BIOGEN INC.
Form 10-Q
April 24, 2019

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

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

For the quarterly period ended March 31, 2019
OR

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

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

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

225 Binney Street, Cambridge, MA 02142
(617) 679-2000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes x No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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

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

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

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of April 19, 2019, was 193,893,397 shares.

Table of Contents

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2019
TABLE OF CONTENTS

		Page
PART I — FINANCIAL INFORMATION		
Item 1.	Financial Statements (unaudited)	
	Condensed Consolidated Statements of Income — For the Three Months Ended March 31, 2019 and 2018	5
	Condensed Consolidated Statements of Comprehensive Income — For the Three Months Ended March 31, 2019 and 2018	6
	Condensed Consolidated Balance Sheets — As of March 31, 2019 and December 31, 2018	7
	Condensed Consolidated Statements of Cash Flows — For the Three Months Ended March 31, 2019 and 2018	8
	Condensed Consolidated Statements of Equity — For the Three Months Ended March 31, 2019 and 2018	9
	Notes to Condensed Consolidated Financial Statements	11
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	43
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	64
Item 4.	Controls and Procedures	67
PART II — OTHER INFORMATION		
Item 1.	Legal Proceedings	68
Item 1A.	Risk Factors	68
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	83
Item 6.	Exhibits	83
Signatures		85

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration, acquisition or divestiture agreements; tax positions and contingencies;
- collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from generics, biosimilars, prodrugs and other products approved under abbreviated regulatory pathways;
- our plans and investments in our core and emerging growth areas, as well as implementation of our 2017 corporate strategy;
- the drivers for growing our business, including our plans and intention to commit resources relating to research and development programs and business development opportunities, as well as the potential benefits and results of, and the anticipated timing to complete, certain business development transactions, including acquisitions and divestitures;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the costs and timing of potential clinical trials, filings and approvals, and the potential therapeutic scope of the development and commercialization of our and our collaborators’ pipeline products;
- adverse safety events involving our marketed products or generic or biosimilar versions of our marketed products;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities, including anticipated investments and divestitures, and activities in new or existing manufacturing facilities;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact on our results of operations and liquidity of the United Kingdom's (U.K.) intent to voluntarily depart from the European Union (E.U.);
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, regulatory requirements, judicial decisions and accounting standards; and
- the anticipated costs and tax treatment of the spin-off of our hemophilia business.

Table of Contents

These forward-looking statements involve risks and uncertainties, including those that are described in Item 1A. Risk Factors included in this report and elsewhere in this report that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

- "Biogen," the "company," "we," "us" and "our" refer to Biogen Inc. and its consolidated subsidiaries; and
- "RITUXAN" refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan).

NOTE REGARDING TRADEMARKS

AVONEX®, PLEGRIDY®, RITUXAN®, RITUXAN HYCELA®, SPINRAZA®, TECFIDERA®, TYSABRI® and ZINBRYTA® are registered trademarks of Biogen.

BENEPALI™, FLIXABI™, FUMADERM™ and IMRALDI™ are trademarks of Biogen.

ENBREL®, FAMPYRA™, GAZYVA®, HUMIRA®, OCREVUS®, REMICADE®, SkySTAR™ and other trademarks referenced in this report are the property of their respective owners.

Table of Contents

PART I FINANCIAL INFORMATION

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

	For the Three Months Ended March 31,	
	2019	2018
Revenues:		
Product, net	$2,680.0	$2,523.5
Revenues from anti-CD20 therapeutic programs	517.4	443.2
Other	292.4	164.4
Total revenues	3,489.8	3,131.1
Cost and expenses:		
Cost of sales, excluding amortization and impairment of acquired intangible assets	602.0	446.0
Research and development	563.7	496.7
Selling, general and administrative	567.7	501.3
Loss on assets and liabilities held for sale	115.5	—
Amortization and impairment of acquired intangible assets	68.2	103.9
Collaboration profit (loss) sharing	58.1	42.5
Acquired in-process research and development	—	10.0
Loss (gain) on fair value remeasurement of contingent consideration	11.5	(5.6)
Restructuring charges	0.4	1.6
Total cost and expenses	1,987.1	1,596.4
Income from operations	1,502.7	1,534.7
Other income (expense), net	357.3	(41.0)
Income before income tax expense and equity in loss of investee, net of tax	1,860.0	1,493.7
Income tax expense	422.5	322.5
Equity in loss of investee, net of tax	28.7	—
Net income	1,408.8	1,171.2
Net income (loss) attributable to noncontrolling interests, net of tax	—	(1.7)
Net income attributable to Biogen Inc.	$1,408.8	$1,172.9
Net income per share:		
Basic earnings per share attributable to Biogen Inc.	$7.17	$5.55
Diluted earnings per share attributable to Biogen Inc.	$7.15	$5.54
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	196.6	211.4
Diluted earnings per share attributable to Biogen Inc.	197.0	211.7

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	For the Three Months Ended March 31,	
	2019	2018
Net income attributable to Biogen Inc.	$1,408.8	$1,172.9
Other comprehensive income:		
Unrealized gains (losses) on securities available for sale, net of tax	6.9	(2.2)
Unrealized gains (losses) on cash flow hedges, net of tax	16.9	(29.0)
Gains (losses) on net investment hedges	14.0	—
Unrealized gains (losses) on pension benefit obligation, net of tax	0.6	(0.5)
Currency translation adjustment	(17.8)	44.7
Total other comprehensive income (loss), net of tax	20.6	13.0
Comprehensive income attributable to Biogen Inc.	1,429.4	1,185.9
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	—	(1.7)
Comprehensive income	$1,429.4	$1,184.2

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	As of March 31, 2019	As of December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$2,243.2	$1,224.6
Marketable securities	1,665.8	2,313.4
Accounts receivable, net	2,088.9	1,958.5
Due from anti-CD20 therapeutic programs	527.1	526.9
Inventory	770.2	929.9
Assets held for sale	682.0	—
Other current assets	965.4	687.6
Total current assets	8,942.6	7,640.9
Marketable securities	1,372.7	1,375.9
Property, plant and equipment, net	3,013.8	3,601.2
Operating lease assets	447.8	—
Intangible assets, net	3,056.2	3,120.0
Goodwill	5,639.7	5,706.4
Deferred tax asset	2,074.4	2,153.9
Investments and other assets	1,898.3	1,690.6
Total assets	$26,445.5	$25,288.9
LIABILITIES AND EQUITY		
Current liabilities:		
Taxes payable	238.5	63.5
Accounts payable	378.0	370.5
Liabilities held for sale	97.2	—
Accrued expenses and other	2,435.0	2,861.2
Total current liabilities	3,148.7	3,295.2
Notes payable	5,943.2	5,936.5
Deferred tax liability	1,741.7	1,636.2
Long-term operating lease liabilities	436.1	—
Other long-term liabilities	1,353.8	1,389.4
Total liabilities	12,623.5	12,257.3
Commitments and contingencies		
Equity:		
Biogen Inc. shareholders' equity:		
Preferred stock, par value $0.001 per share	—	—
Common stock, par value $0.0005 per share	0.1	0.1
Additional paid-in capital	—	—
Accumulated other comprehensive loss	(219.8)	(240.4)
Retained earnings	17,026.7	16,257.0
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	13,829.9	13,039.6
Noncontrolling interests	(7.9)	(8.0)

Total equity	13,822.0	13,031.6
Total liabilities and equity	$26,445.5	$25,288.9

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	For the Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income	$1,408.8	$1,171.2
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and impairments	121.1	168.9
Acquired in-process research and development	—	10.0
Share-based compensation	45.7	43.4
Contingent consideration	11.5	(5.6)
Loss on assets and liabilities held for sale	115.5	—
Deferred income taxes	228.0	53.1
Unrealized (gain) loss on strategic investments	(375.0)	—
Other	50.7	31.7
Changes in operating assets and liabilities, net:		
Accounts receivable	(136.6)	(134.0)
Inventory	129.0	2.6
Accrued expenses and other current liabilities	(138.4)	(121.8)
Income tax assets and liabilities	170.3	257.6
Other changes in operating assets and liabilities, net	(171.1)	(20.0)
Net cash flows provided by operating activities	1,459.5	1,457.1
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	1,489.2	4,068.9
Purchases of marketable securities	(825.0)	(1,919.2)
Contingent consideration paid related to Fumapharm AG acquisition	(300.0)	(600.0)
Purchases of property, plant and equipment	(127.1)	(194.7)
Acquired in-process research and development	—	(10.0)
Other	1.7	1.6
Net cash flows provided by investing activities	238.8	1,346.6
Cash flows from financing activities:		
Purchases of treasury stock	(655.8)	(250.0)
Payments related to issuance of stock for share-based compensation arrangements, net	(32.2)	(21.2)
Other	8.7	2.6
Net cash flows used in financing activities	(679.3)	(268.6)
Net increase (decrease) in cash and cash equivalents	1,019.0	2,535.1
Effect of exchange rate changes on cash and cash equivalents	(0.4)	(0.9)
Cash and cash equivalents, beginning of the period	1,224.6	1,573.8
Cash and cash equivalents, end of the period	$2,243.2	$4,108.0

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2018	—	$ —	221.0	$ 0.1	$ —	$ (240.4)	$ 16,257.0	(23.8)	$ (2,977.1)	$ 13,039.6	$ (8.0)	$ 13,031.6
Net income							1,408.8			1,408.8	—	1,408.8
Other comprehensive income (loss), net of tax						20.6				20.6	—	20.6
Capital contribution by noncontrolling interest										—	0.1	0.1
Repurchase of common stock pursuant to the 2018 Share Repurchase Program, at cost								(2.4)	(655.8)	(655.8)		(655.8)
Retirement of common stock pursuant to the 2018 Share Repurchase Program, at cost			(2.4)	—	(65.6)		(590.2)	2.4	655.8	—		—
Issuance of common stock under stock option and stock purchase plans			0.1	—	16.6					16.6		16.6
Issuance of common stock under stock award plan			0.3	—	—		(48.9)			(48.9)		(48.9)
Compensation related to share-based payments					49.0					49.0		49.0
Balance, March 31, 2019	—	$ —	219.0	$ 0.1	$ —	$ (219.8)	$ 17,026.7	(23.8)	$ (2,977.1)	$ 13,829.9	$ (7.9)	$ 13,822.0

See accompanying notes to these unaudited condensed consolidated financial statements.

Table of Contents

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

	Preferred stock	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Shares	Amount				Shares	Amount			
Balance, December 31, 2017	—	235.3	$0.1	$97.8	$(318.4)	$15,810.4	(23.8)	$(2,977.1)	$12,612.8	$(14.7)	$12,598.1
Net income						1,172.9			1,172.9	(1.7)	1,171.2
Other comprehensive income (loss), net of tax					13.0				13.0	0.2	13.2
Repurchase of common stock pursuant to the 2016 Share Repurchase Program, at cost							(0.9)	(250.0)	(250.0)		(250.0)
Retirement of common stock pursuant to the 2016 Share Repurchase Program, at cost		(0.9)	—	(122.9)		(127.1)	0.9	250.0	—		—
Issuance of common stock under stock option and stock purchase plans		0.1	—	16.2					16.2		16.2
Issuance of common stock under stock award plan		0.3	—	(37.8)					(37.8)		(37.8)
Compensation related to share-based payments				46.7					46.7		46.7
Adoption of new accounting guidance					1.5	478.4			479.9		479.9
Balance, March 31, 2018	—	234.8	$0.1	$—	$(303.9)	$17,334.6	(23.8)	$(2,977.1)	$14,053.7	$(16.2)	$14,037.5

See accompanying notes to these unaudited condensed consolidated financial statements.

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

1. Summary of Significant Accounting Policies

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

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology, Alzheimer's disease (AD) and dementia, movement disorders, including Parkinson's disease, and neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS). We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of acute neurology, neurocognitive disorders, pain and ophthalmology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy in our core and emerging growth areas. We also commercialize biosimilars of advanced biologics.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS, SPINRAZA for the treatment of SMA and FUMADERM for the treatment of severe plaque psoriasis. We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL, GAZYVA for the treatment of CLL and follicular lymphoma, OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS) and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018 (2018 Form 10-K).

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities. For over two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as the development of next generation therapies for MS, with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including Parkinson's disease, ALS, progressive supranuclear palsy, AD, stroke, epilepsy, cognitive impairment associated with schizophrenia and pain.

Our innovative drug development and commercialization activities are complemented by our biosimilar products that expand access to medicines and reduce the cost burden for healthcare systems. Through Samsung Bioepis Co., Ltd. (Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics), we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, FLIXABI, an infliximab biosimilar referencing REMICADE, and IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the European Union (E.U.). For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to these unaudited condensed consolidated financial statements (condensed consolidated financial statements).

Basis of Presentation

In the opinion of management, our condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The information included in this quarterly report on Form 10-Q should be read in conjunction with our audited consolidated financial statements and the accompanying notes included in our 2018 Form 10-K. Our accounting policies are described in the

"Notes to Consolidated Financial Statements" in our 2018 Form 10-K and updated, as necessary, in this report. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2019, are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

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

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

Consolidation

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

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

Use of Estimates

The preparation of our condensed consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates.

Assets and Liabilities Held For Sale

Upon determining that a long-lived asset or disposal group meets the criteria to be classified as held for sale, we cease depreciation and separately present such assets and liabilities of the disposal group in our condensed consolidated balance sheet. We initially measure a long-lived asset or disposal group that is classified as held for sale at the lower of its carrying value or fair value less any costs to sell. Any loss resulting from this measurement is recognized in the period in which the held-for-sale criteria are met. Conversely, gains are not recognized on the sale of a long-lived asset or disposal group until the date of sale. We assess the fair value of a long-lived asset or disposal group less any costs to sell each reporting period it remains classified as held for sale and recognize any subsequent changes as an adjustment to the carrying value of the asset or disposal group, as long as the remeasured carrying value does not exceed the carrying value less costs to sell of the asset or disposal group at the time it was initially classified as held for sale.

New Accounting Pronouncements

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

Leases

In February 2016 the FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), a new standard issued to increase transparency and comparability among organizations related to their leasing activities. This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and lease liabilities on their balance sheet that arise from leases as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

12

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

The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU No. 2018-10, Codification Improvements to Topic 842, Leases, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, ASU No. 2018-20, Narrow-Scope Improvement for Lessors, and ASU No. 2019-01, Leases (Topic 842): Codification Improvements. We adopted these amendments with ASU 2016-02 (collectively, the new leasing standards) effective January 1, 2019.

We adopted the new leasing standards using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, we elected the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within our condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in our condensed consolidated statements of income over the lease term. Upon adoption of the new leasing standards we recognized an operating lease asset of approximately $463.0 million and a corresponding operating lease liability of approximately $526.0 million, which are included in our condensed consolidated balance sheet. The adoption of the new leasing standards did not have an impact on our condensed consolidated statements of income.

We determine if an arrangement is a lease at contract inception. Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. We use the implicit rate when readily determinable and use our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. Our incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

The lease payments used to determine our operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in our operating lease assets in our condensed consolidated balance sheets. In addition, our contracts contain lease and non-lease components. We separate lease payments for the identified assets from any non-lease payments included in the contract. For certain equipment leases, such as vehicles, we apply a portfolio approach to effectively account for the operating lease assets and liabilities.

Our operating leases are reflected in operating lease assets, accrued expenses and other and in long-term operating lease liabilities in our condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We also have real estate lease agreements which are subleased to third parties. Operating leases for which we are the sublessor are included in accrued expenses and other and other long-term liabilities in our condensed consolidated balance sheets. We recognize sublease income on a straight-line basis over the lease term in our condensed consolidated statements of income.

For additional information on the adoption of the new leasing standards, please read Note 11, Leases, to these condensed consolidated financial statements.

Credit Losses

In June 2016 the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be

recorded instead of reducing the amortized cost of the investment. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases.

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

This standard will become effective for us on January 1, 2020, and requires adoption using a modified retrospective approach, with certain exceptions. Based on the composition of our investment portfolio, current market conditions and historical credit loss activity, the adoption of this standard is not expected to have a material impact on our consolidated financial position and results of operations and related disclosures.

Debt Securities

In March 2017 the FASB issued ASU No. 2017-08, Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities. This standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period to the earliest call date. This standard became effective for us on January 1, 2019, and was adopted using a modified retrospective transition approach. The adoption of this standard did not result in a significant adjustment to our marketable debt securities.

