

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

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2019

OR

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

Commission File Number 0-19311



BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction of
incorporation or organization)*

33-0112644

*(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)*

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0005 par value	BIIB	The Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

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

The number of shares of the issuer's Common Stock, \$0.0005 par value, outstanding as of October 21, 2019, was 180,441,878 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2019

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the Act. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “potential,” “possible,” “will,” “would” and other words 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 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, certain business development transactions;
- 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 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; and
- the impact of new laws, including the Swiss Federal Act on Tax Reform and AHV Financing, regulatory requirements, judicial decisions and accounting standards.

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.

BENEPALITM, FLIXABITM, FUMADERMTM and IMRALDITM are trademarks of Biogen.

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PART I FINANCIAL INFORMATION

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product, net	\$ 2,894.7	\$ 2,780.1	\$ 8,455.0	\$ 8,061.1
Revenues from anti-CD20 therapeutic programs	595.8	511.7	1,689.6	1,445.3
Other	109.6	147.2	562.0	420.2
Total revenues	<u>3,600.1</u>	<u>3,439.0</u>	<u>10,706.6</u>	<u>9,926.6</u>
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	430.0	460.8	1,508.3	1,327.8
Research and development	540.4	507.9	1,588.9	1,985.6
Selling, general and administrative	554.5	497.7	1,709.8	1,515.2
Amortization and impairment of acquired intangible assets	283.9	281.9	422.2	493.2
Collaboration profit (loss) sharing	60.2	47.5	181.8	129.2
Loss on divestiture of Hillerød, Denmark manufacturing operations	(17.7)	—	95.5	—
(Gain) loss on fair value remeasurement of contingent consideration	(57.8)	(87.9)	(66.3)	(91.6)
Restructuring charges	0.3	6.0	1.5	9.2
Acquired in-process research and development	—	27.5	—	112.5
Total cost and expenses	<u>1,793.8</u>	<u>1,741.4</u>	<u>5,441.7</u>	<u>5,481.1</u>
Income from operations	1,806.3	1,697.6	5,264.9	4,445.5
Other income (expense), net	(27.3)	115.1	132.6	39.6
Income before income tax expense and equity in loss of investee, net of tax	1,779.0	1,812.7	5,397.5	4,485.1
Income tax expense	211.3	369.8	881.9	956.0
Equity in loss of investee, net of tax	21.8	—	66.8	—
Net income	1,545.9	1,442.9	4,448.8	3,529.1
Net income (loss) attributable to noncontrolling interests, net of tax	—	(1.5)	—	45.2
Net income attributable to Biogen Inc.	<u>\$ 1,545.9</u>	<u>\$ 1,444.4</u>	<u>\$ 4,448.8</u>	<u>\$ 3,483.9</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 8.40	\$ 7.17	\$ 23.38	\$ 16.86
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 8.39</u>	<u>\$ 7.15</u>	<u>\$ 23.35</u>	<u>\$ 16.83</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	184.0	201.4	190.3	206.6
Diluted earnings per share attributable to Biogen Inc.	<u>184.2</u>	<u>201.9</u>	<u>190.5</u>	<u>207.0</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Net income attributable to Biogen Inc.	\$ 1,545.9	\$ 1,444.4	\$ 4,448.8	\$ 3,483.9
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	0.1	(0.2)	10.3	(1.8)
Unrealized gains (losses) on cash flow hedges, net of tax	59.1	5.2	38.1	109.0
Gains (losses) on net investment hedges	21.2	—	46.9	—
Unrealized gains (losses) on pension benefit obligation, net of tax	0.8	(0.2)	1.5	0.2
Currency translation adjustment	79.4	8.5	51.3	(38.8)
Total other comprehensive income (loss), net of tax	160.6	13.3	148.1	68.6
Comprehensive income attributable to Biogen Inc.	1,706.5	1,457.7	4,596.9	3,552.5
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	—	(1.5)	(0.4)	45.2
Comprehensive income	\$ 1,706.5	\$ 1,456.2	\$ 4,596.5	\$ 3,597.7

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	As of September 30, 2019	As of December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,343.9	\$ 1,224.6
Marketable securities	2,093.5	2,313.4
Accounts receivable, net	1,933.5	1,958.5
Due from anti-CD20 therapeutic programs	582.3	526.9
Inventory	751.8	929.9
Other current assets	743.2	687.6
Total current assets	8,448.2	7,640.9
Marketable securities	1,813.9	1,375.9
Property, plant and equipment, net	3,138.1	3,601.2
Operating lease assets	422.0	—
Intangible assets, net	3,392.4	3,120.0
Goodwill	5,746.1	5,706.4
Deferred tax asset	3,284.5	2,153.9
Investments and other assets	1,238.8	1,690.6
Total assets	\$ 27,484.0	\$ 25,288.9
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	\$ 1,495.3	\$ —
Taxes payable	125.6	63.5
Accounts payable	382.2	370.5
Accrued expenses and other	2,429.1	2,861.2
Total current liabilities	4,432.2	3,295.2
Notes payable	4,458.2	5,936.5
Deferred tax liability	2,820.4	1,636.2
Long-term operating lease liabilities	410.5	—
Other long-term liabilities	1,370.9	1,389.4
Total liabilities	13,492.2	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	(92.3)	(240.4)
Retained earnings	17,065.2	16,257.0
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	13,995.9	13,039.6
Noncontrolling interests	(4.1)	(8.0)
Total equity	13,991.8	13,031.6
Total liabilities and equity	\$ 27,484.0	\$ 25,288.9

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	For the Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net income	\$ 4,448.8	\$ 3,529.1
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and impairments	567.6	686.9
Acquired in-process research and development	—	112.5
Share-based compensation	143.9	119.0
Contingent consideration	(66.3)	(91.6)
Loss on divestiture of Hillerød, Denmark manufacturing operations	95.5	—
Deferred income taxes	28.4	(44.8)
Unrealized (gain) loss on strategic investments	(189.8)	(136.9)
Loss on equity method investment	63.5	—
Other	87.4	68.7
Changes in operating assets and liabilities, net:		
Accounts receivable	(2.4)	(254.0)
Inventory	47.3	(31.9)
Accrued expenses and other current liabilities	(109.1)	100.7
Income tax assets and liabilities	64.6	315.6
Other changes in operating assets and liabilities, net	(61.0)	(81.0)
Net cash flows provided by operating activities	<u>5,118.4</u>	<u>4,292.3</u>
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	3,867.6	7,994.7
Purchases of marketable securities	(4,052.1)	(6,093.8)
Contingent consideration paid related to Fumapharm AG acquisition	(300.0)	(1,200.0)
Acquisition of Nightstar Therapeutics plc, net of cash acquired	(744.4)	—
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	923.7	—
Purchases of property, plant and equipment	(404.1)	(544.7)
Acquired in-process research and development	—	(112.5)
Acquisitions of intangible assets	—	(3.0)
Purchase of Ionis Pharmaceuticals, Inc. stock	—	(462.9)
Proceeds from sales of strategic investments	476.0	—
Other	(4.6)	1.2
Net cash flows used in investing activities	<u>(237.9)</u>	<u>(421.0)</u>
Cash flows from financing activities:		
Purchases of treasury stock	(3,775.2)	(3,000.0)
Payments related to issuance of stock for share-based compensation arrangements, net	(16.9)	(6.7)
Repayment of borrowings	—	(3.2)
Net distribution to noncontrolling interest	4.3	(36.9)
Other	43.8	11.8
Net cash flows used in financing activities	<u>(3,744.0)</u>	<u>(3,035.0)</u>
Net increase (decrease) in cash and cash equivalents	1,136.5	836.3
Effect of exchange rate changes on cash and cash equivalents	(17.2)	(23.4)
Cash and cash equivalents, beginning of the period	1,224.6	1,573.8
Cash and cash equivalents, end of the period	<u>\$ 2,343.9</u>	<u>\$ 2,386.7</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

