Disability Status Scale.

The Roche Group plans to submit the data for review to regulatory authorities in early 2016.

Genentech, a wholly-owned member of the Roche Group, is solely responsible for development and commercialization of ocrelizumab. If approved for commercial sale by the FDA, we will receive tiered royalties between 13.5% and 24% on U.S. net sales. There will be a 50% reduction to these royalties if a biosimilar to ocrelizumab is approved in the U.S. In addition, we will receive a 3% royalty on worldwide net sales of ocrelizumab outside the U.S.

ISIS-SMN_{Rx}

In June 2015, Isis Pharmaceuticals, Inc. (Isis) announced additional data from two Phase 2 studies of ISIS-SMN_{Rx} for the treatment of spinal muscular atrophy in infants and children. There are two Phase 3 studies that are active and currently enrolling patients.

Biosimilars

In January 2015, the EMA validated and accepted Samsung Bioepis' MAA for BENEPALI, its etanercept biosimilar candidate. In September 2015, Samsung Bioepis announced that its etanercept biosimilar candidate received regulatory approval for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and psoriasis from the South Korean regulatory authority. In South Korea, etanercept will be marketed as BRENZYS. BRENZYS is expected to launch by the end of this year or early next year.

In March 2015, the EMA validated and accepted Samsung Bioepis' MAA for FLIXABI, its infliximab biosimilar candidate.

TYSABRI

In July 2015, the results of our Phase 2 trial investigating TYSABRI in acute ischemic stroke did not demonstrate an impact on change in infarct volume, the primary endpoint. However, exploratory clinical endpoints suggested that TYSABRI did have a beneficial impact on patient functional deficits.

In October 2015, we announced the top-line results from the Phase 3 ASCEND study evaluating TYSABRI in SPMS. The study did not achieve its primary and secondary endpoints. Based on these results, we have discontinued development of TYSABRI in SPMS.

Neublastin

In June 2015, the results of our Phase 2 trial investigating Neublastin in neuropathic pain did not meet its primary endpoint or its efficacy criteria. Based on these results, we have discontinued development of Neublastin in neuropathic pain.

Anti-TWEAK

In September 2015, the results of our interim Phase 2 efficacy results for the development of Anti-TWEAK in lupus nephritis failed to meet the target product profile. Based on these results, we have discontinued development of anti-TWEAK in lupus nephritis.

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Results of Operations

Revenues

Revenues are summarized as follows:

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,						
(In millions, except percentages)	2015		2014			2015		2014				
Product revenues:												
United States	\$1,721.5	62.0	%	\$1,442.5	57.4	%	\$4,820.6	60.8	%	\$3,956.0	56.0	%
Rest of world	670.2	24.1	%	674.8	26.9	%	1,942.0	24.5	%	1,960.4	27.8	%
Total product revenues	2,391.7	86.1	%	2,117.3	84.3	%	6,762.6	85.3	%	5,916.4	83.8	%
Unconsolidated joint business	337.2	12.1	%	290.7	11.6	%	1,005.3	12.7	%	890.9	12.6	%
Other revenues	49.0	1.8	%	103.4	4.1	%	156.6	2.0	%	255.3	3.6	%
Total revenues	\$2,777.9	100.0	%	\$2,511.4	100.0	%	\$7,924.5	100.0	%	\$7,062.6	100.0	%

Product Revenues

Product revenues are summarized as follows:

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,						
(In millions, except percentages)	2015		2014			2015		2014				
Multiple Sclerosis:												
TECFIDERA	\$937.4	39.2	%	\$787.1	37.2	%	\$2,645.6	39.1	%	\$1,993.2	33.7	%
Interferon	784.8	32.8	%	745.2	35.2	%	2,229.0	33.0	%	2,280.5	38.5	%
TYSABRI	479.7	20.1	%	501.2	23.7	%	1,405.4	20.8	%	1,475.6	24.9	%
FAMPYRA	21.0	0.9	%	20.4	1.0	%	62.1	0.9	%	61.7	1.0	%
Hemophilia:												
ALPROLIX	65.7	2.7	%	25.3	1.2	%	163.2	2.4	%	35.7	0.6	%
ELOCTATE	90.6	3.8	%	21.6	1.0	%	218.5	3.2	%	21.6	0.4	%
Other	12.5	0.5	%	16.5	0.8	%	38.8	0.6	%	48.1	0.8	%
Total product revenues	\$2,391.7	100.0	%	\$2,117.3	100.0	%	\$6,762.6	100.0	%	\$5,916.4	100.0	%

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Multiple Sclerosis (MS)

TECFIDERA

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the increase in U.S. TECFIDERA revenues was primarily due to increases in unit sales volume of 8% and 18%, respectively, as TECFIDERA penetrated the U.S. market, and increases in price.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the increase in rest of world TECFIDERA revenues was primarily due to increases in unit sales volume in existing markets and in additional markets as we continue to launch the product and expand our presence around the world. These increases were partially offset by pricing reductions in Germany as described below.

Rest of world TECFIDERA revenues for the three and nine months ended September 30, 2015, compared to the same periods in 2014, were negatively impacted by foreign currency exchange losses totaling \$24.3 million and \$53.1 million, respectively. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program totaling \$11.9 million and \$32.8 million, respectively.