Fair Value Measurements

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

Derivative Instruments and Hedging Activities

In October 2018 the FASB issued ASU No. 2018-16, Derivatives and Hedging (Topic 815): Inclusion of the Secured Overnight Financing Rate (SOFR) Overnight Index Swap (OIS) Rate as a Benchmark Interest Rate for Hedge Accounting Purposes. This standard permits the use of the OIS rate based on the SOFR as a United States (U.S.) benchmark interest rate for hedge accounting purposes under Accounting Standards Codification (ASC) 815, Derivative and Hedging. This standard became effective for us on January 1, 2019, and did not have an impact on our condensed consolidated results of operations or financial position.

Collaborative Arrangements

In November 2018 the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard will become effective for us on January 1, 2020; however, early adoption is permitted. A retrospective transition approach is required for either all contracts or only for contracts that are not completed at the date of initial application of ASC 606, with a cumulative adjustment to opening retained earnings, as of January 1, 2018. We are currently evaluating the potential impact that this standard may have on our consolidated financial position, results of operations and related disclosures.

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

2. Acquisitions

Proposed Acquisition of Nightstar Therapeutics plc

In March 2019 we entered into an agreement to acquire Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. NST's lead asset is NSR-REP1 for the potential treatment of choroideremia, a rare, degenerative, X-linked inherited retinal disorder, which leads to blindness and has no approved treatments. NST’s second clinical program is NSR-RPGR for the potential treatment of X-linked retinitis pigmentosa, which is a rare inherited retinal disease with no approved treatments.

Under the terms of the proposed acquisition, we would pay NST shareholders $25.50 in cash for each issued and outstanding NST share, which represents an expected total transaction value of approximately $800.0 million on a fully diluted basis, after expected transaction expenses and anticipated cash acquired at closing. We plan to fund the proposed acquisition of NST through available cash and to account for it as an acquisition of a business.

It is intended that the proposed acquisition will be implemented by means of a U.K. Court-sanctioned scheme of arrangement under Part 26 of the U.K. Companies Act 2006. The proposed acquisition remains subject to customary closing conditions, including the approval by NST shareholders and the issuance of an order by the U.K. Court. We expect to complete the proposed acquisition by mid-year 2019.

3. Divestitures

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation (FUJIFILM) under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. Upon closing of the proposed transaction, we expect to receive up to $890.0 million in cash, subject to certain working capital adjustments and other contractual terms.

As part of the proposed transaction, we have provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we expect to incur an adverse commitment obligation of approximately $120.0 million associated with such guarantees. We may adjust this estimate based upon changes in business conditions, which may result in the recognition of additional losses. We are also obligated to indemnify FUJIFILM for liabilities that may exist relating to certain business activities incurred prior to the closing of the proposed transaction.

In addition, we may earn certain contingent payments based on future manufacturing activities at the Hillerød facility. For the disposition of a business, our policy is to recognize contingent consideration when the consideration is realizable. We currently believe the probability of earning these payments is remote and therefore we have not included these contingent payments in our estimate of the fair value of the operations.

As part of the proposed transaction, we also expect to enter into certain manufacturing services agreements with FUJIFILM pursuant to which FUJIFILM would use the Hillerød facility to produce commercial products for us, such as TYSABRI, as well as other third-party products.

We determined that the operations to be disposed of in the proposed transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

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

In February 2019 the assets and liabilities related to our Hillerød, Denmark manufacturing operations met the criteria to be classified as held for sale. The following table presents information related to the carrying value of the major classes of assets and liabilities that were reclassified as held for sale in our condensed consolidated balance sheets:

(In millions)	As of March 31, 2019
Assets:	
Inventory	$27.0
Property, plant and equipment, net	629.7
Operating lease assets	2.5
Goodwill	69.5
Other assets	68.8
Valuation allowance on disposal group on assets held for sale	(115.5)
Assets held for sale	$682.0
Liabilities:	
Accrued expenses and other liabilities	$49.0
Long-term operating lease liabilities	1.7
Deferred tax liability	46.5
Liabilities held for sale	$97.2

In the first quarter of 2019 we recorded a loss of approximately $174.6 million in our condensed consolidated statements of income. This estimated loss includes a pre-tax loss of $115.5 million reflecting our current estimated fair value of the assets and liabilities held for sale, adjusting for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately $10.0 million and our estimate of the fair value of an adverse commitment of approximately $120.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. In addition, we recorded a tax expense of $59.1 million related to the proposed transaction.

Our total estimated loss is based on current exchange rates and business conditions, and any changes to these factors through the closing date of the transaction will result in adjustments to the carrying values of the related assets and liabilities as well as a corresponding adjustment to the loss amount recognized on the sale.

Following the closing of the proposed transaction, the final purchase price will be adjusted by an amount equal to the difference between our current estimates of working capital and inventory balances that will be transferred to FUJIFILM and the amounts that are ultimately transferred.

Our estimate of the fair value of assets and liabilities expected to be sold to FUJIFILM is a Level 3 measurement and is based on the expected consideration from the sale, including the valuation of the adverse commitment, as discussed above.

The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act. We expect to complete the proposed transaction in the second half of 2019.

In addition, upon closing of the proposed transaction, we expect to separately sell certain raw materials remaining at the Hillerød facility to FUJIFILM at carrying value.

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

4. Revenues

Product Revenues

Revenues by product are summarized as follows:

(In millions)	For the Three Months Ended March 31, 2019			2018		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$717.7	$281.1	$998.8	$728.9	$258.0	$986.9
Interferon*	327.3	173.6	500.9	371.4	178.9	550.3
TYSABRI	245.0	215.4	460.4	249.7	212.4	462.1
FAMPYRA	—	22.9	22.9	—	24.4	24.4
ZINBRYTA	—	—	—	—	1.4	1.4
Subtotal: MS product revenues	1,290.0	693.0	1,983.0	1,350.0	675.1	2,025.1
Spinal Muscular Atrophy:						
SPINRAZA	223.3	295.2	518.5	188.0	175.9	363.9
Biosimilars:						
BENEPALI	—	124.0	124.0	—	120.9	120.9
FLIXABI	—	14.7	14.7	—	6.6	6.6
IMRALDI	—	35.7	35.7	—	—	—
Subtotal: Biosimilar product revenues	—	174.4	174.4	—	127.5	127.5
Other:						
FUMADERM	—	4.1	4.1	—	7.0	7.0
Total product revenues	$1,513.3	$1,166.7	$2,680.0	$1,538.0	$985.5	$2,523.5

*Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 31.3% and 14.2% of gross product revenues for the three months ended March 31, 2019, and 34.0% and 15.9% of gross product revenues for the three months ended March 31, 2018.

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, 2018	$ 127.8	$ 888.8	$ 34.7	$1,051.3
Current provisions relating to sales in current year	141.2	680.3	4.7	826.2
Adjustments relating to prior years	0.3	(25.1)	0.3	(24.5)
Payments/credits relating to sales in current year	(60.8)	(233.9)	(0.1)	(294.8)
Payments/credits relating to sales in prior years	(92.1)	(378.1)	(4.6)	(474.8)
Balance, as of March 31, 2019	$ 116.4	$ 932.0	$ 35.0	$1,083.4

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

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

(In millions)	As of March 31, 2019	As of December 31, 2018
Reduction of accounts receivable, net	$175.8	$ 176.6
Component of accrued expenses and other	907.6	874.7
Total revenue-related reserves	$1,083.4	$ 1,051.3

Revenues from Anti-CD20 Therapeutic Programs

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

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Biogen’s share of pre-tax profits in the U.S. for RITUXAN, RITUXAN HYCELA and GAZYVA	$390.8	$349.6
Other revenues from anti-CD20 therapeutic programs	126.6	93.6
Total revenues from anti-CD20 therapeutic programs	$517.4	$443.2

For additional information on our collaboration arrangements with Genentech, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Other Revenues

Other revenues are summarized as follows:

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Revenues from collaborative and other relationships:		
(Loss) profit earned under our 50% share of the co-promotion losses on ZINBRYTA in the U.S. with AbbVie	$(0.4)	$(4.7)
Revenues earned under our technical development agreement, manufacturing services agreements and royalty revenues on biosimilar products with Samsung Bioepis	24.8	17.9
Other royalty and corporate revenues:		
Royalty	3.9	10.6
Other corporate	264.1	140.6
Total other revenues	$292.4	$164.4

Other corporate revenues primarily reflect amounts earned under contract manufacturing agreements with our strategic partners, including Bioverativ Inc. (Bioverativ). During the three months ended March 31, 2019 and 2018, we recognized $206.8 million and $47.0 million, respectively, in revenues under the manufacturing and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business.

For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to these condensed consolidated financial statements. For additional information on our collaboration arrangement with AbbVie Inc. (AbbVie), please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K. For additional information on our contract manufacturing agreements with Bioverativ, please read Note 3, Hemophilia Spin-Off, to our consolidated financial statements included in our 2018 Form 10-K.

18

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

5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of March 31, 2019	As of December 31, 2018
Raw materials	$199.7	$ 196.3
Work in process	462.3	606.7
Finished goods	108.2	133.5
Total inventory	$770.2	$ 936.5
Balance Sheet Classification:		
Inventory	$770.2	$ 929.9
Investments and other assets	—	6.6
Total inventory	$770.2	$ 936.5

During the three months ended March 31, 2019, we sold hemophilia related inventory to Bioverativ with a cost basis totaling $173.5 million pursuant to the terms of the manufacture and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business.

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

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. Upon closing of the proposed transaction, we expect to receive up to $890.0 million in cash, subject to certain working capital adjustments and other contractual terms. As a result, $27.0 million of work in process inventory was reclassified to assets held for sale in our condensed consolidated balance sheets as of March 31, 2019. Following the closing of the proposed transaction, the final purchase price will be adjusted by an amount equal to the difference between our current estimates of working capital and inventory balances that will be transferred to FUJIFILM and the amounts that are ultimately transferred. In addition, upon closing of the proposed transaction, we expect to separately sell certain raw materials remaining at the Hillerød facility to FUJIFILM at carrying value.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

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

6. Intangible Assets and Goodwill

Intangible Assets

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

		As of March 31, 2019			As of December 31, 2018		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	$543.3	$ (542.4)	$0.9	$543.3	$ (542.3)	$1.0
Developed technology	15-23 years	3,005.3	(2,744.1)	261.2	3,005.3	(2,734.8)	270.5
In-process research and development	Indefinite until commercialization	480.5	—	480.5	476.0	—	476.0
Trademarks and tradenames	Indefinite	64.0	—	64.0	64.0	—	64.0
Acquired and in-licensed rights and patents	4-18 years	3,638.7	(1,389.1)	2,249.6	3,638.7	(1,330.2)	2,308.5
Total intangible assets		$7,731.8	$ (4,675.6)	$3,056.2	$7,727.3	$ (4,607.3)	$3,120.0

For the three months ended March 31, 2019, amortization and impairment of acquired intangible assets totaled $68.2 million, compared to $103.9 million in the prior year comparative period. The decrease in amortization and impairment of acquired intangible asset was primarily due to a net overall decrease in our expected rate of amortization for acquired intangible assets. This was primarily due to lower amortization subsequent to the impairment in the fourth quarter of 2018 of the U.S. license to Forward Pharma A/S' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, and higher expected lifetime revenues of TYSABRI. For the three months ended March 31, 2019 and 2018, we had no impairment charges.

Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of March 31, 2019, was $256.2 million.

Acquired and In-licensed Rights and Patents

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Pharma International Ltd., an affiliate of Elan Corporation plc. Acquired and in-licensed rights and patents also includes our rest of world license to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, and other amounts related to our other marketed products and other programs acquired through business combinations. The net book value of the TYSABRI asset as of March 31, 2019, was $1,980.8 million and the net book value of the TECFIDERA asset as of March 31, 2019, was $63.1 million. For additional information on our TECFIDERA license rights, please read Note 7, Intangible Assets and Goodwill, to our consolidated financial statements included in our 2018 Form 10-K.

Estimated Future Amortization of Intangible Assets

Our amortization expense is based on the economic consumption and impairment of intangible assets. Our most significant intangible assets are related to our TYSABRI, AVONEX, SPINRAZA and TECFIDERA products and other programs acquired through business combinations. Annually, during our long-range planning cycle, we perform an analysis of anticipated lifetime revenues of our TYSABRI, AVONEX, SPINRAZA and TECFIDERA products. This analysis is also updated whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of any of these products. Impairments are recorded in the period in which they are incurred.

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

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

(In millions)	As of March 31, 2019
2019 (remaining nine months)	$200.0
2020	290.0
2021	250.0
2022	250.0
2023	230.0
2024	190.0

Goodwill

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

(In millions)	As of March 31, 2019
Goodwill, beginning of period	$5,706.4
Reclassification of goodwill to assets held for sale	(69.5)
Other	2.8
Goodwill, end of period	$5,639.7

The reclassification of goodwill to assets held for sale relates to an allocation based upon the relative fair value of the proposed divestiture of our Hillerød, Denmark manufacturing operations.

During the three months ended March 31, 2019, goodwill was reviewed for impairment due to the proposed divestiture of our Hillerød, Denmark manufacturing operations, and based upon this review, no impairments were recognized. As of March 31, 2019, we had no accumulated impairment losses related to goodwill.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

Other includes changes related to foreign currency exchange rate fluctuations.

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

7. Fair Value Measurements

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

As of March 31, 2019 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$1,881.9	$ —	$ 1,881.9	$ —
Marketable debt securities:				
Corporate debt securities	1,835.7	—	1,835.7	—
Government securities	921.3	—	921.3	—
Mortgage and other asset backed securities	281.5	—	281.5	—
Marketable equity securities	904.0	19.5	884.5	—
Derivative contracts	104.4	—	104.4	—
Plan assets for deferred compensation	29.4	—	29.4	—
Total	$5,958.2	$ 19.5	$ 5,938.7	$ —
Liabilities:				
Derivative contracts	$24.1	$ —	$ 24.1	$ —
Contingent consideration obligations	421.3	—	—	421.3
Total	$445.4	$ —	$ 24.1	$ 421.3

As of December 31, 2018 (In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$705.5	$ —	$ 705.5	$ —
Marketable debt securities:				
Corporate debt securities	2,459.2	—	2,459.2	—
Government securities	969.6	—	969.6	—
Mortgage and other asset backed securities	260.5	—	260.5	—
Marketable equity securities	615.4	51.7	563.7	—
Derivative contracts	66.9	—	66.9	—
Plan assets for deferred compensation	25.4	—	25.4	—
Total	$5,102.5	$ 51.7	$ 5,050.8	$ —
Liabilities:				
Derivative contracts	$24.6	$ —	$ 24.6	$ —
Contingent consideration obligations	409.8	—	—	409.8
Total	$434.4	$ —	$ 24.6	$ 409.8

There have been no impairments of our assets measured and carried at fair value during the three months ended March 31, 2019. In addition, there were no changes in valuation techniques or inputs utilized or transfers between fair value measurement levels during the three months ended March 31, 2019. The fair value of Level 2 instruments classified as cash equivalents, marketable debt securities and our marketable equity security investment in Ionis Pharmaceuticals, Inc. (Ionis) were determined through third-party pricing services or an option pricing valuation model. For additional information on our agreement with Ionis, please read Note 19, Collaborative and Other

Relationships, to our consolidated financial statements included in our 2018 Form 10-K. For a description of our validation procedures related to prices provided by third-party pricing services and our option pricing valuation

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

model, please read Note 1, Summary of Significant Accounting Policies - Fair Value Measurements, to our consolidated financial statements included in our 2018 Form 10-K.

Debt Instruments

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

(In millions)	As of March 31, 2019		As of December 31, 2018	
	Fair Value	Carrying Value	Fair Value	Carrying Value
2.900% Senior Notes due September 15, 2020	$1,500.7	$1,486.6	$1,489.5	$1,480.8
3.625% Senior Notes due September 15, 2022	1,022.0	995.8	1,000.4	995.5
4.050% Senior Notes due September 15, 2025	1,795.1	1,738.2	1,745.1	1,737.8
5.200% Senior Notes due September 15, 2045	1,838.0	1,722.6	1,802.6	1,722.4
Total	$6,155.8	$5,943.2	$6,037.6	$5,936.5

The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. For additional information on our debt instruments, please read Note 12, Indebtedness, to our consolidated financial statements included in our 2018 Form 10-K.

Contingent Consideration Obligations

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

(In millions)	For the Three Months Ended March 31,	
	2019	2018
Fair value, beginning of period	$409.8	$523.6
Changes in fair value	11.5	(5.6)
Payments	—	(20.0)
Fair value, end of period	$421.3	$498.0

As of March 31, 2019 and December 31, 2018, $274.0 million and $265.0 million, respectively, of the fair value of our total contingent consideration obligations was reflected as a component of other long-term liabilities in our condensed consolidated balance sheets with the remaining balance reflected as a component of accrued expenses and other.