BIAGEN 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, June 30, 2019	—	\$ —	208.6	\$ 0.1	\$ —	\$ (252.9)	\$16,182.8	(23.8)	\$ (2,977.1)	\$ 12,952.9	\$ (4.1)	\$ 12,948.8
Net income							1,545.9			1,545.9	—	1,545.9
Other comprehensive income (loss), net of tax						160.6				160.6	—	160.6
Capital contribution by noncontrolling interest										—	—	—
Repurchase of common stock pursuant to the 2019 Share Repurchase Program, at cost								(3.1)	(717.9)	(717.9)		(717.9)
Retirement of common stock pursuant to the 2019 Share Repurchase Program, at cost			(3.1)	—	(55.1)		(662.8)	3.1	717.9	—		—
Issuance of common stock under stock option and stock purchase plans			0.1	—	7.3					7.3		7.3
Issuance of common stock under stock award plan			0.1	—	—		(0.7)			(0.7)		(0.7)
Compensation related to share-based payments					47.8					47.8		47.8
Balance, September 30, 2019	—	\$ —	205.7	\$ 0.1	\$ —	\$ (92.3)	\$17,065.2	(23.8)	\$ (2,977.1)	\$ 13,995.9	\$ (4.1)	\$ 13,991.8

See accompanying notes to these unaudited condensed consolidated financial statements.

BIODEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(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							4,448.8			4,448.8	—	4,448.8
Other comprehensive income (loss), net of tax						148.1				148.1	(0.4)	147.7
Capital contribution by noncontrolling interest										—	4.3	4.3
Repurchase of common stock pursuant to the 2019 Share Repurchase Program, at cost								(7.0)	(1,627.8)	(1,627.8)		(1,627.8)
Retirement of common stock pursuant to the 2019 Share Repurchase Program, at cost			(7.0)	—	(74.8)		(1,553.0)	7.0	1,627.8	—		—
Repurchase of common stock pursuant to the 2018 Share Repurchase Program, at cost								(8.9)	(2,147.4)	(2,147.4)		(2,147.4)
Retirement of common stock pursuant to the 2018 Share Repurchase Program, at cost			(8.9)	—	(110.5)		(2,036.9)	8.9	2,147.4	—		—
Issuance of common stock under stock option and stock purchase plans			0.2	—	33.5					33.5		33.5
Issuance of common stock under stock award plan			0.4	—	—		(50.7)			(50.7)		(50.7)
Compensation related to share-based payments					151.8					151.8		151.8
Balance, September 30, 2019	—	\$ —	205.7	\$ 0.1	\$ —	\$ (92.3)	\$17,065.2	(23.8)	\$ (2,977.1)	\$ 13,995.9	\$ (4.1)	\$ 13,991.8

See accompanying notes to these unaudited condensed consolidated financial statements.

BIODEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(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, June 30, 2018	—	\$ —	225.2	\$ 0.1	\$ —	\$ (261.6)	\$15,499.5	(23.8)	\$(2,977.1)	\$ 12,260.9	\$ (7.2)	\$12,253.7
Net income							1,444.4			1,444.4	(1.5)	1,442.9
Other comprehensive income (loss), net of tax						13.3				13.3	—	13.3
Capital contribution by noncontrolling interest										—	1.9	1.9
Issuance of common stock under stock option and stock purchase plans			—	—	8.7					8.7		8.7
Issuance of common stock under stock award plan			—	—	(1.1)					(1.1)		(1.1)
Compensation related to share-based payments					40.2		0.2			40.4		40.4
Balance, September 30, 2018	<u>—</u>	<u>\$ —</u>	<u>225.2</u>	<u>\$ 0.1</u>	<u>\$ 47.8</u>	<u>\$ (248.3)</u>	<u>\$16,944.1</u>	<u>(23.8)</u>	<u>\$(2,977.1)</u>	<u>\$ 13,766.6</u>	<u>\$ (6.8)</u>	<u>\$13,759.8</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

BIODEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(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, 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							3,483.9			3,483.9	45.2	3,529.1
Other comprehensive income (loss), net of tax						68.6				68.6	(0.3)	68.3
Capital contribution by noncontrolling interest										—	13.0	13.0
Distribution to noncontrolling interest										—	(50.0)	(50.0)
Repurchase of common stock pursuant to the 2016 Share Repurchase Program, at cost								(10.5)	(3,000.0)	(3,000.0)		(3,000.0)
Retirement of common stock pursuant to the 2016 Share Repurchase Program, at cost			(10.5)	—	(171.2)		(2,828.8)	10.5	3,000.0	—		—
Issuance of common stock under stock option and stock purchase plans			0.1	—	33.3					33.3		33.3
Issuance of common stock under stock award plan			0.3	—	(39.9)					(39.9)		(39.9)
Compensation related to share-based payments					127.8		0.2			128.0		128.0
Adoption of new accounting guidance						1.5	478.4			479.9		479.9
Balance, September 30, 2018	<u>—</u>	<u>\$ —</u>	<u>225.2</u>	<u>\$ 0.1</u>	<u>\$ 47.8</u>	<u>\$ (248.3)</u>	<u>\$16,944.1</u>	<u>(23.8)</u>	<u>\$(2,977.1)</u>	<u>\$ 13,766.6</u>	<u>\$ (6.8)</u>	<u>\$13,759.8</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

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, neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS), movement disorders, including Parkinson's disease and progressive supranuclear palsy, Alzheimer's disease (AD) and dementia and ophthalmology. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology, neurocognitive disorders, acute neurology and pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

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).

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, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, 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 and nine months ended September 30, 2019, are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

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

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

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.

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*. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2020. These standards require 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, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit 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.

BIOGEN INC. AND SUBSIDIARIES
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(unaudited, continued)

Based on the composition of our investment portfolio and other financial assets, current market conditions and historical credit loss activity, the adoption of these standards 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.

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

2. Acquisitions

Acquisition of Nightstar Therapeutics plc

On June 7, 2019, we completed our acquisition of all of the outstanding shares of Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. As a result of this acquisition, we added two mid-to late-stage clinical assets, as well as preclinical programs, in ophthalmology. These assets include BIIB111 (formerly known as NSR-REP1), which is in Phase 3 development for the potential treatment of choroideremia, a rare, degenerative, X-linked inherited retinal disorder that leads to blindness and currently has no approved treatments, and BIIB112 (formerly known as NSR-RPGR), which is in Phase 2/3 development for the potential treatment of X-linked retinitis pigmentosa, which is a rare inherited retinal disease with no currently approved treatments.

Under the terms of this acquisition, we paid NST shareholders \$25.50 in cash for each issued and outstanding NST share, which totaled \$847.6 million. In addition, we paid \$4.6 million in cash for equity compensation, which is attributable to pre-combination services and is reflected as a component of the total purchase price paid. The fair value of equity compensation attributable to the post-combination service period was \$26.2 million, of which \$18.4 million was recognized as a charge to selling, general and administrative expense with the remaining \$7.8 million as a charge to research and development expense in our condensed consolidated statements of income. These amounts were associated with the accelerated vesting of stock options previously granted to NST employees and were fully paid in cash as of June 30, 2019. We funded this acquisition through available cash and accounted for it as an acquisition of a business.