In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced in the German market. For the first 12 months after launch, pricing is unregulated. We launched TECFIDERA in Germany in February 2014. During the first quarter of 2015, our unregulated pricing ended and we recognized revenue at the fixed price that was established through negotiations with the German authorities. The negotiated annual price is fixed for three years at EUR12,800.

While we continue to see a strong uptake of TECFIDERA in newly launched territories, total market growth and patient switch rates in our maturing markets, such as the U.S. and Germany, are returning to historical averages for MS. During 2015, TECFIDERA's U.S. patient growth versus prior quarters has continued to moderate primarily due to changing physician prescribing patterns.

Interferon

PLEGRIDY

Sales of PLEGRIDY began in the E.U. and the U.S. in the third and fourth quarters of 2014, respectively.

We expect that PLEGRIDY revenues will increase as PLEGRIDY becomes commercially available in additional markets.

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AVONEX

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the decrease in U.S. AVONEX revenues was primarily due to decreases in unit sales volume of 12% and 17%, respectively, which was attributable in part to patients transitioning to PLEGRIDY and oral MS therapies, including TECFIDERA, partially offset by price increases.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the decrease in rest of world AVONEX revenues was primarily due to decreases in unit sales volume of 6% and 13%, respectively, primarily in Europe, attributable to patients transitioning to PLEGRIDY and oral MS therapies, including TECFIDERA.

Rest of world AVONEX revenues for the three and nine months ended September 30, 2015, compared to the same periods in 2014, were negatively impacted by foreign currency exchange losses totaling \$38.3 million and \$128.7 million, respectively. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program totaling \$13.8 million and \$48.8 million, respectively.

TYSABRI

For the three months ended September 30, 2015, compared to the same period in 2014, the increase in U.S. TYSABRI revenues was primarily due to increases in price, partially offset by a decrease in unit sales volume of 3% related to an extra shipping week in the third quarter of 2014.

For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in U.S. TYSABRI revenues was primarily due to increases in price and an increase in unit sales volume of 5%.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the decrease in rest of world TYSABRI revenues was due to pricing reductions in some European countries, partially offset by increases in unit sales volume of 5% and 4%, respectively, primarily in our emerging markets.

Rest of world TYSABRI revenues for the nine months ended September 30, 2014 reflects the recognition of \$53.5 million of revenues previously deferred in Italy relating to the pricing agreement with the Italian National Medicines Agency (Agenzia Italiana del Farmaco, or AIFA), as discussed below.

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Rest of world TYSABRI revenues for the three and nine months ended September 30, 2015, compared to the same periods in 2014, were negatively impacted by foreign currency exchange losses totaling \$34.3 million and \$112.7 million, respectively. These foreign currency exchange losses were partially offset by comparative net gains recognized under our foreign currency hedging program totaling \$11.7 million and \$35.1 million respectively. We remain in discussions with AIFA about a resolution relating to a claim that sales of TYSABRI in Italy exceeded a reimbursement limit established pursuant to a Price Determination Resolution granted by AIFA in December 2006 for the period from mid-February 2009 through January 2013. If AIFA agrees to our current proposal, we could recognize approximately EUR40 million in revenue related to this matter. For information regarding our agreement with AIFA relating to sales of TYSABRI in Italy, please read Note 16, Other Consolidated Financial Statement Detail to our condensed consolidated financial statements included in this report.

Hemophilia

ALPROLIX

Sales of ALPROLIX in the U.S. and Japan began in the second and fourth quarters of 2014, respectively.

ELOCTATE

Sales of ELOCTATE in the U.S. and Japan began in the third quarter of 2014 and in the first quarter of 2015, respectively.

We have a relatively limited product history for ALPROLIX and ELOCTATE. Therefore, it remains difficult to estimate trends of future sales of these products.

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Unconsolidated Joint Business Revenues

Revenues from unconsolidated joint business are summarized as follows:

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

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

(In millions)	For the Three Months Ended September 30,	
	2015	2014
Product revenues, net	\$959.1	\$917.3
Cost and expenses	161.5	244.3
Pre-tax profits in the U.S.	797.6	673.0
Biogen's share of pre-tax profits, including the reimbursement of selling and development expenses	\$319.9	\$271.0

(In millions)	For the Nine Months Ended September 30,	
	2015	2014
Product revenues, net	\$2,901.1	\$2,684.5
Cost and expenses	516.8	610.7
Pre-tax profits in the U.S.	2,384.3	2,073.8
Biogen's share of pre-tax profits, including the reimbursement of selling and development expenses	\$952.7	\$831.1

For the three months ended September 30, 2015, compared to the same period in 2014, the increase in U.S. product revenues was primarily due to price increases.

For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in U.S. product revenues was primarily due to price increases and increases in RITUXAN unit sales volume of 4%, partially offset by higher discounts and allowances.

Collaboration costs and expenses for the three and nine months ended September 30, 2015, compared to the same periods in 2014, decreased in part due to the prior year recognition of \$52.5 million of additional BPD fee expense. During the three months ended September 30, 2014, the Internal Revenue Service issued final regulations related to the BPD fee, which had the effect of changing the recognition of the fee for accounting purposes, from the period in which the fee was paid, to the period when the sale occurs. As a result of these final regulations, we recognized an incremental BPD fee for the periods 2013 through the end of the third quarter of 2014. The final regulations did not change the timing of payments.

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 revenue on sales outside the U.S. and Canada. For the three and nine months ended September 30, 2015, compared to the same periods in 2014, revenue on sales in the rest of world for RITUXAN decreased as a result of lower pre-tax co-promotion profits on RITUXAN in Canada and patent expirations.