For the three months ended March 31, 2019, changes in the fair value of our contingent consideration obligations were primarily due to changes in the expected timing of the achievement of certain remaining development milestones, a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

For the three months ended March 31, 2018, changes in the fair value of our contingent consideration obligations were primarily due to an increase in the interest rate used to revalue our contingent consideration liabilities during the period.

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

8. Financial Instruments

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

(In millions)	As of March 31, 2019	As of December 31, 2018
Commercial paper	$446.0	$ 231.2
Overnight reverse repurchase agreements	192.7	—
Money market funds	1,074.4	279.5
Short-term debt securities	168.8	194.8
Total	$1,881.9	$ 705.5

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

Our marketable equity securities gains (losses) are recorded in other income (expense), net in our condensed consolidated statements of income. The following tables summarize our marketable debt and equity securities:

As of March 31, 2019 (In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities				
Current	$ 981.0	$ 0.5	$ (0.1)	$981.4
Non-current	852.0	2.8	(0.5)	854.3
Government securities				
Current	683.6	0.2	(0.1)	683.7
Non-current	237.5	0.3	(0.2)	237.6
Mortgage and other asset backed securities				
Current	0.7	—	—	0.7
Non-current	280.3	0.8	(0.3)	280.8
Total marketable debt securities	$ 3,035.1	$ 4.6	$ (1.2)	$3,038.5
Marketable equity securities, non-current	489.3	421.7	(7.0)	904.0

As of December 31, 2018 (In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities				
Current	$ 1,608.4	$ —	$ (0.9)	$1,607.5
Non-current	854.9	0.7	(3.9)	851.7
Government securities				
Current	706.1	0.1	(0.4)	705.8
Non-current	264.0	0.1	(0.3)	263.8
Mortgage and other asset backed securities				
Current	0.1	—	—	0.1
Non-current	260.5	0.4	(0.5)	260.4
Total marketable debt securities	$ 3,694.0	$ 1.3	$ (6.0)	$3,689.3
Marketable equity securities, non-current	496.2	127.7	(8.5)	615.4

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

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

	As of March 31, 2019		As of December 31, 2018	
(In millions)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in one year or less	$1,665.3	$1,665.8	$2,314.6	$2,313.4
Due after one year through five years	1,234.8	1,237.8	1,235.9	1,232.7
Due after five years	135.0	134.9	143.5	143.2
Total available-for-sale securities	$3,035.1	$3,038.5	$3,694.0	$3,689.3

The average maturity of our marketable debt securities available-for-sale as of March 31, 2019 and December 31, 2018, were approximately 12 months.
Proceeds from Marketable Debt Securities
The proceeds from maturities and sales of marketable debt securities and resulting realized gains and losses are summarized as follows:

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Proceeds from maturities and sales	$1,489.2	$4,068.9
Realized gains	$0.6	$1.8
Realized losses	$(0.3)	$(9.4)

Strategic Investments
As of March 31, 2019, our strategic investment portfolio was comprised of investments totaling $1,049.7 million, of which $90.1 million was reflected as a component of other current assets in our condensed consolidated balance sheet, with the remaining balance included in investments and other assets. As of December 31, 2018, our strategic investment portfolio was comprised of investments totaling $676.3 million, which is included in investments and other assets in our condensed consolidated balance sheet.
Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies, which are reflected within our disclosures included in Note 7, Fair Value Measurements, to these condensed consolidated financial statements, venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.
Our investments in equity securities include approximately 11.5 million shares of Ionis' common stock, acquired in June 2018 at a cost of approximately $625.0 million, which is remeasured each reporting period and carried at fair value. This investment is classified as a Level 2 marketable security due to certain holding period restrictions. The remainder of our investments in equity securities of certain publicly-traded biotechnology companies are regularly measured and carried at fair value and classified as Level 1. The effect of the holding period restrictions on our Ionis stock valuation are estimated using an option pricing valuation model. The most significant assumptions within the model are the term of the restrictions and the stock price volatility, which is based upon historical volatility of similar companies. We also use a constant maturity risk-free interest rate to match the remaining term of the restrictions on our investment in Ionis' common stock and a dividend yield of zero based upon the fact that Ionis and similar companies generally have not historically granted cash dividends.
The increase in our strategic investment portfolio primarily reflects an increase in the fair value in our investment in Ionis' common stock as well as an increase in the value of a non-marketable equity security.

For additional information on our June 2018 investment in Ionis' common stock, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

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

9. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of March 31, 2019 and December 31, 2018, had durations of 1 to 12 months. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses of such contracts are recognized in revenues when the sale of product in the currency being hedged is recognized and in operating expenses when the expense in the currency being hedged is recorded. We recognize all cash flow hedge reclassifications from accumulated other comprehensive income and fair value changes of excluded portions in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.

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

	Notional Amount	
(In millions)	As of March 31, 2019	As of December 31, 2018
Euro	$1,722.2	$ 1,701.4
British pound	170.9	215.3
Swiss franc	99.2	131.4
Japanese yen	79.5	98.8
Canadian dollar	72.2	92.2
Total foreign currency forward contracts	$2,144.0	$ 2,239.1

The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net gains of $44.3 million and $27.3 million as of March 31, 2019 and December 31, 2018, respectively. We expect the net gains of $44.3 million to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenues or operating expenses. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of March 31, 2019 and December 31, 2018, 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 in our condensed consolidated statements of income:

For the Three Months Ended March 31,					
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)			Net Gains/(Losses) Recognized in Operating Income (in millions)		
Location	2019	2018	Location	2019	2018
Revenues	$14.8	$(32.9)	Revenues	$3.7	$(0.9)
Operating expenses	$(0.5)	$1.3	Operating expenses	$(0.9)	$(0.3)

Interest Rate Contracts - Hedging Instruments

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

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

In connection with the issuance of our 2.90% Senior Notes, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in our 2.90% Senior Notes attributable to changes in interest rates. The carrying value of our 2.90% Senior Notes as of March 31 2019 and December 31, 2018, includes approximately $9.3 million and $14.5 million, respectively, related to changes in the fair value of these interest rate swap contracts. Since the specific terms and notional amount of the swaps match the debt being hedged, it is assumed to be a highly effective hedge and all changes in the fair value of the swaps are recorded as a component of our 2.90% Senior Notes with no net impact recorded in income. Any net interest payments made or received on the interest rate swap contracts are recorded as a component of interest expense in our condensed consolidated statements of income.

Net Investment Hedges - Hedging Instruments

In February 2012 we entered into a joint venture agreement with Samsung BioLogics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products. In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics. Our investment in the equity of Samsung Bioepis is exposed to the currency fluctuations in the South Korean won.

In order to mitigate the currency fluctuations between the U.S. dollar and South Korean won, we have entered into foreign currency forward contracts. Foreign currency forward contracts in effect as of March 31, 2019, had remaining durations of seven months. These contracts have been designated as net investment hedges. We recognize changes in the spot exchange rate in accumulated other comprehensive income (loss). The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net gains of $8.0 million and net losses of $3.8 million as of March 31, 2019 and December 31, 2018, respectively. We exclude fair value changes related to the forward rate from our hedging relationship and will amortize the forward points in other income (expense), net in our condensed consolidated statements of income over the term of the contract. The pre-tax portion of the fair value of the forward points that were included in accumulated other comprehensive income (loss) in total equity reflected gains of $9.5 million and $7.3 million as of March 31, 2019 and December 31, 2018, respectively.

The following table summarizes the effect of our net investment hedge in our condensed consolidated financial statements:

For the Three Months Ended March 31,

Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)			Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)			Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)		
Location	2019	2018	Location	2019	2018	Location	2019	2018
Gains (losses) on net investment hedge	$11.8	$ —	Gains (losses) on net investment hedge	$4.4	$ —	Other income (expense)	$2.2	$ —

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

Foreign Currency Forward Contracts - Other Derivatives

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

The aggregate notional amount of these outstanding foreign currency forward contracts was $895.0 million and $735.1 million as of March 31, 2019 and December 31, 2018, respectively. Net losses of $4.8 million related to these

contracts were recognized as a component of other income (expense), net for the three months ended March 31, 2019, compared to net losses of $5.6 million in the prior year comparative period.

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

Summary of Derivatives

While certain of our derivative instruments are subject to netting arrangements with our counterparties, we do not offset derivative assets and liabilities in our condensed consolidated balance sheets. The amounts in the table below would not be substantially different if the derivative assets and liabilities were offset.

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

(In millions)	Balance Sheet Location	As of March 31, 2019	As of December 31, 2018
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$101.4	$ 65.8
Liability derivative instruments	Accrued expenses and other	$6.6	$ 6.9
Fair Value Hedging Instruments:			
Liability derivative instruments	Other long-term liabilities	$9.3	$ 14.5
Other Derivatives:			
Asset derivative instruments	Other current assets	$3.0	$ 1.1
Liability derivative instruments	Accrued expenses and other	$8.2	$ 3.2

10. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was $1,841.0 million and $1,797.4 million as of March 31, 2019 and December 31, 2018, respectively. For the three months ended March 31, 2019, depreciation expense totaled $52.9 million, compared to $65.0 million in the prior year comparative period.

Solothurn, Switzerland Facility

We are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be operational by the end of 2020. Upon completion, the facility will include 393,000 square feet related to a large-scale biologics manufacturing facility, 290,000 square feet of warehouse, utilities and support space and 51,000 square feet of administrative space. As of March 31, 2019 and December 31, 2018, we had approximately $1.7 billion and $1.6 billion, respectively, capitalized as construction in progress related to this facility. As of March 31, 2019, we had contractual commitments of approximately $92.0 million outstanding related to the construction of this facility.

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. As a result, $629.7 million of property, plant and equipment, which is primarily comprised of $312.8 million for buildings and $286.5 million for machinery and equipment, was reclassified to assets held for sale in our condensed consolidated balance sheets as of March 31, 2019. Additionally, we ceased recording depreciation on these assets as depreciation is not recorded during the period in which a long-lived asset or disposal group is classified as held for sale, even if the asset or disposal group continues to generate revenue during the period. For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

11. Leases

We lease real estate, including laboratory and office space, and certain equipment.

Our leases have remaining lease terms ranging from less than 1 year to 10 years. Certain leases include one or more options to renew, exercised at our sole discretion, with renewal terms that can extend the lease term from one year to six years.

28

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

In addition, we sublease certain real estate to third parties. Our sublease portfolio consists of operating leases, with remaining lease terms ranging from less than 1 year to 10 years. Our subleases do not include an option to renew as they are coterminous with our operating leases.

All of our leases qualify as operating leases. The following table summarizes the presentation in our condensed consolidated balance sheets of our operating leases:

(In millions)	Balance sheet location	As of March 31, 2019
Assets:		
Operating lease assets	Operating lease assets	$447.8
Liabilities		
Current operating lease liabilities	Accrued expenses and other	$72.5
Non-current operating lease liabilities	Long-term operating lease liabilities	436.1
Total operating lease liabilities		$508.6

The following table summarizes the effect of lease costs in our condensed consolidated statements of income:

(In millions)	Income Statement Location	For the Three Months Ended March 31, 2019
Operating lease cost	Research and development	$ 0.3
	Selling, general and administrative	23.5
Sublease income	Selling, general and administrative	(7.1)
	Other (income) expense, net	(1.0)
Net lease cost		$ 15.7

The minimum lease payments, net of income from subleases, for the next five years and thereafter is expected to be as follows:

(In millions)	As of March 31, 2019
2019 (remaining nine months)	$69.4
2020	81.7
2021	76.0
2022	69.2
2023	68.6
2024	66.1
Thereafter	146.2
Total lease payments	$577.2
Less: interest	68.6
Present value of operating lease liabilities	$508.6

29

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

Under the prior lease guidance minimum rental commitments under non-cancelable leases, net of income from subleases, for each of the next five years and total thereafter as of December 31, 2018, were as follows:

(In millions)	2019	2020	2021	2022	2023	Thereafter	Total
Minimum lease payments	$87.0	$80.7	$75.9	$71.7	$71.0	$ 215.3	$601.6
Less: income from subleases (1)	(26.8)	(25.6)	(23.7)	(24.0)	(24.3)	(58.4)	(182.8)
Net minimum lease payments	$60.2	$55.1	$52.2	$47.7	$46.7	$ 156.9	$418.8

(1) Represents sublease income expected to be received for the vacated manufacturing facility in Cambridge, MA, the vacated portion of our Weston, MA facility and other facilities throughout the world.

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

	As of March 31, 2019
Weighted average remaining lease term in years	7.88
Weighted average discount rate	3.3 %

Supplemental disclosure of cash flow information related to our operating leases included in cash flows provided by operating activities in our condensed consolidated statements of cash flows is as follows:

(In millions)	For the Three Months Ended March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 19.4
Operating lease assets obtained in exchange for lease obligations	$ 5.4

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. As a result, $2.5 million of operating lease assets and $2.5 million of operating lease liabilities were reclassified to assets held for sale in our condensed consolidated balance sheets as of March 31, 2019. For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

12. Equity

Share Repurchases

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2019 Share Repurchase Program). Our 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our 2019 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2019 Share Repurchase Program during the three months ended March 31, 2019.

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program). Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $655.8 million during the three months ended March 31, 2019.

From April 1, 2019 through April 24, 2019, we repurchased and retired approximately 2.1 million shares of our common stock at a cost of approximately $491.6 million under our 2018 Share Repurchase Program. Approximately

$1.0 billion remained available under our 2018 Share Repurchase Program as of April 24, 2019.
In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program), which was completed as of June 30, 2018. All share repurchases under our

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

2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired approximately 0.9 million shares of our common stock at a cost of approximately $250.0 million during the three months ended March 31, 2018.

Accumulated Other Comprehensive Income (Loss)

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

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedge	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2018	$ (4.0)	$ 34.7	$ 3.5	$ (31.3)	$ (243.3)	$(240.4)
Other comprehensive income (loss) before reclassifications	7.1	31.2	16.2	0.6	(17.8)	37.3
Amounts reclassified from accumulated other comprehensive income (loss)	(0.2)	(14.3)	(2.2)	—	—	(16.7)
Net current period other comprehensive income (loss)	6.9	16.9	14.0	0.6	(17.8)	20.6
Balance, March 31, 2019	$ 2.9	$ 51.6	$ 17.5	$ (30.7)	$ (261.1)	$(219.8)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedge	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2017	$ (1.6)	$(104.5)	$ —	$ (36.8)	$ (175.5)	$(318.4)
Amounts reclassified, net of tax, upon adoption of ASU No. 2016-01	1.5	—	—	—	—	1.5
Balance, January 1, 2018	(0.1)	(104.5)	—	(36.8)	(175.5)	(316.9)
Other comprehensive income (loss) before reclassifications	(8.2)	(60.4)	—	(0.5)	44.7	(24.4)
Amounts reclassified from accumulated other comprehensive income (loss)	6.0	31.4	—	—	—	37.4
Net current period other comprehensive income (loss)	(2.2)	(29.0)	—	(0.5)	44.7	13.0
Balance, March 31, 2018	$ (2.3)	$(133.5)	$ —	$ (37.3)	$ (130.8)	$(303.9)

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

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

(In millions)	Income Statement Location	Amounts Reclassified from Accumulated Other Comprehensive Income For the Three Months Ended March 31, 2019	2018
Gains (losses) on securities available for sale	Other income (expense)	$0.3	$(7.6)
	Income tax benefit (expense)	(0.1)	1.6
Gains (losses) on cash flow hedges	Revenues	14.8	(32.9)
	Operating expenses	(0.5)	1.3
	Other income (expense)	0.1	0.1
	Income tax benefit (expense)	(0.1)	0.1
Gains (losses) on net investment hedge	Other income (expense)	2.2	—
	Income tax benefit (expense)	—	—
Total reclassifications, net of tax		$16.7	$(37.4)

13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Three Months Ended March 31, 2019	2018
Numerator:		
Net income attributable to Biogen Inc.	$1,408.8	$1,172.9
Denominator:		
Weighted average number of common shares outstanding	196.6	211.4
Effect of dilutive securities:		
Stock options and employee stock purchase plan	—	—
Time-vested restricted stock units	0.3	0.2
Market stock units	0.1	0.1
Performance stock units settled in stock	—	—
Dilutive potential common shares	0.4	0.3
Shares used in calculating diluted earnings per share	197.0	211.7

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

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

14. Share-based Payments

Share-based Compensation Expense

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

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Research and development	$21.7	$21.9
Selling, general and administrative	27.8	28.5
Subtotal	49.5	50.4
Capitalized share-based compensation costs	(3.3)	(3.4)
Share-based compensation expense included in total cost and expenses	46.2	47.0
Income tax effect	(7.4)	(7.6)
Share-based compensation expense included in net income attributable to Biogen Inc.	$38.8	$39.4

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

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Market stock units	$7.7	$6.1
Time-vested restricted stock units	34.7	36.1
Cash settled performance units	(1.0)	4.3
Performance units	0.5	(0.8)
Performance stock units settled in stock	2.0	0.7
Performance stock units settled in cash	1.0	0.1
Employee stock purchase plan	4.6	3.9
Subtotal	49.5	50.4
Capitalized share-based compensation costs	(3.3)	(3.4)
Share-based compensation expense included in total cost and expenses	$46.2	$47.0

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

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

15. Income Taxes

Tax Rate

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

	For the Three Months Ended March 31,	
	2019	2018
Statutory rate	21.0 %	21.0 %
State taxes	0.4	0.9
Taxes on foreign earnings	(4.6)	(2.0)
Credits and net operating loss utilization	(0.8)	(0.8)
Purchased intangible assets	0.3	0.6
Denmark assets held for sale	4.3	—
Global Intangible Low-Taxed Income (GILTI)	1.9	1.3
Other permanent items	0.4	0.4
Other	(0.2)	0.2
Effective tax rate	22.7 %	21.6 %

Changes in Tax Rate

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in our effective tax rate was primarily due to a $59.1 million tax expense related to the proposed divestiture of our subsidiary that owns our Hillerød, Denmark manufacturing operations. Although we are recognizing a loss on the proposed divestiture of such subsidiary, the proposed divestiture requires us to write off certain deferred tax assets upon the classification of our Hillerød, Denmark manufacturing operations as held for sale and results in a taxable gain in certain jurisdictions. The effect of this increase to our 2019 effective tax rate was partially offset by a higher effective tax rate in 2018 resulting from the sale of inventory, the tax effect of which had been included within prepaid taxes at December 31, 2017, at a higher effective tax rate.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

Accounting for Uncertainty in Income Taxes

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

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

International Uncertain Tax Positions

We have made payments totaling approximately $60.0 million to the Danish Tax Authority (SKAT) for assessments received for 2009, 2011 and 2013 regarding withholding taxes on certain payments made by our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. We continue to dispute the assessments for all of these periods and believe that the tax positions taken related to these payments are valid. Any amount refunded by SKAT associated with this withholding tax receivable will be paid to our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark.