The following table summarizes the estimated fair values of the separately identifiable assets acquired and liabilities assumed as of June 7, 2019:

(In millions)	
Cash and cash equivalents	\$ 107.8
Marketable securities	7.5
In-process research and development intangible assets	700.0
Goodwill	112.6
Deferred tax liability	(77.0)
Other, net	1.3
Total purchase price	<u>\$ 852.2</u>

Our estimate of the fair value of the in-process research and development (IPR&D) programs acquired was determined through a probability adjusted discounted cash flow analysis utilizing a discount rate of 12.5%. This valuation was primarily driven by the value associated with BIIB111. The fair value associated with BIIB111 was \$480.0 million. We have recorded an additional IPR&D asset related to BIIB112 of \$220.0 million. Some of the more significant assumptions utilized in our asset valuations included the estimated net cash flows for each year for each asset or product, including net revenues, cost of sales, research and development and other operating expenses, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream as well as other factors. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

We have recognized goodwill in relation to the fair value associated with NST workforce's expertise and early research in retinal disorders. We also recognized goodwill in relation to the establishment of a deferred tax liability for the acquired IPR&D intangible assets, which have no tax basis. This deferred tax liability is net of the related impacts on the deferred taxes for global intangible low-taxed income (GILTI). Goodwill that is tax deductible for GILTI purposes is approximately \$35.0 million.

Our preliminary estimate of the fair value of the specifically identifiable assets acquired and liabilities assumed as of the date of acquisition is subject to the finalization of management's analysis related to certain matters, such as preparing and submitting certain income tax and non-income tax filings and returns. The final determination of these fair values will be completed as additional information becomes available but no later than one year from the date of acquisition. Although the final determination may result in asset and liability fair values that are different

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

than the preliminary estimates of these amounts, it is not expected that those differences will be material to our financial position.

Pro forma results of operations as a result of this acquisition have not been presented as this acquisition is not material to our condensed consolidated statements of income. Subsequent to the acquisition date, our results of operations include the results of operations of NST.

3. Divestitures

Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM Corporation (FUJIFILM). Upon the closing of this transaction, we received approximately \$881.9 million in cash, which is subject to the finalization of certain working capital adjustments and may be further adjusted based on other contractual terms, which are discussed below. We determined that the operations disposed of in this transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

As part of this 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 \$114.0 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 also may be obligated to indemnify FUJIFILM for liabilities that existed relating to certain business activities incurred prior to the closing of this 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 did not include these contingent payments in our calculation of the fair value of the operations.

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

In connection with this transaction we recognized a total net loss of approximately \$160.2 million in our condensed consolidated statements of income. This loss included a pre-tax loss of \$95.5 million, which reflects a decrease of \$17.7 million to our previously recorded pre-tax loss. The loss recognized was based on exchange rates and business conditions on the closing date of this transaction, and included costs to sell our Hillerød, Denmark manufacturing operations of approximately \$11.2 million and our estimate of the fair value of an adverse commitment of \$114.0 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. We also recorded a tax expense of \$64.7 million related to this transaction.

In addition, we sold to FUJIFILM \$41.8 million of raw materials that were remaining at the Hillerød facility on the closing date of this transaction. These materials were sold at cost, which approximates fair value.

Our estimate of the fair value of the adverse commitment is a Level 3 measurement and is based on forecasted batch production at the Hillerød facility.

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 September 30,					
	2019			2018		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 842.0	\$ 280.4	\$ 1,122.4	\$ 842.1	\$ 247.9	\$ 1,090.0
Interferon*	360.3	169.7	530.0	421.5	168.6	590.1
TYSABRI	263.0	220.6	483.6	253.0	217.2	470.2
FAMPYRA	—	24.2	24.2	—	22.5	22.5
Subtotal: MS product revenues	1,465.3	694.9	2,160.2	1,516.6	656.2	2,172.8
Spinal Muscular Atrophy:						
SPINRAZA	236.7	310.4	547.1	223.9	243.8	467.7
Biosimilars:						
BENEPALI	—	115.9	115.9	—	123.4	123.4
IMRALDI	—	49.3	49.3	—	—	—
FLIXABI	—	18.4	18.4	—	11.4	11.4
Subtotal: Biosimilar product revenues	—	183.6	183.6	—	134.8	134.8
Other:						
FUMADERM	—	3.8	3.8	—	4.8	4.8
Total product revenues	\$ 1,702.0	\$ 1,192.7	\$ 2,894.7	\$ 1,740.5	\$ 1,039.6	\$ 2,780.1

*Interferon includes AVONEX and PLEGRIDY.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited, continued)

(In millions)	For the Nine Months Ended September 30,					
	2019			2018		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 2,429.5	\$ 841.9	\$ 3,271.4	\$ 2,396.8	\$ 766.9	\$ 3,163.7
Interferon*	1,067.3	518.0	1,585.3	1,237.5	528.4	1,765.9
TYSABRI	772.3	647.0	1,419.3	768.2	631.3	1,399.5
FAMPYRA	—	71.2	71.2	—	69.9	69.9
ZINBRYTA	—	—	—	—	1.4	1.4
Subtotal: MS product revenues	4,269.1	2,078.1	6,347.2	4,402.5	1,997.9	6,400.4
Spinal Muscular Atrophy:						
SPINRAZA	690.6	863.2	1,553.8	617.8	636.5	1,254.3
Biosimilars:						
BENEPALI	—	360.2	360.2	—	359.9	359.9
IMRALDI	—	132.3	132.3	—	—	—
FLIXABI	—	49.9	49.9	—	29.2	29.2
Subtotal: Biosimilar product revenues	—	542.4	542.4	—	389.1	389.1
Other:						
FUMADERM	—	11.6	11.6	—	17.3	17.3
Total product revenues	\$ 4,959.7	\$ 3,495.3	\$ 8,455.0	\$ 5,020.3	\$ 3,040.8	\$ 8,061.1

*Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 28.7% and 18.4% of gross product revenues for the three months ended September 30, 2019, and 30.1% and 17.0% of gross product revenues for the nine months ended September 30, 2019.

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

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	480.3	2,149.7	16.1	2,646.1
Adjustments relating to prior years	(0.4)	(46.7)	4.6	(42.5)
Payments/credits relating to sales in current year	(349.3)	(1,510.0)	(0.7)	(1,860.0)
Payments/credits relating to sales in prior years	(129.3)	(564.4)	(15.4)	(709.1)
Balance, as of September 30, 2019	\$ 129.1	\$ 917.4	\$ 39.3	\$ 1,085.8

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 September 30, 2019	As of December 31, 2018
Reduction of accounts receivable, net	\$ 201.6	\$ 176.6
Component of accrued expenses and other	884.2	874.7
Total revenue-related reserves	<u>\$ 1,085.8</u>	<u>\$ 1,051.3</u>

Revenues from Anti-CD20 Therapeutic Programs

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Biogen's share of pre-tax profits in the U.S. for RITUXAN, RITUXAN HYCELA and GAZYVA	\$ 393.2	\$ 358.0	\$ 1,161.2	\$ 1,066.6
Other revenues from anti-CD20 therapeutic programs	202.6	153.7	528.4	378.7
Total revenues from anti-CD20 therapeutic programs	<u>\$ 595.8</u>	<u>\$ 511.7</u>	<u>\$ 1,689.6</u>	<u>\$ 1,445.3</u>

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:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	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	\$ 0.3	\$ (0.7)	\$ (0.2)	\$ (7.9)
Revenues earned under our technical development agreement, manufacturing services agreements and royalty revenues on biosimilar products with Samsung Bioepis	12.9	48.1	89.9	80.7
Other royalty and corporate revenues:				
Royalty	3.3	7.9	9.9	35.8
Other corporate	93.1	91.9	462.4	311.6
Total other revenues	<u>\$ 109.6</u>	<u>\$ 147.2</u>	<u>\$ 562.0</u>	<u>\$ 420.2</u>

Other corporate revenues primarily reflect amounts earned under contract manufacturing agreements with our strategic partners, including Bioverativ Inc. (Bioverativ). During the three and nine months ended September 30, 2019, we recognized \$65.6 million and \$306.9 million, respectively, in revenues under the manufacturing and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business, compared to \$36.5 million and \$131.1 million, respectively, in the prior year comparative periods.