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Other Revenues

Royalty Revenues

We receive royalties from net sales on products related to patents that we have out-licensed. Our most significant source of royalty revenue had been derived from net worldwide sales of ANGIOMAX, which was out-licensed to The Medicines Company. On December 15, 2014 we ceased recognizing royalty revenues from U.S. sales of ANGIOMAX, contemporaneous with the U.S. patent's expiration.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, royalty revenues decreased primarily due to the expiration of U.S. patent rights that gave rise to royalty payments related to ANGIOMAX.

Corporate Partner Revenues

Our corporate partner revenues include amounts earned under contract manufacturing agreements, revenues related to our arrangement with Samsung Bioepis, and revenues covering products previously included in our product line that we have sold or exclusively licensed to third parties.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the increase in corporate partner revenues was primarily due to higher contract manufacturing revenue and the start of product shipments to Sobi in relation to our collaboration agreement.

For additional information on our relationship with Samsung Bioepis, please read Note 18, Collaborative and Other Relationships to our condensed consolidated financial statements included in this report. For additional information on our relationship with Sobi, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in our 2014 Form 10-K.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of applicable discounts, allowances and other governmental 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 period of adjustment. To date, such adjustments have not been significant.

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

Discounts include trade term discounts and wholesaler incentives. For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the increase in discounts was primarily driven by our recent product additions and an increase in contractual rates.

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Contractual adjustments relate to Medicaid and managed care rebates, 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, 2015, compared to the same periods in 2014, the increase in contractual adjustments was primarily due to our recent product additions, higher Medicaid, governmental rebates and allowances and managed care rebates as a result of price increases and an increase in governmental rebates in certain international markets.

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. Reserves 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, 2015, compared to the same periods in 2014, return reserves 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.

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Cost and Expenses

A summary of total cost and expenses is as follows:

(In millions, except percentages)	For the Three Months Ended September 30,			For the Nine Months Ended September 30,				
	2015	2014	Change %	2015	2014	Change %		
Cost of sales, excluding amortization of acquired intangible assets	\$310.0	\$302.6	2.4	% \$908.6	\$873.8	4.0	%	
Research and development	519.9	417.2	24.6	% 1,471.1	1,393.3	5.6	%	
Selling, general and administrative	477.8	570.4	(16.2)	)% 1,530.1	1,658.7	(7.8)	)%	
Amortization of acquired intangible assets	98.1	122.4	(19.9)	)% 286.0	382.5	(25.2)	)%	
(Gain) loss on fair value remeasurement of contingent consideration	0.2	(49.4)	) (100.5)	)% 5.9	(46.2)	) (112.7)	)%	
Total cost and expenses	\$1,406.0	\$1,363.2	3.1	% \$4,201.7	\$4,262.1	(1.4)	)%	

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

For the three months ended September 30, 2015 compared to the same period in 2014, the increase in product cost of sales was primarily driven by higher charges related to inventory write-downs.

For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in product cost of sales was primarily driven by higher unit sales volume and higher AVONEX production costs.

Inventory amounts written down as a result of excess, obsolescence, unmarketable or other reasons are included in product cost of sales. For the three and nine months ended September 30, 2015, inventory write-downs totaled \$18.6 million and \$30.0 million, respectively, compared to \$12.3 million and \$33.2 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, the decrease in royalty cost of sales was driven by the decrease in TYSABRI revenues and the expiration of third party royalties related to TYSABRI. These decreases were partially offset by an increase in the contractual rate on TYSABRI contingent payments due to Perrigo Company plc (Perrigo), which is based on the expected level of annual worldwide net sales of TYSABRI, and royalties due on increased sales of our hemophilia products. For additional information on the contingent payments due to Perrigo, please read Note 2, Acquisitions to our consolidated financial statements included in our 2014 Form 10-K.

Research and Development

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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. For several of our programs, the research and development activities are part of our collaborative and other relationships. Our costs reflect our share of the total costs incurred.

For the three months ended September 30, 2015 compared to the same period in 2014, the increase in research and development expense was primarily related to an increase in milestone and upfront expenses, increases in costs incurred in connection with our late stage programs and higher research and discovery costs.

For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in research and development expense was primarily related to increases in costs incurred in connection with our research and discovery, late stage programs and early stage programs, partially offset by a decrease in milestone and upfront expenses.

The increase in spending associated with our late stage programs for the three and nine months ended September 30, 2015 was driven by costs incurred to advance our aducanumab program for Alzheimer's disease and the ISIS-SMN_{Rx} program for the treatment of SMA, partially offset by a decrease in costs related to ZINBRYTA. The decrease for the nine months comparative period was also the result of our approvals of PLEGRIDY and ELOCTATE in 2014.

The increase in spending associated with our early stage programs for the nine months ended September 30, 2015, compared to the same period in 2014 was primarily due to costs incurred in connection with our aducanumab program for Alzheimer's disease, which advanced to a late stage program during the third quarter of 2015, the BAN2401 program for Alzheimer's disease and our Raxatrigine program for trigeminal neuralgia. These increases were partially offset by a decrease in costs incurred in connection with the ISIS-SMN_{Rx} program for the treatment of SMA as the program advanced to a late stage program during the first quarter of 2015.

The increase in spending associated with milestones and upfront expenses for the three months ended September 30, 2015, compared to the same period in 2014, was primarily due to \$48.1 million recorded upon entering into the collaboration with Applied Genetic Technologies Corporation (AGTC).