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. This

withholding tax receivable from SKAT will be included within the assets that will be transferred to FUJIFILM as part of the proposed transaction. Under the share purchase agreement, FUJIFILM is required to remit any future proceeds refunded by SKAT to us. We have assessed the collectability of the receivable from FUJIFILM and regard it as a contingent gain, which does not meet the probable threshold for recognition under ASC 450, Contingencies, and

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

therefore we have recorded a pre-tax charge of $60.0 million to write the asset down to zero as a component of the loss on assets and liabilities held for sale in the first quarter of 2019. For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

Federal and State Uncertain Tax Positions

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

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. As a result, $46.5 million of our deferred tax liability was reclassified to liabilities held for sale in our condensed consolidated balance sheets as of March 31, 2019. For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to these condensed consolidated financial statements.

16. Other Consolidated Financial Statement Detail

Other Income (Expense), Net

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

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Interest income	$31.2	$26.7
Interest expense	(47.9)	(50.5)
Gain (loss) on investments, net	376.4	(14.4)
Foreign exchange gains (losses), net	(2.2)	(1.0)
Other, net	(0.2)	(1.8)
Total other income (expense), net	$357.3	$(41.0)

For the three months ended March 31, 2019, gain (loss) on investments, net, as reflected in the table above, substantially relate to marketable equity securities held at March 31, 2019. The increase in gain (loss) on investments, net, compared to the prior year period, was primarily due to an increase in the fair value in our investment in Ionis' common stock as well as an increase in the value of a non-marketable equity security.

For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to these condensed consolidated financial statements. For additional information on our investment in Ionis, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

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

Accrued Expenses and Other
Accrued expenses and other consists of the following:

(In millions)	As of March 31, 2019	As of December 31, 2018
Revenue-related reserves for discounts and allowances	$907.6	$ 874.7
Collaboration expenses	216.6	261.6
Royalties and licensing fees	195.0	224.7
Employee compensation and benefits	160.8	320.9
Current portion of contingent consideration obligations	147.3	444.8
Construction in progress	99.7	125.2
Other	708.0	609.3
Total accrued expenses and other	$2,435.0	$ 2,861.2

Other Long-term Liabilities
Other long-term liabilities were $1,353.8 million and $1,389.4 million as of March 31, 2019 and December 31, 2018, respectively, and included accrued income taxes totaling $796.1 million and $791.4 million, respectively.

17. Collaborative and Other Relationships

Eisai Co., Ltd.
BAN2401 and Elenbecestat Collaboration
We have a collaboration agreement with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize BAN2401, a monoclonal antibody that targets amyloid beta aggregates, and elenbecestat, the oral BACE (base amyloid cleaving enzyme) inhibitor, two Eisai product candidates for the treatment of AD (the BAN2401 and Elenbecestat Collaboration).
The BAN2401 and Elenbecestat Collaboration also provided Eisai with an option to jointly develop and commercialize aducanumab (Aducanumab Option), and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). In October 2017 Eisai exercised its Aducanumab Option and we entered into a new collaboration agreement for the joint development and commercialization of aducanumab (Aducanumab Collaboration Agreement). Eisai has not yet exercised its Anti-Tau Option.
For additional information on our BAN2401 and Elenbecestat Collaboration, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.
For the three months ended March 31, 2019 and 2018, sales and marketing expenses related to the BAN2401 and Elenbecestat Collaboration were immaterial.
A summary of development expenses related to the BAN2401 and Elenbecestat Collaboration is as follows:

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Total development expense incurred by the collaboration related to the advancement of BAN2401 and Elenbecestat	$68.0	$52.2
Biogen's share of BAN2401 and Elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	$34.0	$26.1

Aducanumab Collaboration Agreement

For the period through March 31, 2018, we were responsible for 100% of development costs incurred by the collaboration for the advancement of aducanumab (aducanumab development expense). For the period April 1, 2018 through December 31, 2018, Eisai reimbursed us for 15% of aducanumab development expense incurred and, beginning January 1, 2019, is reimbursing us for 45% of aducanumab development expense incurred.

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

In March 2019, following the results of a futility analysis conducted by an independent data monitoring committee, we and Eisai announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia. As a result of this decision, in the first quarter of 2019, we accrued approximately $45.0 million related to the termination of various clinical trials and research and development contracts net of the expected 45% Eisai reimbursement of development costs incurred by the collaboration for the advancement of aducanumab.

Sales and marketing expense incurred were shared in proportion to the same region-based profit split that would have been utilized to co-promote aducanumab had it been commercialized. For additional information on the Aducanumab Collaboration Agreement, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

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

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Total aducanumab development expense	$162.5	$63.6
Biogen's share of aducanumab development expense reflected in research and development expense in our condensed consolidated statements of income	$89.4	$63.6
Total aducanumab sales and marketing expense incurred by the collaboration	$20.9	$7.1
Biogen's share of aducanumab sales and marketing expense reflected in selling, general and administrative expense our condensed consolidated statements of income	$11.6	$3.9

In addition, we and Eisai co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai distributes AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

Other Research and Discovery Arrangements

These arrangements may include the potential for future milestone payments based on the achievement of certain clinical and commercial development payable over a period of several years.

Skyhawk Therapeutics, Inc.

In January 2019 we entered into a collaboration and research and development services agreement with Skyhawk Therapeutics, Inc. (Skyhawk) pursuant to which the companies will leverage Skyhawk's SkySTAR technology platform with the goal of discovering innovative small molecule treatments for patients with neurological diseases, including MS and SMA. We will be responsible for the development and potential commercialization of any therapies resulting from this collaboration and we may also pay Skyhawk up to a total of approximately $2.0 billion in additional milestone payments as well as potential royalties on net commercial sales.

In connection with this agreement, we made an upfront payment of $74.0 million to Skyhawk, of which $38.5 million was recorded as research and development expense in our condensed consolidated statements of income and $35.5 million was recorded as prepaid research and development expenditures within investments and other assets in our condensed consolidated balance sheets and will be expensed as the services are provided.

Samsung Bioepis

Joint Venture Agreement

In February 2012 we entered into a joint venture agreement with Samsung BioLogics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products. In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5% to

approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics. As of March 31, 2019, our ownership percentage remained at approximately 49.9%.

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

We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in income (loss) of investee, net of tax in our condensed consolidated statements of income. During 2015, as our share of losses exceeded the carrying value of our initial investment, we suspended recognizing additional losses. During the three months ended March 31, 2019, we restarted recognizing our share of Samsung Bioepis' income (losses), and we began recognizing amortization on certain basis differences resulting from our November 2018 investment.

Upon investment, the equity method of accounting requires us to identify and allocate differences between the fair value of our investment and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life. The total basis difference was approximately $675 million, consisting of approximately $115 million attributed to inventory, approximately $615 million attributed to developed technology and approximately $170 million attributed to in-process research and development. A deferred tax liability of $225 million was established for the acquired assets that had no tax basis. The basis differences related to inventory and developed technology will be amortized, net of tax, over their estimated useful lives of 1.5 years and 15 years, respectively, one quarter in arrears.

For the three months ended March 31, 2019, we recognized a loss on our investment of $28.7 million, reflecting our share of losses for the fourth quarter of 2018 totaling $14.0 million and amortization of basis differences of $14.7 million.

As of March 31, 2019 and December 31, 2018, the carrying value of our investment in Samsung Bioepis totaled 729.9 billion South Korean won ($642.1 million) and 759.5 billion South Korean won ($680.6 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets.

Commercial Agreement

We reflect revenues on sales of BENEPALI, FLIXABI and IMRALDI to third parties in product revenues, net in our condensed consolidated statements of income and record the related cost of revenues and sales and marketing expenses in our condensed consolidated statements of income to their respective line items when these costs are incurred.

In August 2017 the European Commission granted a marketing authorization in the E.U. for IMRALDI. In April 2018 we and Samsung Bioepis entered into an agreement with AbbVie for the commercialization of IMRALDI. Under the terms of the agreement, AbbVie granted us and Samsung Bioepis patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we make royalty payments to AbbVie on behalf of Samsung Bioepis. Royalty payments to AbbVie on sales of IMRALDI are recognized in cost of sales in our condensed consolidated statements of income. We began to recognize revenues on sales of IMRALDI to third parties in the E.U. in the fourth quarter of 2018.

We share 50% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income. For the three months ended March 31, 2019, we recognized net profit-sharing expense of $58.1 million to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to $43.8 million in the prior year comparative period.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a license agreement, a technical development services agreement and a manufacturing agreement with Samsung Bioepis. For the three months ended March 31, 2019, we recognized $24.8 million in revenues in relation to these services, which is reflected in collaborative and other relationships revenues as a component of other revenues in our condensed consolidated statements of income, compared to $17.9 million in the prior year comparative period.

For additional information on our collaboration arrangement with Samsung Bioepis and our other significant collaboration arrangements, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

38

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

18. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

We have a collaboration and license agreement with Neurimmune SubOne AG (Neurimmune) for the development and commercialization of antibodies for the treatment of AD, including aducanumab. We are responsible for the development, manufacturing and commercialization of all collaboration products. This agreement is effective for the longer of the duration of certain patents relating to a licensed product or 12 years from the first commercial sale of any product using such a licensed compound.

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

In March 2019, following the results of a futility analysis conducted by an independent data monitoring committee, we and Eisai announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia.

Research and development costs for which we reimbursed Neurimmune are reflected in research and development expense in our condensed consolidated statements of income. During the three months ended March 31, 2019 and 2018, amounts reimbursed were immaterial.

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

Unconsolidated Variable Interest Entities

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

As of March 31, 2019 and December 31, 2018, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $112.2 million and $28.7 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

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

For additional information on our investments in Neurimmune and other variable interest entities, please read Note 20, Investments in Variable Interest Entities, to our consolidated financial statements included in our 2018 Form 10-K.

19. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read Note 1, Summary of Significant Accounting Policies, to our consolidated financial statements included in our 2018 Form 10-K.

With respect to some loss contingencies, an estimate of the possible loss or range of loss cannot be made until management has further information, including, for example, (i) which claims, if any, will survive dispositive

39

motion practice; (ii) information to be obtained through discovery; (iii) information as to the parties' damages claims and supporting evidence; (iv) the parties' legal theories; and (v) the parties' settlement positions.

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

Loss Contingencies

IMRALDI Patent Litigation

In September 2018 Fresenius Kabi Deutschland GmbH (Fresenius Kabi) commenced proceedings for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris, alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis UK Limited that Biogen commercializes in Europe, infringes the French counterpart of European Patent No. 3 148 510 (the '510 Patent), which was issued in June 2018 and expires in May 2035. In October 2018 Fresenius Kabi commenced preliminary injunction proceedings against Biogen (Denmark) Manufacturing ApS and Biogen Denmark A/S in Denmark's Maritime and Commercial High Court alleging infringement of the Danish Utility Models. In November 2018 Fresenius Kabi commenced infringement proceedings for damages and injunctive relief against Biogen Italia S.R.L. in the District Court of Milan relating to the Italian counterpart of the '510 Patent, and against Biogen GmbH in the Dusseldorf Regional Court relating to the German counterpart of the '510 Patent. A hearing has been scheduled for May 2019 in the proceeding in Denmark. No hearing has been scheduled in the other proceedings.

In August 2018 Biogen Idec Ltd. (Biogen UK) and Samsung Bioepis UK Limited filed an action in the United Kingdom Patents Court to revoke the United Kingdom counterpart of the '510 Patent. Fresenius Kabi has filed a counterclaim asserting infringement of the United Kingdom counterpart of the '510 Patent and seeking damages and an injunction to restrain infringement if the patent is found valid and infringed. A trial has been set for July 2019. In December 2018 Biogen B.V. and Samsung Bioepis UK Limited filed an action in the District Court of the Hague, Netherlands to revoke the Dutch counterpart of the '510 Patent. A trial has been set for October 2019. An estimate of the possible loss or range of loss in the above matters cannot be made at this time.

In October 2018 Gedeon Richter PLC asserted to Biogen and Samsung Bioepis UK Limited that IMRALDI infringes European Patent No. 3 212 667, which was issued in September 2018 and expires in October 2035. We dispute the assertion. An estimate of the possible loss or range of loss cannot be made at this time.

Qui Tam Litigation

In July 2015 a qui tam action filed by Michael Bawduniak on behalf of the U.S. and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. Our motion to dismiss was denied in part. No trial date has been set. The U.S. has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

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

Securities Litigation

We and certain current and former officers are defendants in an action filed by a shareholder in October 2016 in the U.S. District Court for the District of Massachusetts alleging violations of federal securities laws under 15

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

U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeking a declaration of the action as a class action and an award of damages, interest and attorneys' fees. In March 2018 the court dismissed the complaint with prejudice. The plaintiff's appeal is pending. An estimate of the possible loss or range of loss cannot be made at this time.

Other Matters

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

In 2017, 2018 and 2019 we initiated patent infringement proceedings against multiple parties pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in the U.S. District Courts.

Patent infringement proceedings pursuant to the Hatch-Waxman Act are pending against Accord Healthcare Inc., Alkem Laboratories Ltd., Amneal Pharmaceuticals LLC, Aurobindo Pharma U.S.A., Inc., Banner Life Sciences LLC, Cipla Limited, Glenmark Pharmaceuticals Ltd., Graviti Pharmaceuticals Pvt. Ltd., Hetero USA Inc., Lupin Atlantis Holdings SA, Macleods Pharmaceuticals, Ltd., MSN Laboratories Pvt. Ltd., Pharmathen S.A., Prinston Pharmaceutical Inc., Sandoz Inc., Sawai USA, Inc., Shipla Medicare Limited, Slayback Pharma LLC, Torrent Pharmaceuticals Ltd., TWi Pharmaceuticals, Inc., Windlas Healthcare Pvt. Ltd. and Zydus Pharmaceuticals (USA) Inc. in the U.S. District Court for the District of Delaware and against Mylan Pharmaceuticals Inc. in the U.S. District Court for the Northern District of West Virginia.

A trial date has not been set in the Delaware actions against Banner Life Sciences LLC or Zydus Pharmaceuticals (USA) Inc. A December 2019 trial date has been set for the other Delaware actions, and a trial date has been set for February 2020 in the West Virginia action against Mylan Pharmaceuticals Inc.