During the third quarter of 2019 we amended our agreement with a contract manufacturing customer. Under the amended agreement, we will license certain of our manufacturing-related intellectual property to the customer. We will be eligible to receive \$500.0 million in a series of three payments. The first payment is due upon a regulatory achievement related to the customer's product manufactured using our manufacturing-related intellectual property, with subsequent payments payable upon the first and second anniversaries of the regulatory achievement. We do not expect to recognize any amounts related to this arrangement in 2019 as we do not expect the regulatory achievement to occur until 2020. If we earn this payment, we expect to allocate the consideration between the license for the manufacturing-related intellectual property and the manufacturing product supply services.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited, continued)

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., 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 manufacturing and supply agreement with Bioverativ, please read Note 3, *Hemophilia Spin-Off*, to our consolidated financial statements included in our 2018 Form 10-K.

5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of September 30, 2019	As of December 31, 2018
Raw materials	\$ 159.3	\$ 196.3
Work in process	421.7	606.7
Finished goods	170.8	133.5
Total inventory	<u>\$ 751.8</u>	<u>\$ 936.5</u>
<i>Balance Sheet Classification:</i>		
Inventory	\$ 751.8	\$ 929.9
Investments and other assets	—	6.6
Total inventory	<u>\$ 751.8</u>	<u>\$ 936.5</u>

In the first quarter of 2019 we sold to Bioverativ hemophilia-related inventory on hand with a cost basis totaling \$173.5 million pursuant to the terms of the manufacturing 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.

Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. This transaction included the sale of \$14.0 million of work in process inventory.

In addition, we sold to FUJIFILM approximately \$41.8 million of raw materials that were remaining at the Hillerød facility on the closing date of this transaction. These materials were sold at cost, which approximates fair value.

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

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6. Intangible Assets and Goodwill

Intangible Assets

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

(In millions)	Estimated Life	As of September 30, 2019			As of December 31, 2018		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	13-23 years	\$ 543.3	\$ (542.5)	\$ 0.8	\$ 543.3	\$ (542.3)	\$ 1.0
Developed technology	15-28 years	3,005.3	(2,764.6)	240.7	3,005.3	(2,734.8)	270.5
In-process research and development	Indefinite until commercialization	954.8	—	954.8	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	(1,506.6)	2,132.1	3,638.7	(1,330.2)	2,308.5
Total intangible assets		<u>\$ 8,206.1</u>	<u>\$ (4,813.7)</u>	<u>\$ 3,392.4</u>	<u>\$ 7,727.3</u>	<u>\$ (4,607.3)</u>	<u>\$ 3,120.0</u>

For the three and nine months ended September 30, 2019, amortization and impairment of acquired intangible assets totaled \$283.9 million and \$422.2 million, respectively, compared to \$281.9 million and \$493.2 million, respectively, in the prior year comparative periods.

Amortization and impairments of acquired intangible assets for the three and nine months ended September 30, 2019, reflects the impact of a \$215.9 million impairment charge related to certain IPR&D assets associated with the Phase 2b study of BG00011 (STX-100) for the potential treatment of idiopathic pulmonary fibrosis (IPF), which was discontinued during the third quarter of 2019, as discussed below.

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

Amortization of acquired intangible assets, excluding impairment charges, totaled \$68.0 million and \$206.3 million for the three and nine months ended September 30, 2019, respectively, compared to \$92.6 million and \$303.9 million, respectively, in the prior year comparative periods.

The decrease in amortization of acquired intangible assets, excluding impairment charges, was primarily due to a net overall decrease in our expected rate of amortization for acquired intangible assets. This decrease 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.

Developed Technology

Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. The net book value of this asset as of September 30, 2019, was \$236.6 million.

IPR&D

IPR&D represents the fair value assigned to research and development assets that we acquired as part of a business combination 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.

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In connection with our acquisition of NST on June 7, 2019, we acquired IPR&D programs with an estimated fair value of \$700.0 million. For additional information on our acquisition of NST, please read Note 2, *Acquisitions*, to these condensed consolidated financial statements.

BG00011

During the third quarter of 2019 we discontinued the Phase 2b study of BG00011 for the potential treatment of IPF due to safety concerns. As a result, we recognized an impairment charge of approximately \$215.9 million during the third quarter of 2019 to reduce the fair value of the IPR&D intangible asset to zero. We also adjusted the value of our contingent consideration obligations related to this asset resulting in a gain of \$61.2 million in the third quarter of 2019.

Vixotrigine

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

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

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

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 September 30, 2019, was \$1,889.6 million and the net book value of the TECFIDERA asset as of September 30, 2019, was \$45.6 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.

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Our most recent long-range planning cycle was completed in the second quarter of 2019. 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 September 30, 2019
2019 (remaining three months)	\$ 65.0
2020	255.0
2021	215.0
2022	215.0
2023	220.0
2024	210.0

Goodwill

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

(In millions)	As of September 30, 2019
Goodwill, beginning of period	\$ 5,706.4
Increase in goodwill	112.6
Elimination of goodwill allocated to Hillerød, Denmark manufacturing operations	(69.5)
Other	(3.4)
Goodwill, end of period	<u>\$ 5,746.1</u>

The increase in goodwill during the nine months ended September 30, 2019, was related to our acquisition of NST. For additional information on our acquisition of NST, please read Note 2, *Acquisitions*, to these condensed consolidated financial statements.

The elimination of goodwill represents an allocation based upon the relative fair value of our Hillerød, Denmark manufacturing operations. In connection with the divestiture of our Hillerød, Denmark manufacturing operations, our remaining goodwill was reviewed for impairment, and based upon this review, no impairments were recognized. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, *Divestitures*, to these condensed consolidated financial statements.

As of September 30, 2019, we had no accumulated impairment losses related to goodwill.

Other includes changes related to foreign currency exchange rate fluctuations.

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7. Fair Value Measurements

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

As of September 30, 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	\$ 1,655.8	\$ —	\$ 1,655.8	\$ —
Marketable debt securities:				
Corporate debt securities	2,702.2	—	2,702.2	—
Government securities	868.2	—	868.2	—
Mortgage and other asset backed securities	337.0	—	337.0	—
Marketable equity securities	336.7	18.5	318.2	—
Derivative contracts	161.7	—	161.7	—
Plan assets for deferred compensation	26.3	—	26.3	—
Total	<u>\$ 6,087.9</u>	<u>\$ 18.5</u>	<u>\$ 6,069.4</u>	<u>\$ —</u>
Liabilities:				
Derivative contracts	\$ 9.8	\$ —	\$ 9.8	\$ —
Contingent consideration obligations	343.5	—	—	343.5
Total	<u>\$ 353.3</u>	<u>\$ —</u>	<u>\$ 9.8</u>	<u>\$ 343.5</u>
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	<u>\$ 5,102.5</u>	<u>\$ 51.7</u>	<u>\$ 5,050.8</u>	<u>\$ —</u>
Liabilities:				
Derivative contracts	\$ 24.6	\$ —	\$ 24.6	\$ —
Contingent consideration obligations	409.8	—	—	409.8
Total	<u>\$ 434.4</u>	<u>\$ —</u>	<u>\$ 24.6</u>	<u>\$ 409.8</u>

There have been no impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2019. In addition, there were no changes in valuation techniques or inputs utilized or transfers between fair value measurement levels during the three and nine months ended September 30, 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 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. For a description of our validation procedures related to prices provided by third-party pricing