The decrease in spending associated with milestones and upfront expenses for the nine months ended September 30, 2015, compared to the same period in 2014, was driven by charges of \$117.7 million recorded in the prior year upon entering into the collaboration agreement with Eisai Co., Ltd. (Eisai), \$21.6 million as Eisai exercised its option in the collaboration agreement to expand the joint development and commercialization activities to include Japan and \$20.0 million related to an upfront payment made to Sangamo BioSciences, Inc. upon entering into an exclusive worldwide collaboration and license agreement in 2014. This decrease in

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spending was partially offset by a charge of \$48.1 million recorded upon entering into the collaboration with AGTC in the third quarter of 2015 and \$16.0 million paid to AbbVie related to milestones for the development of ZINBRYTA as a result of filing with the FDA and EMA in 2015. For additional information about these transactions, please read Note 20, Collaborative and Other Relationships to our consolidated financial statements included in our 2014 Form 10-K.

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, the ISIS-SMN_{Rx} program, the MT-1303 program and our Raxatrigine program.

Selling, General and Administrative

For the three months ended September 30, 2015, compared to the same period in 2014, the decrease in selling, general and administrative expenses was driven by a decrease in corporate giving, compensation and benefits expense, savings realized through our efforts to control spend associated with our sales and marketing activities and the positive impact of foreign currency translation.

For the nine months ended September 30, 2015, compared to the same period in 2014, the decrease in selling, general and administrative expenses was driven by a decrease in corporate giving and the positive impact of foreign currency translation, partially offset by increased cost related to the BPD fee.

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.

For the three months ended September 30, 2015, compared to the same period in 2014, the decrease in amortization of acquired intangible assets was primarily driven by higher expected lifetime revenues of AVONEX, as discussed below, partially offset by lower expected lifetime revenues of TYSABRI, as described below. Amortization of acquired intangible assets during the three months ended September 30, 2014 included a \$16.2 million impairment loss related to one of our in-process research and development (IPR&D) intangible assets.

For the nine months ended September 30, 2015, compared to the same period in 2014, the decrease in amortization of acquired intangible assets was primarily driven by a decrease in AVONEX revenues during the comparative periods. Amortization of acquired intangible assets during the nine months ended September 30, 2014 included total impairment charges of \$50.9 million related to one of our out-licensed patents and one of our IPR&D intangible assets.

Our most recent long range planning cycle was updated in the third quarter of 2015. Based upon this analysis, there was not a significant change in our expected rate of amortization for acquired intangible assets.

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We monitor events and expectations regarding product performance. If there are any indications that the assumptions underlying our most recent analysis would be 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.

IPR&D

During the three months ended September 30, 2014, we updated the probabilities of success related to the early stage programs acquired through our acquisitions. The change in probability of success, combined with a delay in one of the projects, resulted in an impairment loss of \$16.2 million in one of our IPR&D assets during the three months ended September 30, 2014. In addition, we adjusted the value of our contingent consideration liabilities to reflect these lower probabilities of success in connection with these earlier stage programs resulting in net gains of \$49.4 million in the three months ended September 30, 2014.

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

Out-licensed Patents

During the nine months ended September 30, 2014, we recorded a charge of \$34.7 million related to the impairment of one of our out-licensed patents to reflect a change in its estimated fair value, due to a change in the underlying competitive market for that product, which occurred during the first quarter of 2014.

(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 loss on fair value remeasurement of contingent consideration for the three and nine months ended September 30, 2015 was primarily due to the passage of time and modest changes in the expected timing and probabilities of success related to the achievement of certain developmental milestones.

The gain on fair value remeasurement of contingent consideration for the three and nine months ended September 30, 2014 was primarily due to an adjustment to the value of our contingent consideration liabilities as we updated certain probabilities of success related to the early stage programs we acquired. For additional information, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in our 2014 Form 10-K.

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Other Income (Expense), Net

For the three months ended September 30, 2015 compared to the same period in 2014, the change in other income (expense), net was primarily due to an increase in interest expense as a result of our issuance of the Senior Notes issued on September 15, 2015 (2015 Senior Notes), offset by an increase in gains recognized on the sale of our strategic investments and lower non-state income taxes.

For the nine months ended September 30, 2015 compared to the same period in 2014, the change in other income (expense), net was primarily due to a decrease in gains recognized on the sale of our strategic investments and marketable securities, higher foreign exchange losses and an increase in interest expense as a result of our issuance of the 2015 Senior Notes.

We expect interest expense will continue to increase as a result of our issuance of the 2015 Senior Notes. For additional information related to our 2015 Senior Notes, please read Note 10, Indebtedness, to our condensed consolidated financial statements included in this report.

Income Tax Provision

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

For the three and nine months ended September 30, 2015, compared to the same periods in 2014, our effective tax rate benefited from lower anticipated taxes on foreign earnings. Our effective tax rate for the comparative nine month periods also reflects a benefit, described below, resulting from the remeasurement of one of our uncertain tax positions.

For more information on our uncertain tax positions and income tax rate reconciliation for the three and nine months ended September 30, 2015 and 2014, please read Note 15, Income Taxes to our condensed consolidated financial statements included in this report.

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Equity in Loss of Investee, Net of Tax

In February 2012, we entered into an agreement with Samsung BioLogics Co. Ltd. (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 the three months ended September 30, 2015, our share of losses exceeded the carrying value of our investment. We will suspend recognizing additional losses.