Petition for Inter Partes Review

In July 2018 Mylan Pharmaceuticals Inc. filed a petition with the U.S. Patent Trial and Appeal Board seeking inter partes review of our U.S. Patent No. 8,399,514 (the '514 Patent). The '514 Patent includes claims covering the treatment of MS with 480 mg of dimethyl fumarate per day as provided for in our TECFIDERA label. On February 6, 2019, the U.S. Patent Trial and Appeal Board instituted inter partes review of the '514 Patent.

European Patent Office Oppositions

In 2016 the European Patent Office (EPO) revoked our European patent number 2 137 537 (the '537 Patent), which includes claims covering the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. We have appealed to the Technical Boards of Appeal of the EPO and the appeal is pending. A hearing has been set for March 2020.

In March 2018 the EPO revoked Forward Pharma’s European Patent No. 2 801 355, which expires in October 2025. Forward Pharma has filed an appeal to the Technical Boards of Appeal of the EPO and the appeal is pending. The settlement and license agreement that we entered with Forward Pharma in January 2017 did not resolve the issues pending in this proceeding and we and Forward Pharma intend to permit the Technical Boards of Appeal and the Enlarged Board of Appeal, if applicable, to make a final determination.

TYSABRI Patent Revocation Matters

In November 2017 Bioeq GMBH, affiliated with the Polpharma Group, brought an action in the Polish Patent Office seeking to revoke Polish Patent Number 215263 (the Polish ‘263 Patent), the Polish patent corresponding to our European Patent Number 1 485 127 (the EU ‘127 Patent) (“Administration of agents to treat inflammation”). The Polish ‘263 Patent concerns administration of natalizumab (TYSABRI) to treat MS. The Polish ‘263 Patent expires in February 2023. A hearing has been scheduled for May 2019.

Swiss Pharma International AG, also affiliated with the Polpharma Group, filed actions in the District Court of The Hague (January 2016), the German Patents Court (March 2016) and the Commercial Court of Rome (November 2017) seeking to invalidate the Dutch, German and Italian counterparts of the EU '127 Patent, which also concerns administration of natalizumab (TYSABRI) to treat MS and expires in February 2023. The Dutch and German counterparts were ruled invalid and we have appealed. No date for a hearing on the merits has been set in the Italian action.

41

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

'755 Patent Litigation

In May 2010 Biogen MA Inc. (formerly Biogen Idec MA Inc.) filed a complaint in the U.S. District Court for the District of New Jersey alleging infringement by Bayer Healthcare Pharmaceuticals Inc. (Bayer) (manufacturer, marketer and seller of BETASERON and manufacturer of EXTAVIA), EMD Serono, Inc. (EMD Serono) (manufacturer, marketer and seller of REBIF), Pfizer Inc. (Pfizer) (co-marketer of REBIF) and Novartis Pharmaceuticals Corp. (Novartis) (marketer and seller of EXTAVIA) of our U.S. Patent No. 7,588,755 ('755 Patent), which claims the use of interferon beta for immunomodulation or treating a viral condition, viral disease, cancers or tumors. The complaint seeks monetary damages, including lost profits and royalties.

Bayer, Pfizer, Novartis and EMD Serono filed counterclaims seeking declaratory judgments of patent invalidity and non-infringement and seeking monetary relief in the form of costs and attorneys' fees. Bayer had previously filed a complaint against us in the same court, on May 27, 2010, seeking a declaratory judgment that it does not infringe the '755 Patent and that the '755 Patent is invalid, and seeking monetary relief in the form of attorneys' fees, costs and expenses.

In September 2018 the trial court entered judgment against EMD Serono and Pfizer that the '755 Patent is infringed and valid and ordered a new trial on damages. In October 2018 EMD Serono and Pfizer filed an appeal from the judgment in the U.S. Court of Appeals for the Federal Circuit, which is pending. The trial court has not yet scheduled the new damages trial or a trial against Bayer and Novartis.

Government Matters

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

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

In July 2016 we received civil investigative demands from the federal government for documents and information relating to our treatment of certain service agreements with wholesalers when calculating and reporting Average Manufacturer Prices in connection with the Medicaid Drug Rebate Program. We are cooperating with the government.

In July 2017 we learned that the Prosecution Office of Milan was investigating our interactions with certain healthcare providers in Italy. In January 2019 the Prosecution Office dismissed the proceeding. We consider the matter closed.

Tax Matter

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

Product Liability and Other Legal Proceedings

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

Table of Contents

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

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements (condensed consolidated financial statements) and the accompanying notes beginning on page 5 of this quarterly report on Form 10-Q and our audited consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2018 (2018 Form 10-K).

Executive Summary

Introduction

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology, Alzheimer's disease (AD) and dementia, movement disorders, including Parkinson's disease, and neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS). We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of acute neurology, neurocognitive disorders, pain and ophthalmology. In addition, we are employing innovative technologies to discover potential treatments for rare and genetic disorders, including new ways of treating diseases through gene therapy in our core and emerging growth areas. We also commercialize biosimilars of advanced biologics.

Our marketed products include TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS, SPINRAZA for the treatment of SMA and FUMADERM for the treatment of severe plaque psoriasis. We also have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions, RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL, GAZYVA for the treatment of CLL and follicular lymphoma, OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS) and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read Note 19, Collaborative and Other Relationships,

to our consolidated financial statements included in our 2018 Form 10-K.

Our revenues depend upon continued sales of our products, as well as the financial rights we have in our anti-CD20 therapeutic programs, and, unless we develop, acquire rights to and/or commercialize new products and technologies, we will be substantially dependent on sales from our products and our financial rights in our anti-CD20 therapeutic programs for many years. Additionally, a significant portion of our revenues are concentrated on sales of our products in increasingly competitive markets.

In the longer term, our revenue growth will depend upon the successful clinical development, regulatory approval and launch of new commercial products as well as additional indications for our existing products, our ability to obtain and maintain patents and other rights related to our marketed products, assets originating from our research and development efforts and/or successful execution of external business development opportunities. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval.

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities. For over two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on additional improvements in the treatment of MS, such as the development of next generation therapies for MS, with a goal to reverse or possibly repair damage caused by the disease. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including Parkinson's disease, ALS, progressive supranuclear palsy, AD, stroke, epilepsy, cognitive impairment associated with schizophrenia (CIAS) and pain.

Our innovative drug development and commercialization activities are complemented by our biosimilar products that expand access to medicines and reduce the cost burden for healthcare systems. Through Samsung Bioepis Co., Ltd.

(Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics), we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, FLIXABI, an infliximab biosimilar referencing REMICADE, and IMRALDI, an adalimumab biosimilar referencing HUMIRA, in the E.U. For additional

Table of Contents

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

Business Environment

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. In addition, the commercialization of certain of our own approved MS products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing MS products. Our products may also face increased competitive pressures from the introduction of generic versions, prodrugs of existing therapies, biosimilars of existing products, other products approved under abbreviated regulatory pathways and other technologies.

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

Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis.

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

In addition to the impact of competition, pricing actions and other measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, our sales and operations could also be affected by other risks of doing business internationally, including the impact of foreign currency exchange fluctuations, changes in intellectual property legal protections and changes in trade regulations and procedures as well as the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe.

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

Brexit

In June 2016 the U.K. electorate voted in a referendum to voluntarily depart from the E.U., known as Brexit. In March 2017 the U.K. government formally notified the European Council of its intention to leave the E.U. and began to negotiate the terms of the future relationship between the U.K. and the E.U. upon exit, which is expected to occur in October 2019.

The potential impact on our results of operations and liquidity resulting from Brexit remains unclear. The actual effects of Brexit will depend upon many factors and significant uncertainty remains with respect to the ultimate resolution of the Brexit negotiations. The final outcome of these negotiations may impact certain of our research, commercial and general business operations in the U.K. and the E.U., including the approval and supply of our products.

Compliance with any resulting regulatory mandates may prove challenging and the macroeconomic impact on our sales and consolidated results of operations from these developments remains unknown. We do not, however, expect Brexit to have a material impact on our consolidated results of operations as approximately 2% of our total product revenues for each of the three months ended March 31, 2019 and 2018, were derived from U.K. sales.

We have implemented measures to meet E.U. legal requirements and continue to modify our business operations to prepare for the U.K.'s separation from the E.U. However, we cannot predict the direction Brexit-related developments will take nor the impact of those developments on our European operations and the economies of the markets where we operate. Therefore, we will continue to monitor developments in this area and assess any potential impact on our business and results of operations.

44

Table of Contents

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was $7.15 for the three months ended March 31, 2019, representing an increase of 29.1% over $5.54 in the same period in 2018.

As described below under Results of Operations, our net income and diluted earnings per share attributable to Biogen Inc. for the three months ended March 31, 2019, compared to the three months ended March 31, 2018, reflects the following:

- Total revenues were $3,489.8 million for the first quarter of 2019, representing an increase of 11.5% over $3,131.1 million in the same period in 2018.
- Product revenues, net totaled $2,680.0 million for the first quarter of 2019, representing an increase of 6.2% over $2,523.5 million in the same period in 2018. This increase was primarily due to a 42.5% increase in revenues from SPINRAZA and a 36.8% increase in revenues from our biosimilar products. These increases were partially offset by a 2.1% net decrease in our MS product revenues, primarily resulting from a decrease in our Interferon product revenues, as well as the unfavorable impact of foreign currency exchange, net of gains recognized in relation to the settlement of certain cash flow hedge instruments under

our foreign currency hedging program, of $23.3 million.

- Revenues from anti-CD20 therapeutic programs totaled $517.4 million for the first quarter of 2019, representing an increase of 16.7% over $443.2 million in the same period in 2018. This increase was primarily due to a 11.5% increase in net sales of RITUXAN in the U.S. and a 45.5% increase in royalty revenues on sales of OCREVUS.
- Other revenues totaled $292.4 million for the first quarter of 2019, representing an increase of 77.9% over $164.4 million in the same period in 2018. This increase was primarily due to the sale of hemophilia related inventory to Bioverativ Inc. (Bioverativ) totaling $206.8 million.
- Total cost and expenses totaled $1,987.1 million for the first quarter of 2019, representing an increase of 24.5% over $1,596.4 million in the same period in 2018. This increase was primarily due to a 35.0% increase in cost of sales, a $115.5 million loss recorded on assets and liabilities held for sale, a 13.5% increase in research and development and a 13.2% increase in selling, general and administrative expenses. These increases were partially offset by a 34.4% decrease in amortization and impairment of acquired intangible assets.
- Net income attributable to Biogen Inc. was unfavorably impacted by an increase in our effective tax rate to 22.7% for the first quarter of 2019, from 21.6% for the same period in 2018.

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

- We generated $1,459.5 million of net cash flows from operations for the first quarter of 2019, which were primarily driven by earnings.
- Cash, cash equivalents and marketable securities totaled approximately $5.3 billion and $4.9 billion as of March 31, 2019 and December 31, 2018, respectively.
- We repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $655.8 million during the first quarter of 2019 under a program authorized by our Board of Directors in August 2018 to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program).

Table of Contents

Acquisitions, Divestitures, Collaborative and Other Relationships

Skyhawk Therapeutics, Inc.

In January 2019 we entered into a collaboration and research and development services agreement with Skyhawk Therapeutics Inc. (Skyhawk) pursuant to which the companies will leverage Skyhawk's SkySTAR technology platform with the goal of discovering innovative small molecule treatments for patients with neurological diseases, including MS and SMA. In connection with this agreement, we made an upfront payment of $74.0 million to Skyhawk.

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

Proposed Acquisition of Nightstar Therapeutics plc

In March 2019 we entered into an agreement to acquire Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. NST's lead asset is NSR-REP1 for the potential treatment of choroideremia, a rare, degenerative, X-linked inherited retinal disorder, which leads to blindness and has no approved treatments. NST’s second clinical program is NSR-RPGR for the potential treatment of X-linked retinitis pigmentosa, which is a rare inherited retinal disease with no approved treatments.

Under the terms of the proposed acquisition, we would pay NST shareholders $25.50 in cash for each issued and outstanding NST share, which represents an expected total transaction value of approximately $800.0 million on a fully diluted basis, after expected transaction expenses and anticipated cash acquired at closing.

It is intended that the proposed acquisition will be implemented by means of a U.K. Court-sanctioned scheme of arrangement under Part 26 of the U.K. Companies Act 2006. The proposed acquisition remains subject to customary closing conditions, including the approval by NST shareholders and the issuance of an order by the U.K. Court. We expect to complete the proposed acquisition by mid-year 2019.

For additional information on the proposed acquisition of NST, please read Note 2, Acquisitions, to our condensed consolidated financial statements included in this report.

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation

(FUJIFILM) under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. Upon closing of the proposed transaction, we expect to receive up to $890.0 million in cash, subject to certain working capital adjustments and other contractual terms. The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act. We expect to complete the proposed transaction in the second half of 2019.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to our condensed consolidated financial statements included in this report.

Other Key Developments

BIIB098 (diroximel fumarate)

In February 2019 we and Alkermes plc announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for diroximel fumarate (BIIB098), a novel oral fumarate in development for the treatment of RMS. The NDA has been assigned a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. If approved, we intend to market diroximel fumarate under the brand name VUMERITY, which has been conditionally accepted by the FDA and will be confirmed upon approval.

Aducanumab (AB mAb)

In March 2019, following the results of a futility analysis conducted by an independent data monitoring committee, we and Eisai Co., Ltd. (Eisai) announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia.

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

2019 Share Repurchase Program

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2019 Share Repurchase Program). Our 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our 2019 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2019 Share Repurchase Program during the three months ended March 31, 2019.

Table of Contents

Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended March 31, 2019		2018	
Product revenues, net:				
United States	$1,513.3	43.4 %	$1,538.0	49.1 %
Rest of world	1,166.7	33.4 %	985.5	31.5 %
Total product revenues, net	2,680.0	76.8 %	2,523.5	80.6 %
Revenues from anti-CD20 therapeutic programs	517.4	14.8 %	443.2	14.2 %
Other revenues	292.4	8.4 %	164.4	5.3 %
Total revenues	$3,489.8	100.0%	$3,131.1	100.0%

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended March 31, 2019		2018	
Multiple Sclerosis:				
TECFIDERA	$998.8	37.3 %	$986.9	39.1 %
Interferon*	500.9	18.7 %	550.3	21.8 %
TYSABRI	460.4	17.2 %	462.1	18.3 %
FAMPYRA	22.9	0.9 %	24.4	1.0 %
ZINBRYTA	—	— %	1.4	0.1 %
Subtotal: MS product revenues	1,983.0	74.0 %	2,025.1	80.2 %
Spinal Muscular Atrophy:				
SPINRAZA	518.5	19.3 %	363.9	14.4 %
Biosimilars:				
BENEPALI	124.0	4.6 %	120.9	4.8 %
FLIXABI	14.7	0.5 %	6.6	0.3 %
IMRALDI	35.7	1.3 %	—	— %
Subtotal: Biosimilar product revenues	174.4	6.5 %	127.5	5.1 %
Other:				
FUMADERM	4.1	0.2 %	7.0	0.3 %
Total product revenues	$2,680.0	100.0%	$2,523.5	100.0%

*Interferon includes AVONEX and PLEGRIDY.

Table of Contents

Multiple Sclerosis (MS)

TECFIDERA

For the three months ended March 31, 2019, compared to the same period in 2018, the 1.5% decrease in U.S. TECFIDERA revenues was primarily due to a decrease in unit sales volume of 6% and higher discounts and allowances, partially offset by price increases.

For the three months ended March 31, 2019, compared to the same period in 2018, the 9.0% increase in rest of world TECFIDERA revenues was primarily due to an increase in unit sales volumes of 15%, primarily related to our European and Latin American markets, partially offset by pricing reductions in certain European countries.

We anticipate an increase in TECFIDERA demand on a global basis in 2019, compared to 2018, notwithstanding increasing competition from additional treatments for MS. We expect volume growth in our international markets to exceed volume declines in the U.S. We also expect price reductions in certain European countries.

Interferon

For the three months ended March 31, 2019, compared to the same period in 2018, the 11.9% decrease in U.S. Interferon revenues was primarily due to a decrease in Interferon unit sales volumes of 13%, which was primarily attributable to patients transitioning to other MS therapies, partially offset by price increases.

For the three months ended March 31, 2019, compared to the same period in 2018, the 3.0% decrease in rest of world Interferon revenues was primarily due to pricing reductions in certain European countries.

We expect that Interferon revenues will continue to decline in both the U.S. and international markets in 2019, compared to 2018, as a result of increasing competition from our other MS products as well as other treatments for MS, including biosimilars, and pricing reductions in certain European markets.