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services and our option pricing valuation 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 September 30, 2019		As of December 31, 2018	
	Fair Value	Carrying Value	Fair Value	Carrying Value
2.900% Senior Notes due September 15, 2020	\$ 1,509.9	\$ 1,495.3	\$ 1,489.5	\$ 1,480.8
3.625% Senior Notes due September 15, 2022	1,037.8	996.3	1,000.4	995.5
4.050% Senior Notes due September 15, 2025	1,888.8	1,739.1	1,745.1	1,737.8
5.200% Senior Notes due September 15, 2045	2,054.2	1,722.8	1,802.6	1,722.4
Total	\$ 6,490.7	\$ 5,953.5	\$ 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. (Stromedix) and Biogen International Neuroscience GmbH in 2015, 2012 and 2010, respectively, we agreed to make additional payments based upon the achievement of certain milestone events. The following table provides a roll forward of the fair values of our contingent consideration obligations, which includes Level 3 measurements:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Fair value, beginning of period	\$ 401.3	\$ 499.9	\$ 409.8	\$ 523.6
Changes in fair value	(57.8)	(87.9)	(66.3)	(91.6)
Payments	—	—	—	(20.0)
Fair value, end of period	\$ 343.5	\$ 412.0	\$ 343.5	\$ 412.0

As of September 30, 2019 and December 31, 2018, \$196.0 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 and nine months ended September 30, 2019, changes in the fair value of our contingent consideration obligations were primarily due to the discontinuation of the Phase 2b study of BG00011 for the potential treatment of IPF resulting in a reduction of our contingent consideration obligations of \$61.2 million, partially offset by a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

For the three and nine months ended September 30, 2018, changes in the fair value of our contingent consideration obligations were primarily due to lower cumulative probabilities of success related to our vixotrigine program for the potential treatment of TGN, an increase in interest rates used to revalue our contingent consideration liabilities and the passage of time. In addition, we dosed our first patient in the Phase 2b study of BG00011 for the potential treatment of IPF in September 2018 and paid an \$81.5 million milestone payment to the former shareholders of Stromedix during the fourth quarter of 2018.

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8. Financial Instruments

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

(In millions)	As of September 30, 2019	As of December 31, 2018
Commercial paper	\$ 255.9	\$ 231.2
Overnight reverse repurchase agreements	176.9	—
Money market funds	1,103.2	279.5
Short-term debt securities	119.8	194.8
Total	<u>\$ 1,655.8</u>	<u>\$ 705.5</u>

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 September 30, 2019 (In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities				
Current	\$ 1,655.9	\$ 1.5	\$ —	\$ 1,657.4
Non-current	1,040.4	4.7	(0.3)	1,044.8
Government securities				
Current	435.6	0.5	(0.1)	436.0
Non-current	431.8	0.8	(0.4)	432.2
Mortgage and other asset backed securities				
Current	0.1	—	—	0.1
Non-current	335.7	1.6	(0.4)	336.9
Total marketable debt securities	<u>\$ 3,899.5</u>	<u>\$ 9.1</u>	<u>\$ (1.2)</u>	<u>\$ 3,907.4</u>
Marketable equity securities, non-current	<u>\$ 218.8</u>	<u>\$ 120.7</u>	<u>\$ (2.8)</u>	<u>\$ 336.7</u>
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	<u>\$ 3,694.0</u>	<u>\$ 1.3</u>	<u>\$ (6.0)</u>	<u>\$ 3,689.3</u>
Marketable equity securities, non-current	<u>\$ 496.2</u>	<u>\$ 127.7</u>	<u>\$ (8.5)</u>	<u>\$ 615.4</u>

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Summary of Contractual Maturities: Available-for-Sale Securities

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

(In millions)	As of September 30, 2019		As of December 31, 2018	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 2,091.6	\$ 2,093.5	\$ 2,314.6	\$ 2,313.4
Due after one year through five years	1,686.0	1,691.7	1,235.9	1,232.7
Due after five years	121.9	122.2	143.5	143.2
Total available-for-sale securities	<u>\$ 3,899.5</u>	<u>\$ 3,907.4</u>	<u>\$ 3,694.0</u>	<u>\$ 3,689.3</u>

The average maturity of our marketable debt securities available-for-sale as of September 30, 2019 and December 31, 2018, were approximately 15 months and 12 months, respectively.

Proceeds from Marketable Debt Securities

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Proceeds from maturities and sales	\$ 611.8	\$ 1,192.0	\$ 3,867.6	\$ 7,994.7
Realized gains	\$ 0.7	\$ 0.4	\$ 2.3	\$ 3.0
Realized losses	\$ (0.1)	\$ (0.6)	\$ (0.7)	\$ (10.8)

Strategic Investments

As of September 30, 2019 and December 31, 2018, our strategic investment portfolio was comprised of investments totaling \$394.5 million and \$676.3 million, respectively, 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 shares of Ionis common stock acquired in June 2018. This investment is classified as a Level 2 marketable security due to certain holding period restrictions and is remeasured each reporting period and carried at fair value. The effect of the holding period restrictions on our investment in Ionis common 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 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 decrease in our strategic investment portfolio for the nine months ended September 30, 2019, primarily reflects our sale of a portion of our investment in Ionis common stock for approximately \$382.0 million as well as our sale of our investment in a non-marketable equity security, partially offset by an increase in the fair value of our remaining investment in Ionis common stock.

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.

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9. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of September 30, 2019 and December 31, 2018, had durations of 1 to 15 months and 1 to 12 months, respectively. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses of such contracts are recognized in revenues when the sale of product in the currency being hedged is recognized and in operating expenses when the expense in the currency being hedged is recorded. 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:

(In millions)	Notional Amount	
	As of September 30, 2019	As of December 31, 2018
Euro	\$ 1,943.7	\$ 1,701.4
British pound	60.9	215.3
Swiss franc	36.9	131.4
Japanese yen	29.8	98.8
Canadian dollar	25.0	92.2
Total foreign currency forward contracts	<u>\$ 2,096.3</u>	<u>\$ 2,239.1</u>

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 \$65.7 million and \$27.3 million as of September 30, 2019 and December 31, 2018, respectively. We expect the net gains of \$65.7 million to be settled over the next 15 months, of which \$59.8 million of these gains are expected to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenues or operating expenses. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of September 30, 2019 and December 31, 2018, credit risk did not change the fair value of our foreign currency forward contracts.

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

For the Three Months Ended September 30,					
Location	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Location	Net Gains/(Losses) Recognized in Operating Income (in millions)	
	2019	2018		2019	2018
Revenues	\$ 35.2	\$ (8.4)	Revenues	\$ 0.8	\$ 0.3
Operating expenses	\$ (0.8)	\$ (0.3)	Operating expenses	\$ 0.4	\$ 0.4

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For the Nine Months Ended September 30,

Location	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Location	Net Gains/(Losses) Recognized in Operating Income (in millions)	
	2019	2018		2019	2018
Revenues	\$ 79.8	\$ (51.7)	Revenues	\$ 8.2	\$ 7.3
Operating expenses	\$ (2.0)	\$ 0.6	Operating expenses	\$ (0.8)	\$ —

Interest Rate Contracts - Hedging Instruments

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

In connection with the issuance of our 2.90% Senior Notes, we entered into interest rate swaps with an aggregate notional amount of \$675.0 million, which expire on September 15, 2020. The interest rate swap contracts are designated as hedges of the fair value changes in our 2.90% Senior Notes attributable to changes in interest rates. The carrying value of our 2.90% Senior Notes as of September 30, 2019 and December 31, 2018, includes approximately \$2.1 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 September 30, 2019, had remaining durations of one month. 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 \$41.6 million and net losses of \$3.8 million as of September 30, 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 \$8.8 million and \$7.3 million as of September 30, 2019 and December 31, 2018, respectively.