For the three months ended September 30, 2015, compared to the same period in 2014, the increase in our equity in loss of investee, net of tax, was due to increases in the joint venture's clinical activity and milestone revenue earned by the joint venture in the third quarter of 2014, partially offset by a decrease in our ownership interest.

For the nine months ended September 30, 2015, compared to the same period in 2014, the decrease in our equity in loss of investee, net of tax, was due to the suspension of equity method investment losses due to our share of losses exceeding the carrying value of our investment in 2015 and a decrease in our ownership interest.

For additional information related to this transaction, please read Note 18, 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 related to a \$60.0 million milestone payment made to Neurimmune. For additional information, please read Note 17, Investments in Variable Interest Entities, to our condensed consolidated financial statements included in this report.

Quantitative and Qualitative Disclosures About 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. Further, we only enter into contracts with parties that have at least an "A" (or equivalent) credit rating. 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, Switzerland, Australia, New Zealand, Japan and Central and South America. In addition, we receive royalty revenues based on sales of RITUXAN outside the U.S. and Canada. As a result, our financial position, results of operations and cash flows can be affected by market fluctuations in foreign

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exchange rates, primarily with respect to the Euro, Canadian dollar, Swiss franc, Danish krone, Japanese yen, Australian dollar and British pound sterling.

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 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.

Revenue 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. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue 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 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.

The following quantitative information includes the impact of currency movements on forward contracts used in both our revenue and balance sheet hedging programs. As of September 30, 2015 and December 31, 2014, 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 \$195.0 million and \$160.0 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, 2015 and December 31, 2014, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately \$29.6 million and \$14.5 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.

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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, 2015, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately \$6.8 million.

Pricing Pressure

Governments in some international markets in which we operate have implemented measures aimed at reducing healthcare costs to 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 and 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 large 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. Our historical write-offs of accounts receivable have not been significant.

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

Our accounts receivable in Portugal continue to be subject to significant payment delays due to government funding and reimbursement practices, although Portugal has introduced various programs periodically to pay down significantly overdue payables. Our net accounts receivable balance from product sales in Portugal totaled \$20.4 million and \$22.7 million as of September 30, 2015 and December 31, 2014, respectively, of which \$8.9 million and \$7.6 million were classified as non-current and included in investments and other assets in our condensed consolidated balance sheets.

Our accounts receivable collection efforts in Spain have improved during the nine months ended September 30, 2015. All of our accounts receivable in Spain are expected to be collected within one year and are included in accounts receivable, net in our condensed consolidated balance sheets.

We believe that our allowance for doubtful accounts was adequate as of September 30, 2015 and December 31, 2014, respectively. 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.

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Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions, except percentages)	As of September 30, 2015	As of December 31, 2014	Change	%
Financial assets:				
Cash and cash equivalents	\$4,089.0	\$1,204.9	239.4	%
Marketable securities — current	1,753.5	640.5	173.8	%
Marketable securities — non-current	1,947.4	1,470.7	32.4	%
Total cash, cash equivalents and marketable securities	\$7,789.9	\$3,316.0	134.9	%
Borrowings:				
Current portion of notes payable and other financing arrangements	\$5.2	\$3.1	64.9	%
Notes payable and other financing arrangements	6,529.3	580.3	**	
Total borrowings	\$6,534.4	\$583.4	**	
Working capital:				
Current assets	\$9,270.9	\$4,672.2	98.4	%
Current liabilities	(2,634.0)	(2,219.7)	18.7	%
Total working capital	\$6,636.9	\$2,452.5	170.6	%

** Percentage not meaningful.

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

\$5,930.9 million in proceeds from the issuance of our senior unsecured notes (2015 Senior Notes);

\$2,998.2 million 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, including \$104.8 million related to a purchased facility;

\$198.8 million net cash paid for the acquisition of Convergence; and

\$124.0 million used for an upfront payment made to AGTC.

For the nine months ended September 30, 2014, certain significant cash flows were as follows:

\$813.5 million in total payments for income taxes;

\$360.0 million used for share repurchases;

\$180.9 million used for purchases of property, plant and equipment;

\$175.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;

and

\$155.0 million used for upfront and milestone payments in collaborative arrangements.

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Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. On September 15, 2015, we issued our 2015 Senior Notes for an aggregate principal amount of \$6.0 billion. 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 and proceeds received from our 2015 Senior Notes. 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, 2015, approximately \$2,925 million 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 May 2015, our Board of Directors authorized a program to repurchase up to \$5.0 billion of our common stock (2015 Share Repurchase Program). This authorization does not have an expiration date. Repurchased shares will be retired. The 2015 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 nine months ended September 30, 2015, we repurchased and retired approximately 9.7 million shares of common stock at a cost of \$2,998.2 million under our 2015 Share Repurchase Program and did not repurchase any shares of common stock under our 2011 Share Repurchase Program. During the nine months ended September 30, 2014, we purchased approximately 1.2 million shares of common stock at a cost of \$360.0 million under our 2011 Share Repurchase Program.

From October 1, 2015 through October 20, 2015, we repurchased and expect to retire approximately 3.2 million shares of common stock at a cost of \$896.3 million under our 2015 Share Repurchase Program. As of October 20, 2015, approximately \$1,105.5 million remains available to repurchase shares under this program. We expect to complete the 2015 Share Repurchase Program by the end of 2015.