Table of Contents

TYSABRI

For the three months ended March 31, 2019, compared to the same period in 2018, the 1.9% decrease in U.S. TYSABRI revenues was primarily due to a decrease in unit sales volumes of 7%, partially offset by price increases and lower discounts and allowances.

For the three months ended March 31, 2019, compared to the same period in 2018, the 1.4% increase in rest of world TYSABRI revenues was primarily due to an increase in unit sales volumes of 6%.

We anticipate TYSABRI demand to be stable on a global basis in 2019, compared to 2018, with expected volume declines in the U.S. due to increasing competition from additional treatments for MS, including OCREVUS, to be offset by volume growth in our international markets.

Spinal Muscular Atrophy

SPINRAZA

For the three months ended March 31, 2019, compared to the same period in 2018, the 18.8% increase in U.S. SPINRAZA revenues was primarily due to an increase in unit sales volumes of 17%.

For the three months ended March 31, 2019, compared to the same period in 2018, the 67.8% increase in rest of world SPINRAZA revenues was primarily due to an increase in unit sales volumes of 93%, partially offset by the unfavorable impact of foreign currency exchange of $13.1 million. Rest of world SPINRAZA revenues for the first quarter of 2019 were also favorably impacted by approximately $14.0 million as we reached a price reimbursement agreement in France, which resulted in the recognition of additional revenues in relation to sales for the period August 2017, the date upon which we began to sell SPINRAZA in France, and December 2018 as we had a change in the estimated amount of revenues for which we determined that a significant reversal was not probable.

We expect that the rate at which SPINRAZA revenues will grow will moderate in 2019, compared to 2018, primarily due to a lower rate of new patient starts combined with the impact of loading dose dynamics as patients transition to dosing once every four months.

In addition, we are aware of other products in development that, if successfully developed and approved, may compete with SPINRAZA in the SMA market, including a potential gene therapy product for the treatment of SMA Type 1, which could come to market in the U.S. in 2019. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products.

Table of Contents

For additional information on our collaboration arrangements with Ionis Pharmaceuticals, Inc. (Ionis), please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Biosimilars

BENEPALI, FLIXABI and IMRALDI

For the three months ended March 31, 2019, compared to the same period in 2018, the 36.8% increase in biosimilar revenues was primarily due to the launch of IMRALDI in the fourth quarter of 2018, partially offset by the unfavorable impact of foreign currency exchange of $9.6 million.

In 2019 we expect strong revenue growth for our biosimilar business, primarily driven by the continued launch of IMRALDI.

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

Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN, including RITUXAN HYCELA, and GAZYVA collaboration operating profits in the U.S. and other revenues from anti-CD20 therapeutic programs are summarized in the table below. For purposes of this discussion we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

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

The following table provides a summary of amounts comprising our share of pre-tax profits in the U.S. for RITUXAN and GAZYVA:

	For the Three Months Ended March 31,	
(In millions)	2019	2018
Product revenues, net	$1,226.7	$1,096.2
Cost and expenses	172.9	153.7
Pre-tax profits in the U.S.	1,053.8	942.5
Biogen's share of pre-tax profits	$390.8	$349.6

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in U.S. product revenues, net was primarily due to increased net sales of RITUXAN in the U.S. of 11.5%. This increase in net sales of RITUXAN in the U.S. reflects selling price increases and an increase in unit sales volume of 7%, partially offset by higher discounts and allowances.

Table of Contents

The increase in U.S. product revenues, net compared to the same period in 2018, also reflects an increase in GAZYVA unit sales volume of 12%.

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in collaboration costs and expenses was primarily due to higher cost of goods sold on RITUXAN.

We are aware of anti-CD20 molecules, including biosimilar products, in development that if successfully developed and approved, may compete with RITUXAN. In 2018 the FDA approved a rituximab biosimilar in the U.S. A biosimilar of RITUXAN could come to market in the U.S. in 2019, which may adversely affect the pre-tax profits of our collaboration arrangements with Genentech, which would, in turn, adversely affect our co-promotion profits in the U.S. in future years.

Other Revenues from Anti-CD20 Therapeutic Programs

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

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in other revenues from anti-CD20 therapeutic programs was primarily due to sales growth of OCREVUS. Royalty revenues recognized on sales of OCREVUS for the three months ended March 31, 2019 and 2018, totaled $111.6 million and $76.7 million, respectively.

For additional information on our collaboration arrangements with Genentech, including information regarding the pre-tax profit-sharing formula and its impact on future revenues from anti-CD20 therapeutic programs, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Other Revenues

Other revenues are summarized as follows:

	For the Three Months Ended March 31,					
(In millions, except percentages)	2019			2018		
Revenues from collaborative and other relationships	$24.4	8.3	%	$13.2	8.0	%
Other royalty and corporate revenues	268.0	91.7	%	151.2	92.0	%
Total other revenues	$292.4	100.0	%	$164.4	100.0	%

Revenues from Collaborative and Other Relationships

Revenues from collaborative and other relationships include revenues from our technical development services and manufacturing agreements with Samsung Bioepis and royalty revenues on biosimilar products from Samsung Bioepis. Revenues from collaborative and other relationships also include our 50% share of the co-promotion losses of ZINBRYTA in the U.S. with AbbVie Inc. (AbbVie).

Following the closing of the proposed divestiture of our Hillerød, Denmark manufacturing operations, FUJIFILM will assume responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis and we will no longer recognize revenue amounts earned under our manufacturing and technical services agreements with Samsung Bioepis.

For additional information on our collaborative and other relationships, including revenues recognized under our technical development services and manufacturing agreements with Samsung Bioepis, and our collaboration arrangement with AbbVie, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 10-K.

Table of Contents

Other Royalty and Corporate Revenues

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

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in other royalty and corporate revenues was due to higher contract manufacturing revenues, primarily resulting from $206.8 million in revenues recognized under the manufacturing and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business, compared to $47.0 million recognized in the first quarter of 2018. These increases were partially offset by the reduction in royalty revenues due to the expiration of certain of our patents. The increase in Bioverativ revenues over the prior year comparative period was due to sales of most of the remaining hemophilia inventory on hand.

Reserves for Discounts and Allowances

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

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

vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

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

For the three months ended March 31, 2019, reserves for discounts and allowances as a percentage of gross product revenues was 23.0%, as compared to 24.3% in the prior year comparative period.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three months ended March 31, 2019, compared to the same period in 2018, the decrease in discounts was primarily due to changes in wholesaler invoicing in certain European markets.

Contractual Adjustments

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

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in contractual adjustments was primarily due to higher governmental rebates and allowances in the rest of world, due in part to an increase in SPINRAZA sales volumes worldwide, partially offset by decreased Medicaid rebates in the U.S.

Table of Contents

Returns

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

For the three months ended March 31, 2019, compared to the same period in 2018, return reserves were relatively consistent.

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

Cost and Expenses

A summary of total cost and expenses is as follows:

	For the Three Months Ended March 31,		
(In millions, except percentages)	2019	2018	Change %
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 602.0	$ 446.0	35.0 %
Research and development	563.7	496.7	13.5 %
Selling, general and administrative	567.7	501.3	13.2 %
Loss on assets and liabilities held for sale	115.5	—	**
Amortization and impairment of acquired intangible assets	68.2	103.9	(34.4)%
Collaboration profit (loss) sharing	58.1	42.5	36.7 %
Acquired in-process research and development	—	10.0	(100.0)%
Loss (gain) on fair value remeasurement of contingent consideration	11.5	(5.6)	(305.4)%
Restructuring charges	0.4	1.6	(75.0)%
Total cost and expenses	$ 1,987.1	$ 1,596.4	24.5 %

** Percentage not meaningful.

Cost of Sales, Excluding Amortization and Impairment of Acquired Intangible Assets

Product Cost of Sales

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in product cost of sales was primarily due to higher contract manufacturing shipments, primarily resulting from the sale of hemophilia related inventory to Bioverativ with a cost basis totaling $173.5 million pursuant to the terms of the manufacture and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business, and increased sales of our biosimilar products.

Royalty Cost of Sales

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in royalty cost of sales was primarily due to increased royalties payable to Ionis on higher sales of SPINRAZA, partially offset by a decrease in royalties payable on sales of TYSABRI resulting from the expiration of certain third party royalties.

Table of Contents

Research and Development

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

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

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

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in research and development expense was primarily due to an increase in milestone and upfront expenses and an increase in costs incurred in connection with our early and late stage programs. These increases were partially offset by a decrease in costs incurred with our marketed products and other research and development costs.

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

Milestone and Upfront Expenses

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in milestone and upfront expenses was primarily due to the recognition of a $38.5 million charge to research and development expense upon entering into our collaboration and research development services agreement with Skyhawk.

Table of Contents

Early Stage Programs

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in spending related to our early stage programs was primarily due to the development of BIIB054 (-synuclein mAb) in Parkinson's disease, the development of BAN2401(A mAb) in AD pursuant to our collaboration arrangement with Eisai and the development of BIIB104 (AMPA) in CIAS, partially offset by a decrease in costs associated with the development of BIIB074 (vixotrigine) in trigeminal neuralgia and the development of BIIB093 (glibenclamide IV) in large hemispheric infarction (LHI), which was advanced to a late stage program in the third quarter of 2018.

Late Stage Programs

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in spending related to our late stage programs was primarily due to costs incurred resulting from the discontinuation of our Phase 3 aducanumab trials, net of an expected Eisai reimbursement, and the development of BIIB093 in LHI.

In March 2019, following the results of a futility analysis conducted by an independent data monitoring committee, we and Eisai announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to AD and mild AD dementia. As a result of this decision, in the first quarter of 2019, we accrued approximately $45.0 million related to the termination of various clinical trials and research and development contracts net of the expected 45% Eisai reimbursement of development costs incurred by the collaboration for the advancement of aducanumab.

In March 2019 Eisai initiated a global Phase 3 trial for the development of BAN2401 in early AD. Under our collaboration arrangement, Eisai serves as the global operational and regulatory lead for BAN2401 and all costs, including research, development, sales and marketing expenses, are shared equally between us and Eisai.

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

Marketed Products

For the three months ended March 31, 2019, compared to the same period in 2018, the decrease in spending related to our marketed products was primarily due to a decrease in spend on ZINBRYTA subsequent to the voluntary worldwide withdrawal of ZINBRYTA for RMS, which we and AbbVie announced in March 2018.

Selling, General and Administrative

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in selling, general and administrative expenses was primarily due to an increase in corporate giving, an increase in commercialization costs as we continued to expand into new international markets and an increase in pre-commercialization costs related to our AD programs. These increases were partially offset by a decrease in operational spend on ZINBRYTA subsequent to the voluntary worldwide withdrawal of ZINBRYTA for RMS, which we and AbbVie announced in March 2018.

Table of Contents

Loss on Assets and Liabilities Held For Sale

Proposed Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. Upon closing of the proposed transaction, we expect to receive up to $890.0 million in cash, subject to certain working capital adjustments and other contractual terms.

As part of the proposed transaction, we have provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum batch production commitments will not be met. Based upon current estimates we expect to incur an adverse commitment obligation of approximately $120.0 million associated with such guarantees. We may adjust this estimate based upon changes in business conditions, which may result in the recognition of additional losses. We are also obligated to indemnify FUJIFILM for liabilities that may exist relating to certain business activities incurred prior to the closing of the proposed transaction.

In addition, we may earn certain contingent payments based on future manufacturing activities at the Hillerød facility. For the disposition of a business, our policy is to recognize contingent consideration when the consideration is realizable. We currently believe the probability of earning these payments is remote and therefore we have not included these contingent payments in our estimate of the fair value of the operations.

As part of the proposed transaction, we also expect to enter into certain manufacturing services agreements with FUJIFILM pursuant to which FUJIFILM would use the Hillerød facility to produce commercial

products for us, such as TYSABRI, as well as other third-party products.

We determined that the operations to be disposed of in the proposed transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

In February 2019 the assets and liabilities related to our Hillerød, Denmark manufacturing operations met the criteria to be classified as held for sale and were reclassified to assets and liabilities held for sale in our condensed consolidated balance sheets.

In the first quarter of 2019 we recorded a loss of approximately $174.6 million in our condensed consolidated statements of income. This estimated loss includes a pre-tax loss of $115.5 million reflecting our current estimated fair value of the assets and liabilities held for sale, adjusting for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately $10.0 million and our estimate of the fair value of an adverse commitment of approximately $120.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. In addition, we recorded a tax expense of $59.1 million related to the proposed transaction. Our total estimated loss is based on current exchange rates and business conditions, and any changes to these factors through the closing date of the transaction will result in adjustments to the carrying values of the related assets and liabilities as well as a corresponding adjustment to the loss amount recognized on the sale.

Following the closing of the proposed transaction, the final purchase price will be adjusted by an amount equal to the difference between our current estimates of working capital and inventory balances that will be transferred to FUJIFILM and the amounts that are ultimately transferred.

Our estimate of the fair value of assets and liabilities expected to be sold to FUJIFILM is a Level 3 measurement and is based on the expected consideration from the sale, including the valuation of the adverse purchase commitment, as discussed above.

The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act. We expect to complete the proposed transaction in the second half of 2019.

Table of Contents

We expect to complete the proposed transaction in the second half of 2019.

In addition, upon closing of the proposed transaction, we expect to separately sell certain raw materials remaining at the Hillerød facility to FUJIFILM at carrying value.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to our condensed consolidated financial statements included in this report.

Amortization and Impairment of Acquired Intangible Assets

Our amortization expense is based on the economic consumption and impairment of intangible assets. Our most significant intangible assets are related to our TYSABRI, AVONEX, SPINRAZA and TECFIDERA products and other programs acquired through business combinations.

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

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

related to higher expected lifetime revenues of TYSABRI.

Amortization and impairment of acquired intangible assets for the three months ended March 31, 2019, compared to the same period in 2018, decreased primarily due to a net overall decrease in our expected rate of amortization for acquired intangible assets. This was primarily due to lower amortization subsequent to the impairment in the fourth quarter of 2018 of the U.S. license to Forward Pharma A/S' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, and higher expected lifetime revenues of TYSABRI. For the three months ended March 31, 2019 and 2018, we had no impairment charges.

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

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

IPR&D represents the fair value assigned to research and development assets that we acquired and had not yet reached technological feasibility at the date of acquisition. We review amounts capitalized as acquired IPR&D for impairment annually, as of October 31, and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable.

Overall, the value of our acquired IPR&D assets is dependent upon several variables, including estimates of future revenues and the effects of competition, our ability to secure sufficient pricing in a competitive market, our ability to confirm safety and efficacy based on data from clinical trials and regulatory feedback, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from one clinical trial phase to the next. We are continually reevaluating our estimates concerning these and other variables, including our life cycle management strategies and changes in program economics and related impact of foreign currency exchange rates, and evaluating industry data regarding the productivity of clinical research and the

Table of Contents

development process. Changes in our estimates of these items may result in a significant change to our valuation of our IPR&D assets.

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

Collaboration Profit (Loss) Sharing

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

For the three months ended March 31, 2019, we recognized a net profit-sharing expense of $58.1 million to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to $43.8 million in the prior year comparative period. The increase in profit-sharing expense was primarily due to increased collaboration profits resulting from increased biosimilar sales.

For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report. For additional information on our collaboration arrangement with AbbVie, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Loss (Gain) on Fair Value Remeasurement of Contingent Consideration

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

The change in the fair value remeasurement of contingent consideration for the three months ended March 31, 2019, was primarily due to changes in the expected timing of the achievement of certain remaining development milestones, a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

Table of Contents

Other Income (Expense), Net

For the three months ended March 31, 2019, compared to the same period in 2018, the changes in other income (expense), net primarily reflects an increase in the fair value in our investment in Ionis' common stock, as well as an increase in the value of a non-marketable equity security.

Income Tax Provision

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

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in

our effective tax rate was primarily due to a $59.1 million tax expense related to the proposed divestiture of our subsidiary that owns our Hillerød, Denmark manufacturing operations. Although we are recognizing a loss on the proposed divestiture of such subsidiary, the proposed divestiture requires us to write off certain deferred tax assets upon the classification of our Hillerød, Denmark manufacturing operations as held for sale and results in a taxable gain in certain jurisdictions. The effect of this increase to our 2019 effective tax rate was partially offset by a higher effective tax rate in 2018 resulting from the sale of inventory, the tax effect of which had been included within prepaid taxes at December 31, 2017, at a higher effective tax rate.

For additional information on the proposed divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, Divestitures, to our condensed consolidated financial statements included in this report.

For additional information on our uncertain tax positions and income tax rate reconciliation for the three months ended March 31, 2019 and 2018, please read Note 15, Income Taxes, to our condensed consolidated financial statements included in this report.