The following tables summarize the effect of our net investment hedge in our condensed consolidated financial statements:

For the Three Months Ended September 30,

Location	Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)		Location	Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)		Location	Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)	
	2019	2018		2019	2018		2019	2018
Gains (losses) on net investment hedge	\$ 22.0	\$ —	Gains (losses) on net investment hedge	\$ 1.4	\$ —	Other income (expense)	\$ 2.2	\$ —

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For the Nine Months Ended September 30,

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
Gains (losses) on net investment hedge	\$ 45.4	\$ —	Gains (losses) on net investment hedge	\$ 8.1	\$ —
			Other income (expense)	\$ 6.6	\$ —

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 \$848.4 million and \$735.1 million as of September 30, 2019 and December 31, 2018, respectively. Net losses of \$10.3 million and \$14.2 million related to these contracts were recognized as a component of other income (expense), net for the three and nine months ended September 30, 2019, respectively, compared to net gains of \$5.2 million and \$4.8 million, respectively, in the prior year comparative periods.

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 materially 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 September 30, 2019	As of December 31, 2018
<i>Cash Flow Hedging Instruments:</i>			
Asset derivative instruments	Other current assets	\$ 152.2	\$ 65.8
	Investments and other assets	\$ 7.5	\$ —
Liability derivative instruments	Accrued expenses and other	\$ 1.6	\$ 6.9
<i>Fair Value Hedging Instruments:</i>			
Liability derivative instruments	Accrued expenses and other	\$ 2.1	\$ 14.5
<i>Other Derivatives:</i>			
Asset derivative instruments	Other current assets	\$ 2.0	\$ 1.1
Liability derivative instruments	Accrued expenses and other	\$ 6.1	\$ 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 \$1,555.3 million and \$1,797.4 million as of September 30, 2019 and December 31, 2018, respectively. For the three and nine months ended September 30, 2019, depreciation expense totaled \$45.5 million and \$145.4 million, respectively, compared to \$64.8 million and \$194.0 million, respectively, in the prior year comparative periods.

Solothurn, Switzerland Facility

We are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially 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

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51,000 square feet of administrative space. As of September 30, 2019 and December 31, 2018, we had approximately \$1.8 billion and \$1.6 billion, respectively, capitalized as construction in progress related to this facility. As of September 30, 2019, we had contractual commitments of approximately \$63.7 million outstanding related to the construction of this facility.

Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. This transaction included \$631.5 million of property, plant and equipment, which was primarily comprised of \$312.5 million for buildings and \$287.3 million for machinery and equipment. For additional information on the 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 one year to nine 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.

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 one year to nine 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 September 30, 2019
Assets:		
Operating lease assets	Operating lease assets	\$ 422.0
Liabilities		
Current operating lease liabilities	Accrued expenses and other	\$ 70.6
Non-current operating lease liabilities	Long-term operating lease liabilities	410.5
Total operating lease liabilities		\$ 481.1

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 September 30,		For the Nine Months Ended September 30,	
		2019		2019	
Operating lease cost	Research and development	\$ 1.8	\$	5.5	\$
	Selling, general and administrative	21.3	\$	62.7	\$
Sublease income	Selling, general and administrative	(6.2)	\$	(19.3)	\$
	Other (income) expense, net	(1.0)	\$	(2.9)	\$
Net lease cost		\$ 15.9	\$	46.0	\$

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The minimum lease payments for the next five years and thereafter is expected to be as follows:

(In millions)	As of September 30, 2019
2019 (remaining three months)	\$ 29.9
2020	80.0
2021	74.8
2022	71.5
2023	70.2
2024	67.3
Thereafter	148.7
Total lease payments	\$ 542.4
Less: interest	61.3
Present value of operating lease liabilities	\$ 481.1

Under the prior lease accounting 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 September 30, 2019
Weighted average remaining lease term in years	7.2
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 September 30, 2019	For the Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	\$ 23.5	\$ 70.3
Operating lease assets obtained in exchange for lease obligations	\$ 4.6	\$ 17.3

Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. This transaction included \$2.2 million of operating lease assets and \$2.2 million of operating lease liabilities. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, *Divestitures*, to these condensed consolidated financial statements.

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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. Under our 2019 Share Repurchase Program, we repurchased and retired approximately 3.1 million and 7.0 million shares of our common stock at a cost of approximately \$717.9 million and \$1.6 billion during the three and nine months ended September 30, 2019, respectively.

From October 1, 2019 through October 21, 2019, we repurchased and retired approximately 2.3 million shares of our common stock at a cost of approximately \$508.6 million under our 2019 Share Repurchase Program. Approximately \$2.9 billion remained available under our 2019 Share Repurchase Program as of October 21, 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), which was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million shares of our common stock at a cost of approximately \$2.1 billion during the nine months ended September 30, 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 10.5 million shares of our common stock at a cost of approximately \$3.0 billion during the nine months ended September 30, 2018.

Accumulated Other Comprehensive Income (Loss)

The following tables summarize 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	11.6	115.8	53.5	1.5	51.3	233.7
Amounts reclassified from accumulated other comprehensive income (loss)	(1.3)	(77.7)	(6.6)	—	—	(85.6)
Net current period other comprehensive income (loss)	10.3	38.1	46.9	1.5	51.3	148.1
Balance, September 30, 2019	\$ 6.3	\$ 72.8	\$ 50.4	\$ (29.8)	\$ (192.0)	\$ (92.3)

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(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	(7.9)	58.3	—	0.2	(38.8)	11.8
Amounts reclassified from accumulated other comprehensive income (loss)	6.1	50.7	—	—	—	56.8
Net current period other comprehensive income (loss)	(1.8)	109.0	—	0.2	(38.8)	68.6
Balance, September 30, 2018	<u>\$ (1.9)</u>	<u>\$ 4.5</u>	<u>\$ —</u>	<u>\$ (36.6)</u>	<u>\$ (214.3)</u>	<u>\$ (248.3)</u>

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

(In millions)	Income Statement Location	Amounts Reclassified from Accumulated Other Comprehensive Income			
		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
		2019	2018	2019	2018
Gains (losses) on securities available for sale	Other income (expense)	\$ 0.6	\$ (0.1)	\$ 1.6	\$ (7.7)
	Income tax benefit (expense)	(0.1)	—	(0.3)	1.6
Gains (losses) on cash flow hedges	Revenues	35.2	(8.4)	79.8	(51.7)
	Operating expenses	(0.8)	(0.3)	(2.0)	0.6
	Other income (expense)	0.1	0.1	0.2	0.2
	Income tax benefit (expense)	(0.1)	—	(0.3)	0.2
Gains (losses) on net investment hedge	Other income (expense)	2.2	—	6.6	—
	Income tax benefit (expense)	—	—	—	—
Total reclassifications, net of tax		<u>\$ 37.1</u>	<u>\$ (8.7)</u>	<u>\$ 85.6</u>	<u>\$ (56.8)</u>

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13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
<i>Numerator:</i>				
Net income attributable to Biogen Inc.	\$ 1,545.9	\$ 1,444.4	\$ 4,448.8	\$ 3,483.9
<i>Denominator:</i>				
Weighted average number of common shares outstanding	184.0	201.4	190.3	206.6
<i>Effect of dilutive securities:</i>				
Stock options and employee stock purchase plan	—	—	—	—
Time-vested restricted stock units	0.1	0.4	0.1	0.3
Market stock units	0.1	0.1	0.1	0.1
Performance stock units settled in stock	—	—	—	—
Dilutive potential common shares	0.2	0.5	0.2	0.4
Shares used in calculating diluted earnings per share	184.2	201.9	190.5	207.0

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

14. Share-based Payments

Share-based Compensation Expense

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 15.4	\$ 21.0	\$ 65.2	\$ 60.5
Selling, general and administrative	34.2	29.4	116.8	83.1
Subtotal	49.6	50.4	182.0	143.6
Capitalized share-based compensation costs	(1.7)	(3.5)	(7.8)	(9.7)
Share-based compensation expense included in total cost and expenses	47.9	46.9	174.2	133.9
Income tax effect	(8.1)	(7.7)	(29.1)	(21.8)
Share-based compensation expense included in net income attributable to Biogen Inc.	\$ 39.8	\$ 39.2	\$ 145.1	\$ 112.1

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Market stock units	\$ 9.3	\$ 7.4	\$ 24.8	\$ 20.6
Time-vested restricted stock units	37.9	29.9	104.4	96.6
Cash settled performance units	0.3	5.8	(0.3)	9.4
Performance units	0.2	3.0	1.0	4.2
Performance stock units settled in stock	(1.1)	1.3	13.0	3.4
Performance stock units settled in cash	1.3	1.1	3.2	1.5
Employee stock purchase plan	1.7	1.9	9.7	7.9
NST stock options	—	—	26.2	—
Subtotal	49.6	50.4	182.0	143.6
Capitalized share-based compensation costs	(1.7)	(3.5)	(7.8)	(9.7)
Share-based compensation expense included in total cost and expenses	\$ 47.9	\$ 46.9	\$ 174.2	\$ 133.9

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.