Cash, Cash Equivalents and Marketable Securities

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

The increase in cash, cash equivalents and marketable securities from December 31, 2014, is primarily due to the issuance of our 2015 Senior Notes and net cash flows provided by operating activities, partially offset by purchases of our common stock, net purchases of marketable securities, income tax payments, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, the acquisition of Convergence, net purchases of property,

plant and equipment and the upfront payment made to AGTC.

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On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion, consisting of the following:

\$1.5 billion of 2.90% Senior Notes due September 15, 2020, valued at 99.792% of par;

\$1.0 billion of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;

\$1.75 billion of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and

\$1.75 billion of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

In addition to the 2015 Senior Notes, we have \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 that were originally priced at 99.184% of par.

The discounts will be amortized as additional interest expense over the period from issuance through maturity.

In August 2015, we entered into a \$1.0 billion senior unsecured revolving credit facility, under which we are permitted to draw funds for working capital and general corporate purposes for 5 years. As of

September 30, 2015, we had no outstanding borrowings under this facility.

In connection with our 2006 distribution agreement with Fumedica, we issued notes totaling 61.4 million Swiss Francs which were payable to Fumedica in varying amounts from June 2008 through June 2018. Our remaining note payable to Fumedica had a carrying value of 8.8 million Swiss Francs (\$9.1 million) and 11.6 million Swiss Francs (\$11.7 million) as of September 30, 2015 and December 31, 2014, respectively.

For a summary of the fair and carrying values of our outstanding borrowings as of September 30, 2015 and December 31, 2014, 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 from December 31, 2014 reflects an increase in total current assets of \$4,598.7 million, partially offset by an increase in current liabilities of \$414.3 million. The increase in total current assets was primarily driven by an increase in cash, cash equivalents and marketable securities due to the issuance of our 2015 Senior Notes, partially offset by purchases of our common stock, and prepaid taxes. The increase in total current liabilities primarily resulted from an increase in taxes payable and accrued expenses and other.

Cash Flows

The following table summarizes our cash flow activity:

(In millions, except percentages)	For the Nine Months Ended September 30,			% Change	%
	2015	2014			
Net cash flows provided by operating activities	\$2,675.7	\$2,009.3		33.2	%
Net cash flows used in investing activities	\$(2,746.1)	\$(1,164.7)	)	135.8	%
Net cash flows provided by (used in) financing activities	\$2,984.8	\$(242.6)	)	**	

** Percentage not meaningful.

Operating Activities

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

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

- Non-cash operating items such as depreciation and amortization, impairment charges 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.

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For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in cash provided by operating activities is primarily driven by higher net income and a decrease in the comparative growth in outstanding accounts receivable balances due to collection efforts, partially offset by a decrease in the change of accrued expenses and other current liabilities.

Investing Activities

For the nine months ended September 30, 2015, compared to the same period in 2014, the increase in net cash flows used in investing activities is primarily due to an increase in net purchases of marketable securities, an increase in the total amount of contingent consideration paid to the former shareholders of Fumapharm AG, an increase in purchases of property, plant and equipment and cash paid for the acquisition of Convergence.

Financing Activities

For the nine months ended September 30, 2015, compared to the same period in 2014, the change in net cash flows provided by financing activities is primarily due to the issuance of our 2015 Senior Notes, partially offset by an increase in the amount of common stock we repurchased.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, notes payable, and defined benefit and other purchase obligations, excluding amounts related to uncertain tax positions, amounts payable to tax authorities, funding commitments, contingent development, regulatory and commercial milestone payments, TYSABRI contingent payments and contingent consideration related to our business combinations, as described below.

In March 2015, we signed a lease for additional laboratory space in Cambridge, Massachusetts through June 2025. We are subject to future minimum rental commitments related to this lease in the amount of approximately \$55.5 million over the term of the lease.

On September 15, 2015, we issued senior unsecured notes for an aggregate principal amount of \$6.0 billion.

There have been no other material changes in our contractual obligations since December 31, 2014.

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, 2015, we have approximately \$53.9 million of liabilities associated with uncertain tax positions.

Other Funding Commitments

As of September 30, 2015, 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 \$25.0 million on our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2015. We have approximately \$680.0 million in cancellable future commitments based on existing CRO contracts as of September 30, 2015.

As of September 30, 2015, we have planned clinical trials for our ISIS-SMN_{Rx} and ISIS-DMPK_{Rx} programs which are managed by Isis. We have agreed to pay up to approximately \$140 million in payments to Isis as the trials for these programs proceed. If these trials advance and we continue with our Isis programs, it is possible that we could make a significant amount of additional development payments in the future.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of September 30, 2015, we could make potential future milestone payments to third parties of up to approximately \$2.9 billion 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, 2015, 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.

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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 purchase of the noncontrolling interests in our joint venture investments in Biogen Dompé SRL and Biogen Dompé Switzerland GmbH and our acquisitions of Convergence, Stromedix, Inc. (Stromedix), Biogen International Neuroscience GmbH (formerly Biogen Idec International Neuroscience GmbH) (BIN) and Biogen Hemophilia Inc. (formerly Biogen Idec Hemophilia Inc.) (BIH), we may pay up to approximately \$1.3 billion in remaining milestones based upon the achievement of certain events. These milestones may not be achieved. As the acquisitions of the noncontrolling interests in our joint venture investments and our 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. For additional information related to our acquisition of Convergence, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report. For additional information related to our acquisition of Stromedix, please read Note 2, Acquisitions, to our consolidated financial statements included in our 2014 Form 10-K.