Equity in Loss of Investee, Net of Tax

In February 2012 we entered into a joint venture agreement with Samsung BioLogics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products.

In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5% to approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics. As of March 31, 2019, our ownership percentage remained at approximately 49.9%.

Table of Contents

We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in income (loss) of investee, net of tax in our condensed consolidated statements of income. During 2015, as our share of losses exceeded the carrying value of our initial investment, we suspended recognizing additional losses. During the three months ended March 31, 2019, we restarted recognizing our share of Samsung Bioepis' income (losses), and we began recognizing amortization on certain basis differences resulting from our November 2018 investment.

For the three months ended March 31, 2019, we recognized a loss on our investment of $28.7 million, reflecting our share of losses for the fourth quarter of 2018 totaling $14.0 million and amortization of basis differences of $14.7 million, which is recorded one quarter in arrears.

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

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions, except percentages)	As of March 31, 2019	As of December 31, 2018	Change	%
Financial assets:				
Cash and cash equivalents	$2,243.2	$1,224.6	83.2	%
Marketable securities — current	1,665.8	2,313.4	(28.0)	%
Marketable securities — non-current	1,372.7	1,375.9	(0.2)	%
Total cash, cash equivalents and marketable securities	$5,281.7	$4,913.9	7.5	%
Borrowings:				
Notes payable	5,943.2	5,936.5	0.1	%
Total borrowings	$5,943.2	$5,936.5	0.1	%
Working capital:				
Current assets	$8,942.6	$7,640.9	17.0	%
Current liabilities	(3,148.7)	(3,295.2)	(4.4)	%
Total working capital	$5,793.9	$4,345.7	33.3	%

For the three months ended March 31, 2019, certain significant cash flows were as follows:

- $1.5 billion in net cash flows provided by operating activities, net of:
  - $74.0 million upfront payment made to Skyhawk upon entering into a collaboration and research and development services agreement; and
  - $45.0 million upfront payment made to C4 Therapeutics (C4T) upon entering into a collaborative research and license agreement;
- $655.8 million used for share repurchases;
- $300.0 million for the final contingent payment made to former shareholders of Fumapharm AG and holders of their rights; and
- $127.1 million used for purchases of property, plant and equipment.

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

- $1.5 billion in net cash flows provided by operating activities;
- $600.0 million in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- $250.0 million used for share repurchases; and
- $194.7 million used for purchases of property, plant and equipment.

Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned from our operations. We expect to continue funding our current and planned operating requirements principally through our cash flows from operations, as well as our existing cash resources. We believe that our existing funds, when combined

Table of Contents

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.

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

Share Repurchase Programs

In March 2019 our Board of Directors authorized our 2019 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our 2019 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2019 Share Repurchase Program during the three months ended March 31, 2019.

In August 2018 our Board of Directors authorized our 2018 Share Repurchase Program, which is a program to repurchase up to $3.5 billion of our common stock. Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $655.8 million during the three months ended March 31, 2019.

From April 1, 2019 through April 24, 2019, we repurchased and retired approximately 2.1 million shares of our common stock at a cost of approximately $491.6 million under our 2018 Share Repurchase Program. Approximately $1.0 billion remained available under our 2018 Share Repurchase Program as of April 24, 2019.

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired

approximately 0.9 million shares of our common stock at a cost of approximately $250.0 million during the three months ended March 31, 2018.

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, overnight reverse repurchase agreements and other interest-bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type.

As of March 31, 2019, we had cash, cash equivalents and marketable securities totaling approximately $5.3 billion compared to approximately $4.9 billion as of December 31, 2018. The net increase in cash, cash equivalents and marketable securities at March 31, 2019 from December 31, 2018, was primarily due to cash flows from operations, partially offset by cash used for share repurchases, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, net purchases of property, plant and equipment and upfront payments made to Skyhawk and C4T.

Investments and other assets in our condensed consolidated balance sheet as of March 31, 2019 and December 31, 2018, includes the carrying value of our investment in Samsung Bioepis of $642.1 million and $680.6 million, respectively. As Samsung Bioepis is a privately-held entity, our ability to liquidate our investment in Samsung Bioepis may be limited and we may realize significantly less than the value of such investment. Investments and other assets, as of March 31, 2019 and December 31, 2018, also includes an asset of $884.5 million and $563.8 million, respectively, reflecting the fair value of our investment in Ionis' common stock, which is subject to certain holding period restrictions.

For additional information on our collaboration arrangements with Skyhawk and Samsung Bioepis, please read Note 17, Collaborative and Other Relationships, to our condensed consolidated financial statements included in this report. For additional information on our collaboration arrangements with Ionis and C4T, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Table of Contents

Borrowings

The following is a summary of our principal indebtedness:

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

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

During the third quarter of 2015, we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of March 31, 2019, we had no outstanding borrowings and were in compliance with all covenants under this facility.

For a summary of the fair and carrying values of our outstanding borrowings as of March 31, 2019 and December 31, 2018, please read Note 7, Fair Value Measurements, to our condensed consolidated financial statements included in this report.

Working Capital

Working capital is defined as current assets less current liabilities. The change in working capital at March 31, 2019, from December 31, 2018, reflects an increase in total current assets of approximately $1,301.7 million and a decrease in total current liabilities of approximately $146.5 million.

The net increase in total current assets was primarily driven by the reclassification of assets associated with the proposed divestiture of our Hillerød, Denmark manufacturing operations, an increase in net cash, cash equivalents and marketable securities, as described above, an increase in net amounts due in connection with our collaboration arrangement with Samsung Bioepis and an increase in accounts receivable, net related to our ongoing operations. These increases were partially offset by a decrease in inventory resulting from the sale of hemophilia related inventory to Bioverativ.

The net decrease in current liabilities was primarily due to a reduction in accrued expenses and other, partially offset by an increase in income taxes payable and a reclassification of deferred tax liabilities to liabilities held for sale in relation to our proposed divestiture of our Hillerød, Denmark manufacturing operations. The net decrease in accrued expenses and other was primarily related to a decrease in the accrual of contingent payments related to FUMADERM and TECFIDERA and a decrease in the accrual for employee compensation and benefits.

Cash Flows

The following table summarizes our cash flow activity:

	For the Three Months Ended March 31,		
(In millions, except percentages)	2019	2018	% Change
Net cash flows provided by operating activities	$1,459.5	$1,457.1	0.2 %
Net cash flows provided by investing activities	$238.8	$1,346.6	(82.3)%
Net cash flows used in financing activities	$(679.3)	$(268.6)	152.9 %

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all 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,unrealized gain (loss) on strategic investments, acquired IPR&D and share-based compensation;
-

changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with

Table of Contents

transactions and when they are recognized in results of operations; and

- changes in the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For the three months ended March 31, 2019, compared to the same period in 2018, net cash flows provided by operating activities increased primarily due to higher net income offset by changes in assets and liabilities.

Investing Activities

For the three months ended March 31, 2019, compared to the same period in 2018, the decrease in net cash flows provided by investing activities was primarily due to a decrease in net proceeds related to marketable securities, partially offset by a decrease in contingent payments made to former shareholders of Fumapharm AG and holders of their rights.

Financing Activities

For the three months ended March 31, 2019, compared to the same period in 2018, the increase in net cash flows used in financing activities was primarily due to an increase in cash used for share repurchases.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

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

There have been no material changes in our contractual obligations since December 31, 2018.

Contingent Payments

TYSABRI

In 2013 we acquired from Elan Pharma International Ltd. (Elan), an affiliate of Elan Corporation plc, full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the acquisition agreement, we are obligated to make contingent payments to Elan of 18% on annual worldwide net sales up to $2.0 billion and 25% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are

recognized as cost of sales in our condensed consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013 and Perrigo subsequently sold its rights to these payments to a third-party effective January 2017.

SPINRAZA

In 2016 we exercised our option to develop and commercialize SPINRAZA from Ionis. Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net sales of SPINRAZA using a tiered royalty rate between 11% and 15%, which are recognized as cost of sales in our condensed consolidated statements of income. For additional information on our collaboration arrangements with Ionis, please read Note 19, Collaborative and Other Relationships, to our consolidated financial statements included in our 2018 Form 10-K.

Contingent Consideration related to Business Combinations

In connection with our acquisitions of Convergence Pharmaceuticals Ltd. (Convergence), Stromedix, Inc. (Stromedix) and Biogen International Neuroscience GmbH (BIN) in 2015, 2012 and 2010, respectively, we agreed to make additional payments based upon the achievement of certain milestone events.

As the acquisitions of Convergence, Stromedix and BIN occurred after January 1, 2009, we recognized the contingent consideration liabilities associated with these transactions at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately $1.0 billion in remaining milestones related to these acquisitions.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of March 31, 2019, we could make potential future milestone payments to third parties of up to approximately $6.9 billion, including approximately $0.9 billion in development milestones, approximately $1.8 billion in regulatory milestones and approximately $4.2 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements

generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of March 31, 2019, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered

Table of Contents

contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval or commercial milestones.

Provided various development, regulatory or commercial milestones are achieved, we anticipate that we may pay approximately $187.0 million of milestone payments during the remainder of 2019.

Other Funding Commitments

As of March 31, 2019, we have several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to contract research organizations (CROs). The contracts with CROs are generally cancellable, with notice, at our option. We recorded accrued expenses of approximately $58.0 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of March 31, 2019. We have approximately $480.0 million in cancellable future commitments based on existing CRO contracts as of March 31, 2019.

Tax Related Obligations

We exclude liabilities pertaining to uncertain tax positions from our summary of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of March 31, 2019, we have approximately $119.3 million of liabilities associated with uncertain tax positions.

As of both March 31, 2019 and December 31, 2018, we have accrued income tax liabilities of $697.0 million under a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). Of the amounts accrued as of March 31, 2019, no amounts are expected to be paid within one year due to a $150.0 million overpayment of taxes made in 2018. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

Other Off-Balance Sheet Arrangements

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

New Accounting Standards

For a discussion of new accounting standards please read Note 1, Summary of Significant

Accounting Policies - New Accounting Pronouncements, to our condensed consolidated financial statements included in this report.

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., requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates.

Assets and Liabilities Held For Sale

Upon determining that a long-lived asset or disposal group meets the criteria to be classified as held for sale, we cease depreciation and separately present such assets and liabilities of the disposal group in our condensed consolidated balance sheet. We initially measure a long-lived asset or disposal group that is classified as held for sale at the lower of its carrying value or fair value less any costs to sell. Any loss resulting from this measurement is recognized in the period in which the held-for-sale criteria are met. Conversely, gains are not recognized on the sale of a long-lived asset or disposal group until the date of sale. We assess the fair value of a long-lived asset or disposal group less any costs to sell each reporting period it remains classified as held for sale and recognize any subsequent changes as an adjustment to the carrying value of the asset or disposal group, as long as the remeasured carrying value does not exceed the carrying value less costs to sell of the asset or disposal group at the time it was initially classified as held for sale.

For a discussion of our critical accounting estimates, please read Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2018 Form 10-K. Except as discussed above, there have been no material changes to these critical accounting estimates since our 2018 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are subject to certain risks that may affect our results of operations, cash flows and fair values

Table of Contents

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

Foreign Currency Exchange Risk

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. We have operations or maintain distribution relationships in the U.S., Europe, Canada, Asia and Central and South America. In addition, we recognize our share of pre-tax co-promotion profits on RITUXAN in Canada. As a result, our condensed consolidated financial position, results of operations and cash flows can be affected by market fluctuations in foreign currency exchange rates, primarily with respect to the Euro, British pound sterling, Canadian dollar, Swiss franc, Danish krone, Japanese yen and South Korean won.

While the financial results of our global activities are reported in U.S. dollars, the functional currency for most of our foreign subsidiaries is their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar strengthens versus other currencies, the value of the non-U.S. revenues will decline when reported in U.S. dollars. The impact to net income as a result of a strengthening U.S. dollar will be partially mitigated by the value of non-U.S. expenses, which will also decline when reported in U.S. dollars. As the U.S. dollar weakens versus other currencies, the value of the non-U.S. revenues and expenses will increase when reported in U.S. dollars. We have established revenue and operating expense hedging and balance sheet risk management programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign currency exchange rates.

During the second quarter of 2018 the International Practices Task Force of the Center for Audit Quality categorized Argentina as a country with a projected three-year cumulative inflation rate greater than 100%, which indicated that Argentina's economy is highly inflationary. This categorization did not have

a material impact on our results of operations or financial position as of March 31, 2019, and is not expected to have a material impact on our results of operations or financial position in the future.

Revenue and Operating Expense Hedging Program

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues and operating expenses. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 12 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 9, Derivative Instruments, to our condensed consolidated financial statements included in this report.

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

Balance Sheet Risk Management Hedging Program

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

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of March 31, 2019 and December 31, 2018, a hypothetical adverse 10% movement in foreign currency exchange rates compared to the U.S. dollar across all maturities would result in a hypothetical decrease in the fair value of forward contracts of approximately $296.0 million and $290.0 million, respectively. The estimated fair value change was determined by measuring the impact of the hypothetical exchange rate movement on outstanding forward contracts. Our

Table of Contents

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.

Net Investment Hedge Program

Our net investment hedging program is designed to mitigate currency fluctuations between the U.S. dollar and the South Korean won as a result of exercising our option to increase our ownership percentage in Samsung Bioepis to approximately 49.9%. We entered into foreign currency forward contracts to manage the foreign currency risk with our forward contracts used to hedge changes in the spot rate over the next seven months. As of March 31, 2019 and December 31, 2018, a hypothetical adverse 10% movement would result in a hypothetical decrease in fair value of approximately $63.0 million and $64.0 million, respectively. The estimated fair value was determined by measuring the impact of the hypothetical spot rate movement on outstanding forward contracts.

Interest Rate Risk

Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of March 31, 2019 and December 31, 2018, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $18.0 million and $19.0 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

To achieve a desired mix of fixed and floating interest rate debt, we entered into interest rate swap contracts during 2015 for certain of our fixed-rate debt. These derivative contracts effectively converted a fixed-rate interest coupon to a floating-rate LIBOR-based coupon over the life of the respective note. As of March 31, 2019 and December 31, 2018, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately $6.8 million.

Pricing Pressure

Governments in certain international markets in which we operate have implemented measures, and may in the future implement new or additional

measures, to reduce health care costs to limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to obtain and maintain adequate prices in a particular country may adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. The continued implementation of pricing actions throughout Europe may also lead to higher levels of parallel trade.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the way our products are prescribed and purchased. It is possible that additional federal health care reform measures will be adopted in the future, which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our financial position or results of operations. There is also significant economic pressure on state budgets that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. Managed care organizations are also continuing to seek price discounts and, in some cases, to impose restrictions on the coverage of certain drugs.

Our products are also susceptible to increasing competition in many markets from generics, biosimilars, prodrugs and other products approved under abbreviated regulatory pathways. Generic versions of drugs, biosimilars and other products approved under abbreviated regulatory pathways are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products, as well as other lower-priced competing products,

may significantly reduce both the price that we receive for branded products and the volume of branded products that we sell, which will negatively impact our revenues.

Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk

Table of Contents

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

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

We believe that our allowance for doubtful accounts was adequate as of March 31, 2019 and December 31, 2018. However, if significant changes occur in the availability of government funding or the reimbursement practices of these or other governments, we may not be able to collect on amounts due to us from customers in such countries and our results of operations could be adversely affected.

Item 4. Controls and Procedures

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of March 31, 2019. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure management properly assessed the impact of the new lease accounting standards on our condensed consolidated financial statements to facilitate adoption of the new leasing standards effective January 1, 2019. There were no significant changes to our internal control over financial reporting due to the adoption of the new standards.

Table of Contents

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

For a discussion of legal proceedings as of March 31, 2019, please read Note 19, Litigation, to our unaudited 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 products.

Our revenues depend upon continued sales of our products, as well as the financial rights we have in our anti-CD20 therapeutic programs, and, unless we develop, acquire rights to and/or commercialize new products and technologies, we will be substantially dependent on sales from our products and our financial rights in our anti-CD20 therapeutic programs for many years. Additionally, a significant portion of our revenues are concentrated on sales of our products in increasingly competitive markets. Any of the following negative developments relating to any of our products or any of our anti-CD20 therapeutic programs may adversely affect our revenues and results of operations or could cause a decline in our stock price:

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

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

- our limited marketing experience within certain SMA markets, which may impact our ability to develop additional relationships with the associated medical and scientific community;
- the lack of readiness of healthcare providers to treat patients with SMA;
- the effectiveness of our commercial strategy for marketing SPINRAZA;
- our ability to maintain a positive reputation among patients, healthcare providers and others in the SMA community, which may be impacted by pricing and reimbursement decisions relating to SPINRAZA; and
- the introduction of other products in development that, if successfully developed and approved, may compete with SPINRAZA in the SMA market, including potential gene therapy or oral products.