Stock option expense reflects the accelerated vesting of stock options previously granted to NST employees as a result of our acquisition of NST. For additional information on our acquisition of NST, please read Note 2, *Acquisitions*, to these condensed consolidated financial statements.

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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Statutory rate	21.0 %	21.0 %	21.0 %	21.0 %
State taxes	0.9	0.6	0.7	0.7
Taxes on foreign earnings	(5.0)	(0.5)	(4.7)	(1.3)
Credits and net operating loss utilization	(1.5)	(1.0)	(1.0)	(0.8)
Purchased intangible assets	0.4	0.3	0.4	0.5
Divestiture of Denmark manufacturing operations	—	—	1.5	—
Internal reorganization of certain intellectual property rights	(1.5)	—	(2.1)	—
GILTI	1.6	1.3	1.6	1.4
U.S. tax reform	—	(0.6)	—	(0.3)
Swiss tax reform	(3.1)	—	(1.0)	—
Other permanent items	(0.1)	0.3	0.2	0.3
Other	(0.8)	(1.0)	(0.3)	(0.2)
Effective tax rate	11.9 %	20.4 %	16.3 %	21.3 %

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Changes in Tax Rate

For the three months ended September 30, 2019, compared to the same period in 2018, the decrease in our effective tax rate was primarily due to the enactment of a new taxing regime in the country and certain cantons of Switzerland, which we refer to as Swiss Tax Reform. As a result of the impact of Swiss Tax Reform, in the three months ended September 30, 2019, we recorded an income tax benefit of approximately \$54.3 million, resulting from a remeasurement of our deferred tax assets and liabilities. In addition, in the three months ended September 30, 2019, we recognized a net benefit for the impact of the internal reorganization of certain intellectual property rights and a net benefit of \$15.8 million resulting from the finalization of tax returns in various jurisdictions related to the 2018 fiscal year. We also had a higher effective tax rate in 2018 resulting from our sale of inventory, the tax effect of which had been included within prepaid taxes at January 1, 2018, at a higher effective tax rate than the 2018 statutory tax rate.

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease in our effective tax rate was primarily due to the combination of the internal reorganization of certain intellectual property rights and the impact of Swiss Tax Reform. This decrease was partially offset by a \$64.7 million tax expense related to the divestiture of our subsidiary that owned our Hillerød, Denmark manufacturing operations. We also had a higher effective tax rate in 2018 resulting from our sale of inventory, the tax effect of which had been included within prepaid taxes at January 1, 2018, at a higher effective tax rate than the 2018 statutory tax rate.

Although we are recognizing a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture requires us to write off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions.

As a result of the internal reorganization of certain intellectual property rights, as of September 30, 2019, we recorded a deferred tax asset of \$754.2 million and a deferred tax liability of \$603.4 million.

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.

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, collaboration and other issues as we receive additional information from various taxing authorities, including reaching settlements with such authorities.

16. Other Consolidated Financial Statement Detail

Other Income (Expense), Net

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Interest income	\$ 30.5	\$ 26.0	\$ 90.8	\$ 81.4
Interest expense	(45.8)	(49.0)	(141.4)	(151.2)
Gain (loss) on investments, net	(4.1)	141.1	198.9	132.0
Foreign exchange gains (losses), net	(4.2)	0.2	(4.7)	(13.8)
Other, net	(3.7)	(3.2)	(11.0)	(8.8)
Total other income (expense), net	<u>\$ (27.3)</u>	<u>\$ 115.1</u>	<u>\$ 132.6</u>	<u>\$ 39.6</u>

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Gain (loss) on investments, net, as reflected in the table above, relate to debt securities, equity securities of certain biotechnology companies, venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.

The following table summarizes our gain (loss) on investments, net that relates to our equity securities held as of September 30, 2019:

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Net gains (losses) recognized during the period on equity securities	\$ (4.6)	\$ 141.2	\$ 197.3	\$ 139.7
Less: Net gains (losses) recognized during the period on equity securities sold during the period	\$ 4.4	\$ —	\$ 46.8	\$ (0.5)
Unrealized gains (losses) recognized during the period on equity securities held as of September 30, 2019	\$ (9.0)	\$ 141.2	\$ 150.5	\$ 140.2

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2019	As of December 31, 2018
Revenue-related reserves for discounts and allowances	\$ 884.2	\$ 874.7
Employee compensation and benefits	259.5	320.9
Royalties and licensing fees	222.3	224.7
Collaboration expenses	188.7	261.6
Current portion of contingent consideration obligations	147.5	444.8
Construction in progress	49.5	125.2
Other	677.4	609.3
Total accrued expenses and other	\$ 2,429.1	\$ 2,861.2

Other Long-term Liabilities

Other long-term liabilities were \$1,370.9 million and \$1,389.4 million as of September 30, 2019 and December 31, 2018, respectively, and included accrued income taxes totaling \$801.7 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 potential treatment of AD (the BAN2401 and Elenbecestat Collaboration).

In September 2019 we and Eisai announced the decision to discontinue the global Phase 3 trials, MISSION AD1 and MISSION AD2, designed to assess the efficacy and safety of elenbecestat in patients with mild cognitive impairment and mild AD. As a result of this decision, in the third quarter of 2019, we accrued approximately \$48.0 million related to our share of the termination of various clinical trials and research and development contracts incurred under the BAN2401 and Elenbecestat Collaboration.

The BAN2401 and Elenbecestat Collaboration also provided Eisai with an option to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for early AD (Aducanumab Option), and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). In October

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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 and nine months ended September 30, 2019 and 2018, sales and marketing expense related to the BAN2401 and Elenbecestat Collaboration was immaterial.

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Total development expense incurred by the collaboration related to the advancement of BAN2401 and elenbecestat	\$ 168.7	\$ 64.9	\$ 305.3	\$ 176.0
Biogen's share of BAN2401 and elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	\$ 84.3	\$ 32.5	\$ 152.6	\$ 88.0

Aducanumab Collaboration Agreement

Under the Aducanumab Collaboration Agreement, we and Eisai will co-promote aducanumab with a region-based profit split and we lead the ongoing development of aducanumab.

In March 2019, based on a pre-specified futility analysis, we discontinued the global Phase 3 trials, EMERGE and ENGAGE, designed to evaluate the efficacy and safety of aducanumab in patients with early AD. A new analysis of a larger dataset from these trials, conducted in consultation with the FDA, showed that the Phase 3 EMERGE study met its pre-specified primary and secondary endpoints. On October 22, 2019, we and Eisai announced that we plan to pursue regulatory approval for aducanumab in the U.S.

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.

In the first quarter of 2019, as a result of the decision to discontinue the Phase 3 EMERGE and ENGAGE trials following the futility analysis, 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 under the Aducanumab Collaboration Agreement.