BIH

In connection with our acquisition of BIH, formerly Syntonix, in January 2007, we agreed to pay up to an additional \$80.0 million if certain milestone events associated with the development of BIH's lead product, ALPROLIX are achieved. The final \$20.0 million contingent payment will occur if prior to the tenth anniversary of the closing date, a marketing authorization is granted by the EMA for ALPROLIX. This payment will be accounted for as an increase to intangible assets if achieved.

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, as defined in the acquisition agreement.

During the nine months ended September 30, 2015, we paid \$550.0 million in contingent payments as we reached the \$4.0 billion and \$5.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2014 and second quarter of 2015, respectively, and accrued \$300.0 million upon reaching \$6.0 billion in total cumulative sales of Fumapharm Products in the third quarter of 2015.

We will owe an additional \$300.0 million contingent payment for every additional \$1.0 billion in cumulative sales level of Fumapharm Products reached if the prior 12 months sales of the Fumapharm Products exceed \$3.0 billion, until such time as the cumulative sales level reaches \$20.0 billion, at which time no further contingent payments shall be due. 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 on-going basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that are believed 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 revenue 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 2014 Form 10-K. There have been no material changes to these critical accounting estimates since our 2014 Form 10-K.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

The information required by this Item is incorporated by reference to the discussion under “Quantitative and Qualitative Disclosures About Market Risk” in Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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

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Part II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

We are substantially dependent on revenues from our principal products.

Our current revenues depend upon continued sales of our principal products. We may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales and growth of TECFIDERA as we continue to expand into additional markets. 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 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 related prodrug derivatives or from off-label use by physicians of therapies indicated for other conditions to treat MS patients;
- patient dynamics, including the size of the patient population and our ability to attract new patients to our therapies;
- damage to physician and patient confidence in any of our MS products or to our sales and reputation as a result of label changes or adverse experiences or events that may occur with patients treated with our MS products;

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inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key international markets; or

our ability to obtain and maintain patent, data or market exclusivity for our MS products.

Similarly, the hemophilia treatment market is highly competitive, 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 penetrating this market if our therapies are not regarded as offering significant benefits over current treatments;

the introduction by other companies of longer-lasting or more efficacious, safer, less expensive or more convenient treatments than our therapies;

our limited marketing experience within the hemophilia treatment market, which may impact our ability to develop well-established relationships with the associated medical and scientific community; or

if one of several companies that are working to develop additional treatments for hemophilia obtains marketing approval of its treatment in the E.U. before we do, our applications with the EMA could be barred under operation of the EMA's orphan medicinal product regulation.

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, 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.

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

Our long-term viability and growth will depend upon successful development of additional indications for our existing products as well as successful development of new products and technologies resulting 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 or raise other concerns that may significantly reduce the likelihood of regulatory approval. This may result in 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.

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 substantially all 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.

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

Adverse safety events involving our marketed products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, 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 TYSABRI and in the U.S. label for TECFIDERA, may significantly reduce expected revenues for those products and require significant expense and management time.

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 government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs; and
- 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 marketing of 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. Drug pricing and other health care costs continues to be subject to intense political and societal pressures which we anticipate will continue and escalate 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.

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

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals 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 that would control the prices of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. 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 addition, under the PPACA, as states implement their health care marketplaces or operate under the federal exchange, the impact on drug manufacturers, including us, will depend in part on the formulary and benefit design decisions made by insurance sponsors or plans participating in these programs. It is possible that we may need to provide discounts or rebates to such plans in order to maintain favorable formulary access for our products for this patient population, which could have an adverse impact on our sales and results of operations.

In the European Union 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.

We depend on relationships with collaborators and other third-parties for revenue, and the development, regulatory approval process, 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 process, commercialization, and marketing of certain of our products and product candidates. Reliance on collaborative relationships subjects us to a number of risks, including:

- we may be unable to control the resources our collaborator devotes to our programs or products;
- disputes may arise with respect to ownership of rights to technology developed with our collaborator, and the underlying contract with our collaborator may fail to provide significant protection or may fail to be effectively enforced if the collaborator fails to perform;
- our collaborator's interests may not always be aligned with our interests and a collaborator 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;
- collaborations often require the parties to cooperate, and failure to do so effectively could adversely affect product sales by our collaborator 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

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any failure on the part of our collaborator 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.

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

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

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

Risks of Reliance on Third Parties and Single Source Providers. We rely on third party suppliers and manufacturers for, among other things: manufacturing of RITUXAN and GAZYVA; the majority of our clinical and commercial requirements for TECFIDERA and other small molecule products and product candidates; raw materials and supplies for production of products we manufacture; delivery devices such as syringes and auto-injectors; drug product and fill-finish operations; the majority of our final product storage; and a substantial portion of our packaging operations. In addition, 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 manufacturing facilities in Cambridge, Massachusetts, RTP, North Carolina and Hillerød, Denmark for the production of drug substance for certain of our large molecule products and product candidates, including AVONEX, TYSABRI, PLEGRIDY, ZINBRYTA, ALPROLIX and ELOCTATE. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

Risks Relating to Compliance with Current Good Manufacturing Practices. We and our third party providers are generally required to maintain compliance with current Good Manufacturing Practices 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.