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

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

Table of Contents

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

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

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

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

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

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

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

Our success depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our products and product candidates. The degree of patent protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We may fail to successfully obtain or preserve patent protection for the technologies incorporated into our products and processes, or the protection we obtain may not be of sufficient breadth and degree

to protect our commercial interests in all countries where we conduct business. Under the Drug Price

Table of Contents

Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, a manufacturer may file an Abbreviated New Drug Application, seeking approval of a generic copy of an approved innovator product, or a NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which may be for a new or improved version of the original innovator product. The manufacturers are allowed to rely on the safety and efficacy data of the innovator's product, may not need to conduct clinical trials, can market a competing version of a product after the expiration or loss of patent exclusivity or the expiration or loss of regulatory exclusivity and often charge significantly lower prices. Upon the expiration or loss of patent protection or the expiration or loss of regulatory exclusivity for a product, especially a small molecule product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. If we cannot prevent others from exploiting our inventions, we will not derive the expected benefit from them. Furthermore, our products may be determined to infringe patents or other intellectual property rights held by third parties, which could result in financial, legal, business or reputational harm to us.

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

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

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

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

Product development is very expensive and involves a high degree of uncertainty and risk. Only a small number of research and development programs result in the commercialization of a product. Furthermore, the development of novel approaches for the treatment of diseases, including development efforts in new modalities such as those based on the antisense oligonucleotide platform and gene therapy, may present additional challenges and risks, including obtaining regulatory approval from the FDA and other regulatory agencies that have limited experience with the development of such therapies. In addition, clinical trial data are subject to differing interpretations and, even if we view data as sufficient to support the safety, effectiveness and/or approval of an investigational therapy, regulatory authorities may disagree and may require additional data, may limit the scope of the approval or may deny approval altogether. Consequently, it may be difficult to predict the time and cost of product development of novel approaches for the treatment of diseases.

In addition, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects, result in unexpected adverse events or raise other concerns that may significantly reduce the likelihood of regulatory approval. This may result in terminated programs, significant restrictions on use and safety

Table of Contents

warnings in an approved label, adverse placement within the treatment paradigm or significant reduction in the commercial potential of the product candidate.

Even if we are able to successfully develop new products or indications, we may make a strategic decision to discontinue development of a product candidate or indication if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline.

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, substantially greater financial, marketing and research and development and other resources and other technological or competitive advantages. One or more of our competitors may benefit from significantly greater sales and marketing capabilities, may develop products that are accepted more widely than ours or may receive patent protection that dominates, blocks or adversely affects our product development or business.

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

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

- the introduction of more efficacious, safer, less expensive or more convenient alternatives to our MS products, including our own products and products of our collaborators;
- the introduction of biosimilars, follow-on products, generic versions of branded MS products, prodrugs or products approved under other abbreviated regulatory pathways, which would be significantly less costly than our products to bring to market and would be offered for sale at lower prices, and could result in a significant percentage of the sales of our products being lost to such biosimilars, follow-on products, generic versions of branded MS products, prodrugs or products approved under other abbreviated regulatory pathways;
- the off-label use by physicians of therapies indicated for other conditions to treat MS patients;
- patient dynamics, including the size of the patient population and our ability to attract and maintain new and current patients to our therapies;
- damage to physician and patient confidence in any of our MS products or generic or biosimilars of our MS products, or to our sales and reputation as a result of label changes or adverse experiences or events that may occur with patients treated with our MS products or generic or biosimilars of our MS products;
- inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key international markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our MS products.

Our business may be adversely affected if we do not successfully execute or realize the anticipated benefits of our strategic and growth initiatives.

The successful execution of our strategic and growth initiatives may depend upon internal development projects, commercial initiatives, external opportunities, which may include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations, or the disposition of certain of our assets or operations.

Table of Contents

While we believe we have a number of promising programs in our pipeline, failure or delay of internal development projects to advance or difficulties in executing on our commercial initiatives could impact our current and future growth, resulting in additional reliance on external development opportunities for growth. Supporting 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.

The availability of high quality, fairly valued external product development is limited and the opportunity for their acquisition is highly competitive. As such, we are not certain that we will be able to identify suitable candidates for acquisition or if we will be able to reach agreement. Furthermore, if we decide to dispose of certain of our assets or operations, we are not certain that we will be able to identify a suitable counterparty or if we will be able to reach agreement.

We may fail to initiate or complete transactions for many reasons and we may not be able to achieve the full strategic and financial benefits expected to result from transactions, or the benefits may be delayed or not occur at all. We may also face additional costs or liabilities in completed transactions that were not contemplated prior to completion. Any failure in the execution of a transaction, in the integration of an acquired asset or business or in achieving expected synergies could result in slower growth, higher than expected costs, the recording of asset impairment charges and other actions which could adversely affect our business, financial condition and results of operations.

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

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

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

Positive results in a clinical trial may not be replicated in subsequent or confirmatory trials. Additionally, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful or that regulatory approval will be obtained. In addition, even if later stage clinical trials are successful, regulatory authorities may delay or decline approval of our product candidates. Regulatory authorities may disagree with our view of the data, require additional studies or disagree with our trial design or endpoints. Regulatory authorities may also fail to approve the facilities or 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

Table of Contents

development of a product or indication if, for example, we believe commercialization will be difficult relative to the standard of care or other opportunities in our pipeline.

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

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

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

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

Adverse safety events involving our marketed products, or generic or biosimilar versions of our marketed products, may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and the imposition of fines or criminal penalties. Adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any of these could result in liabilities, loss of revenues, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges or 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 or liver injury in the label for certain of our products, may significantly reduce expected revenues for those products and require significant expense and management time.

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

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

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

be effectively enforced if the collaborators or third parties fail to perform;

Table of Contents

- the interests of our collaborators or third parties may not always be aligned with our interests, and such parties may not pursue regulatory approvals or market a product in the same manner or to the same extent that we would, which could adversely affect our revenues;
- third-party relationships and collaborations often require the parties to cooperate, and failure to do so effectively could adversely affect product sales, or the clinical development or regulatory approvals of products under joint control, could result in termination of the research, development or commercialization of product candidates or could result in litigation or arbitration;
- any failure on the part of our collaborators or other third parties to comply with applicable laws and regulatory requirements in the marketing, sale and maintenance of the marketing authorization of our products or to fulfill any responsibilities our collaborators or other third parties may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings; and
- any improper conduct or actions on the part of our collaborators or other third parties could subject us to civil or criminal investigations and monetary and injunctive penalties, and could adversely impact our ability to conduct business, our operating results and our reputation.

Given these risks, there is considerable uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed, or revenues from products could decline and/or we may not realize the anticipated benefits of the collaboration arrangements.

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

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

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

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

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

In the E.U. and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures, and may in the future implement new or additional measures, to reduce health care costs to limit the overall level of government

Table of Contents

expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries. These measures have negatively impacted our revenues and may continue to adversely affect our revenues and results of operations in the future.

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 products and place significant restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies such as ours have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. If we, or our vendors or donation recipients, are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

Conditions and regulations governing the health care industry are subject to change, with possible retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or judicial decisions, related to health care availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- government shutdowns or relocations may result in delays to the review and approval process, slowing the time necessary for new drug candidates to be reviewed and/or approved, which may adversely affect our business;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the European Medicines Agency's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action, which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or otherwise adversely affect the market for our products.

Violations of governmental regulation may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and

75

Table of Contents

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

Our 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. There is no guarantee that our efforts and strategies to expand sales in international markets will succeed. Emerging market countries may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability and may have a higher incidence of corruption and fraudulent business practices. Further, certain countries may require local clinical trial data as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we partner with or acquire in emerging markets.

Our sales and operations are subject to the risks of doing business internationally, including:

- less favorable intellectual property or other applicable laws;
- the introduction or greater acceptance of competing products, including generics, biosimilars and prodrugs;
- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- limitations and additional pressures on our ability to obtain and maintain product pricing or receive price increases, including those resulting from governmental or regulatory requirements;
- the inability to successfully complete subsequent or confirmatory clinical trials in countries where our experience is limited;
- longer payment and reimbursement cycles and uncertainties regarding the collectability of accounts receivable;
- fluctuations in foreign currency exchange rates that may adversely impact our revenues, net income and value of certain of our investments;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- diverse data privacy and protection requirements;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- the effects of the implementation of the U.K.'s decision to voluntarily depart from the E.U., known as Brexit;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions;
- greater political or economic instability;
- changes in tax laws; and

Table of Contents

- the imposition of tariffs or embargoes and other trade restrictions, including the recent tariffs imposed by the U.S. and China and the possibility of additional tariffs or other trade restrictions relating to trade between the two countries.

In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act (FCPA) prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. Failure to comply with domestic or foreign laws could result in various adverse consequences, including: possible delay in approval or refusal to approve a product, recalls, seizures or withdrawal of an approved product from the market, disruption in the supply or availability of our products or suspension of export or import privileges, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

Management and key personnel changes may disrupt our operations, and we may have difficulty retaining key personnel or attracting and retaining qualified replacements on a timely basis for management and other key personnel who may leave the Company.

We have experienced changes in management and other key personnel in critical functions across our organization in recent years. Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition or results of operations. Further, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs.

Our success is dependent upon our ability to attract and retain qualified management and key personnel in a highly competitive environment. Qualified individuals are in high demand, and we may incur significant costs to attract them, particularly at the executive level. We may face difficulty in attracting and retaining key talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more late stage programs or recruitment by competitors. We cannot ensure you that we will be able to hire or retain the personnel necessary for our operations or that the loss of any such personnel will not have a material impact on our financial condition and results of operations.

We are building a large-scale biologics manufacturing facility, which will result in the incurrence of significant investment with no assurance that such investment will be recouped.

We believe we currently have sufficient large-scale manufacturing capacity to meet our near-term manufacturing requirements. However, due to the long lead times necessary for the expansion of manufacturing capacity, in 2015 we made the decision to expand our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland with no assurance that the additional capacity will be required. In addition, we have made and expect to make significant investments in connection with the building of this manufacturing facility 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. Charges resulting from excess capacity would have a negative effect on our financial condition and results of operations.

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

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

- Risks of Reliance on Third Parties and Single Source Providers. We rely on third-party suppliers and manufacturers for many aspects of our manufacturing process for our products and product candidates. In some cases, due to the unique manner in which our products are manufactured, we rely on single source providers of raw materials and manufacturing supplies. These third parties are independent entities subject to their own unique operational and financial risks that are outside of our control. These third parties may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations, and they may be unable or unwilling to increase

production capacity commensurate with

Table of Contents

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.

- Risks Relating to Compliance with current Good Manufacturing Practices (cGMP). We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.
- Global Bulk Supply Risks. We rely on our principal manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- 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.

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

In addition, although we have business continuity plans to reduce the potential for manufacturing disruptions or delays and reduce the severity of a disruptive event, there is no guarantee that these plans will be adequate, which could adversely affect our business and operations.

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

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

- Reliance on Third Parties. We are dependent on the efforts of Samsung Bioepis and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If Samsung Bioepis or such other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;
- Regulatory Compliance. Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- Intellectual Property and Regulatory Challenges. Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years or result in imposition of monetary damages, penalties or other civil sanctions and damage our reputation;

Table of Contents

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

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

In addition, as Samsung Bioepis is a privately-held entity, our ability to liquidate our investment in Samsung Bioepis may be limited and we may realize significantly less than the value of such investment.

Our operating results are subject to significant fluctuations.

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

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

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

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

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

As a global biopharmaceutical company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate, however, may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from country to country, the results of examinations and audits of our tax filings, adjustments to the value of our uncertain tax positions, changes in accounting for income taxes and changes in tax laws, including the Tax Cuts and Jobs Act of 2017 (2017 Tax Act).

Table of Contents

Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations.

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

The 2017 Tax Act resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as global intangible low-taxed income and includes base erosion prevention measures on non-U.S. earnings. These changes became effective in 2018.

The 2017 Tax Act also includes the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

Our estimates concerning the impact of the 2017 Tax Act on our accounting and on our business remain subject to developing interpretations of the provisions of the 2017 Tax Act. U.S. Treasury regulations, administrative interpretations or court decisions interpreting the 2017 Tax Act may require further adjustments and changes in our estimates, which could have a material adverse effect on our business, results of operations or financial condition.

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

Our investments in properties may not be fully realized.

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

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

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

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

From time to time our Board of Directors authorizes share repurchase programs, including, most recently, our 2018 Share Repurchase Program and our 2019 Share Repurchase Program. The amount and timing of share repurchases are subject to capital availability and our determination that share repurchases are in the best interest of our shareholders and are in compliance with all respective laws and our agreements applicable to the repurchase

80

Table of Contents

of shares. Our ability to repurchase shares will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, our results of operations, our financial condition and other factors beyond our control that we may deem relevant. A reduction in repurchases under, or the completion of, our share repurchase programs could have a negative effect on our stock price. We can provide no assurance that we will repurchase shares at favorable prices, if at all.

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

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

Our indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

Our indebtedness, together with our significant contingent liabilities, including milestone and royalty payment obligations, could have important consequences to our business; for example, such obligations could:

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

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

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

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

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

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

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

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we

81

Table of Contents

fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

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

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

We may be exposed to claims and liabilities as a result of the spin-off of our hemophilia business.

On February 1, 2017, in connection with the spin-off of our hemophilia business, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen shareholders pursuant to a separation agreement. In March 2018 Bioverativ was acquired by Sanofi and is now an indirect wholly-owned subsidiary of Sanofi.

The spin-off of our hemophilia business was intended to qualify for tax-free treatment to Biogen and its shareholders under the Internal Revenue Code. Completion of the spin-off was conditioned upon, among other things, our receipt of a favorable opinion from our tax advisors with respect to the tax-free nature of the transaction. The opinion is not binding on the U.S. Internal Revenue Service (IRS) or the courts, and there can be no assurance that the IRS or the courts will not challenge the qualification of the spin-off as a tax-free transaction or that any such challenge would not prevail. If the spin-off is determined to be taxable, the full financial benefits expected to result from the separation may not be achieved and/or Biogen and its shareholders could incur significant tax liabilities, which could adversely affect our business, financial condition or results of operations and the value of our stock could be adversely impacted. Bioverativ agreed to indemnify us for certain potential liabilities that may arise, but we cannot guarantee that Bioverativ will be able to satisfy its indemnification obligations. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Bioverativ may be significant. These risks could negatively affect our business, financial condition or results of operations.

Table of Contents

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

Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity under our 2018 Share Repurchase Program during the first quarter of 2019:

Period	Total Number of Shares Purchased (#)	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Programs (#)	Maximum Approximate Dollar Value of Shares That May Yet Be Purchased Under Our Programs ($ in millions)
January 2019	484,590	$ 304.14	484,590	$ 2,000.0
February 2019	225,000	$ 321.78	225,000	$ 1,927.6
March 2019	1,733,664	$ 251.49	1,733,664	$ 1,491.6
Total	2,443,254	$ 268.41		

In March 2019 our Board of Directors authorized our 2019 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2019 Share Repurchase Program does not have an expiration date. All share repurchases under our 2019 Share Repurchase Program will be retired. We did not repurchase any shares of our common stock under our 2019 Share Repurchase Program during the three months ended March 31, 2019.

In August 2018 our Board of Directors authorized our 2018 Share Repurchase Program, which is a program to repurchase up to $3.5 billion of our common stock. Our 2018 Share Repurchase Program does not have an expiration date. All share repurchases under our 2018 Share Repurchase Program will be retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $655.8 million during the three months ended March 31, 2019.

From April 1, 2019 through April 24, 2019, we repurchased and retired approximately 2.1 million shares of our common stock at a cost of approximately $491.6 million under our 2018 Share Repurchase Program. During this time, we paid an average price per share of $235.99. As of April 24, 2019, we have repurchased and retired approximately 8.8 million shares of our common stock at a cost of approximately $2.5 billion under our 2018 Share Repurchase Program. Approximately $1.0 billion remained available under our 2018 Share Repurchase Program as of April 24, 2019.

Item 6. Exhibits

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1*+	Biogen Inc. 2019 Form of Performance-Based Management Incentive Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.
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 March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Statements of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheets, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

* Management contract or compensatory plan or arrangement

\+ Filed herewith

++ Furnished herewith

Table of Contents

SIGNATURES

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

BIOGEN INC.

/s/ Jeffrey D. Capello
Jeffrey D. Capello
Executive Vice President, and
Chief Financial Officer
(principal financial officer)
April 24, 2019