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

We anticipate growth through internal development projects, commercial initiatives, and external opportunities, which may include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. The availability of high quality 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. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us 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.

To manage our current and future potential growth effectively, we need to continue to enhance our operational, financial and management processes and to expand, train and manage our employee base. Our growth is also dependent upon our ability to attract and retain qualified scientific, information technology, manufacturing, sales and marketing and executive personnel and to develop and maintain relationships with qualified clinical researchers and key distributors in a highly competitive environment. Supporting our growth initiatives and the further development of our existing products and potential new products in our pipeline will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing capabilities and other areas of our business. If we do not successfully manage our current growth and do not successfully execute our growth initiatives, then our business and financial results may be adversely affected and we may incur asset impairment or restructuring charges.

We may fail to achieve the expected financial and operating benefits of our corporate restructuring and the restructuring may harm our business and financial results.

We face significant risks associated with our corporate restructuring actions that may impair our ability to achieve anticipated savings and operational efficiencies or that may otherwise harm our business. These risks include delays in implementation of anticipated workforce reductions, loss of workforce capabilities, decreases in employee focus and morale, attrition of necessary or key employees, higher than anticipated separation expenses, litigation and the failure to meet financial and operational targets. In addition, the calculation of the anticipated cost savings and other benefits resulting from our corporate restructuring actions are subject to many estimates and assumptions. These estimates and assumptions are subject to significant business, economic, competitive and other uncertainties and contingencies, many of which are beyond our control. If these estimates and assumptions are incorrect or if we experience delays or unforeseen events, our business and financial results could be adversely affected.

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 greater restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, we along with many other pharmaceutical and biotechnology companies 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. These risks may be heightened as we continue to expand our global operations and introduce additional products to the market. 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

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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.

Examples of previously enacted and possible future changes in laws that could adversely affect our business include the enactment in the U.S. of health care reform, regulatory pathways easing the entry of competing biosimilars in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, enhanced penalties for and investigations into non-compliance with U.S. fraud and abuse laws, and compliance with the Physician Payment Sunshine Act in the U.S. and similar foreign rules and regulations that require collection and reporting of payments or other transfers of value made to physicians and teaching hospitals.

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. 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. 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. While we continue to build and improve our systems and infrastructure and believe we have taken appropriate security measures to minimize 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. 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, it could:

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

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

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

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- 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.

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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 manufacturing capacity for future clinical and commercial requirements for product candidates, which would result in the incurrence of significant investment with no assurance that such investment will be recouped.

While we believe we currently have sufficient manufacturing capacity to meet our near-term manufacturing requirements, it is probable that we would need additional manufacturing capacity to support future clinical and commercial manufacturing requirements for product candidates in our pipeline, if such candidates are successful and approved. We recently announced our intent to build a biologics manufacturing facility in Solothurn, Switzerland and our acquisition of 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.

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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. If we decide to fully or partially vacate a leased property, such as we did following our 2013 relocation of our corporate headquarters from Weston, Massachusetts to Cambridge, Massachusetts, we may incur significant cost, including lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements. 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.

Our Board of Directors has approved stock repurchase programs. The amount and timing of such 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.

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 and federal 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, or permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

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

Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing, distribution and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name. In addition, 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.

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

Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity under our 2015 Share Repurchase Program during the third quarter of 2015:

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 2015	145,289	351.71	145,289	\$4,906.7
August 2015	4,513,238	312.25	4,513,238	\$3,497.5
September 2015	4,892,530	305.70	4,892,530	\$2,001.8
Total	9,551,057	309.49		

The following table summarizes our common stock repurchase activity under our 2011 Share Repurchase Program during the third quarter of 2015:

Period	Total Number of Shares Purchased (#)	Average Price Paid per Share (\$)	Total Number of Shares Purchased as Part of Publicly Announced Programs (#)	Maximum Number of Shares That May Yet Be Purchased Under Our Programs (#)
July 2015	—	—	—	1,264,156
August 2015	—	—	—	1,264,156
September 2015	—	—	—	1,264,156
Total	—	—		

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). This authorization does not have an expiration date. Repurchased shares will be retired. The 2015 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 nine months ended September 30, 2015, we repurchased and retired approximately 9.7 million shares of common stock at a cost of \$2,998.2 million under our 2015 Share Repurchase Program and did not repurchase any shares of common stock under our 2011 Share Repurchase Program. During the nine months ended September 30, 2014, we purchased approximately 1.2 million shares of common stock at a cost of \$360.0 million under our 2011 Share Repurchase Program.

From October 1, 2015 through October 20, 2015, we repurchased and expect to retire approximately 3.2 million shares of common stock at a cost of \$896.3 million under our 2015 Share Repurchase Program. During this time, we paid an average price per share of \$276.09. As of October 20, 2015, approximately \$1,105.5 million remains available to repurchase shares under this 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.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOGEN INC.

/s/ Paul J. Clancy
Paul J. Clancy
Executive Vice President and
Chief Financial Officer
(principal financial officer)
October 21, 2015

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EXHIBIT INDEX

Exhibit Number	Description of Exhibit
4.1+++	Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015.
4.2+++	First Supplemental Indenture, dated September 15, 2015, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015.
10.1+++	Credit Agreement, dated August 28, 2015, between Biogen Inc., Bank of America, N.A., as administrative agent, swing line lender and an L/C issuer, and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015.
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, 2015, 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
 +++ Previously filed