Sales and marketing expense are shared in proportion to the same region-based profit split that will be utilized to co-promote aducanumab. 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.

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

(In millions)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Total aducanumab development expense	\$ 4.7	\$ 64.8	\$ 170.5	\$ 204.8
Biogen's share of aducanumab development expense reflected in research and development expense in our condensed consolidated statements of income	\$ 2.6	\$ 55.1	\$ 93.8	\$ 183.6
Total aducanumab sales and marketing expense incurred by the collaboration	\$ 0.1	\$ 12.1	\$ 21.3	\$ 33.3
Biogen's share of aducanumab sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	\$ —	\$ 5.1	\$ 11.7	\$ 19.0

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 September 30, 2019, our ownership percentage remained at approximately 49.9%.

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. In the first quarter of 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

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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 IPR&D. 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.

Our joint venture partner, Samsung BioLogics, is currently subject to an ongoing criminal investigation that we continue to monitor. While this investigation could impact the operations of Samsung Bioepis and its business, we have assessed the value of our investment in Samsung Bioepis and continue to believe that the fair value of the investment is in excess of its net book value.

For the three and nine months ended September 30, 2019, we recognized losses on our investment of \$21.8 million and \$66.8 million, respectively. These losses reflect our share of losses totaling \$0.8 million and \$9.3 million, respectively, and amortization of basis differences totaling \$21.1 million and \$57.6 million, respectively.

As of September 30, 2019 and December 31, 2018, the carrying value of our investment in Samsung Bioepis totaled 687.3 billion South Korean won (\$572.8 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, IMRALDI and FLIXABI to third parties in product revenues, net in our condensed consolidated statements of income and record the related cost of revenues and sales and marketing expenses in our condensed consolidated statements of income to their respective line items when these costs are incurred.

We share 50% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income. For the three and nine months ended September 30, 2019, we recognized net profit-sharing expense of \$60.1 million and \$181.6 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to \$47.7 million and \$131.2 million, respectively, in the prior year comparative periods.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a license agreement, a technical development services agreement and a manufacturing agreement with Samsung Bioepis. For the three and nine months ended September 30, 2019, we recognized \$12.9 million and \$89.9 million, respectively, in revenues related 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 \$48.1 million and \$80.7 million, respectively, in the prior year comparative periods.

Following the divestiture of our Hillerød, Denmark manufacturing operations on August 1, 2019, FUJIFILM assumed responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis. We no longer recognize revenues for the manufacturing completed after the divestiture date under our technical development services and manufacturing agreements with Samsung Bioepis. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read Note 3, *Divestitures*, to these condensed consolidated financial statements.

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.

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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 potential 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.

Under the terms of our collaboration and license agreement with Neurimmune (the Neurimmune Agreement), the royalty rates payable on products developed under the Neurimmune Agreement, including royalty rates payable on potential commercial sales of aducanumab, range from the high single digits to sub-teens.

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 and nine months ended September 30, 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 September 30, 2019 and December 31, 2018, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled \$23.1 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

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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. No hearing on the merits has been scheduled.

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 June 2019 the Danish court denied Fresenius Kabi's request for a preliminary injunction and Fresenius Kabi has appealed that decision.

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 Düsseldorf Regional Court relating to the German counterpart of the '510 Patent. A hearing in the proceeding in Germany has been set for March 2020. No hearing on the merits has been scheduled.

An estimate of the possible loss or range of loss in the above matters cannot be made at this time.

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 (U.K.) counterpart of the '510 Patent. Fresenius Kabi counterclaimed for infringement, damages and injunctive relief. In July 2019 the United Kingdom Patents Court entered a consent order in which it declared that the U.K. counterpart of the '510 Patent is invalid, ordered the patent revoked and dismissed Fresenius Kabi's counterclaims.

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. In September 2019 the parties entered an Agreement to Discontinue Proceedings wherein Fresenius Kabi declared the Dutch counterpart of the '510 Patent invalid and surrendered it in full.

In July 2019 Gedeon Richter PLC commenced proceedings against Biogen GmbH in the Düsseldorf Regional Court alleging infringement of the German counterpart of European Patent No. 3 212 667 (the '667 Patent), which was issued in September 2018 and expires in October 2035, and seeking damages and injunctive relief. A hearing has been set for November 2020. An estimate of the possible loss or range of loss cannot be made at this time.

In July 2019 Biogen Idec Ltd. (Biogen UK) and Samsung Bioepis UK Limited filed an action in the United Kingdom Patents Court to revoke the U.K. counterpart of the '667 Patent, and in August 2019 Biogen B.V. (Netherlands) and Samsung Bioepis UK Limited filed an action in the District Court of the Hague, Netherlands to revoke the Dutch counterpart of the '667 Patent. A hearing has been set for May 2020 in the Dutch matter and October 2020 in the U.K. matter.

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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. government declined to intervene. The case alleged 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. In September 2019 the court dismissed the action on the U.S. government's motion.

Securities Litigation

We and certain current and former officers were defendants in an action filed by a shareholder in October 2016 in the U.S. District Court for the District of Massachusetts alleging violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeking a declaration of the action as a class action and an award of damages, interest and attorneys' fees. In June 2019 the U.S. Court of Appeals for the First Circuit affirmed the judgment dismissing the complaint with prejudice.

Dismissed Shareholder Derivative Litigation

On January 13, 2017, Mary Ann Mullaney, a Biogen shareholder, filed a complaint in the U.S. District Court for the District of Delaware asserting derivative claims on behalf of Biogen against certain of the company's current and former directors and officers alleging that those individuals (i) breached their fiduciary duties by failing to oversee the company's operations, (ii) breached their fiduciary duties and Section 14(a) of the Securities Exchange Act of 1934, as amended, and (iii) were unjustly enriched. The complaint sought unspecified damages, interest, attorneys' fees and other costs. The parties filed a Joint Stipulation for Voluntary Dismissal and Proposed Order, which the court granted on August 6, 2019.

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., Princeton Pharmaceutical Inc., Sandoz Inc., Sawai USA, Inc., Shilpa 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 been set in the Delaware action against Banner Life Sciences LLC for March 2020. A trial date has been set for December 2019 in 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 (PTAB) 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 PTAB instituted *inter partes* review of the '514 Patent (the "Mylan IPR"). Thereafter, the PTAB

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granted the petition of Sawai USA, Inc. and Sawai Pharmaceutical Co. Ltd. and joined them as petitioners in the Mylan IPR. A hearing has been scheduled for November 2019.

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. A hearing has been set for June 2020. 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. No hearing on the merits has been set in this matter.

Swiss Pharma International AG, also affiliated with the Polpharma Group, filed actions in the District Court of the Hague, Netherlands (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. The decision in the Dutch action was affirmed in September 2019 and our appeal as to the German action is pending. No date for a hearing on the merits has been set in the Italian action.

'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 (the '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 U.S. governmental authorities are investigating our sales and promotional practices and have received related subpoenas. We are cooperating with the investigation.

We have also received subpoenas and other requests from the U.S. government for documents and information relating to our relationship with non-profit organizations that assist patients taking drugs sold by Biogen and the government has challenged some of our contributions to these organizations. We are cooperating with the

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investigation and have participated in preliminary discussions with the government regarding potential resolution of aspects of the matter.

We have also received subpoenas and other requests from the U.S. government for documents and information relating to Biogen's co-pay assistance programs. We cooperated with the investigation and have received no communication from the government in this matter since December 2017.

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.

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, neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS), movement disorders, including Parkinson's disease and progressive supranuclear palsy (PSP), Alzheimer's disease (AD) and dementia and ophthalmology. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology, neurocognitive disorders, acute neurology and pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

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 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, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in the E.U. For additional information on our collaboration arrangement with Samsung Bioepis, please read Note 17, *Collaborative and Other Relationships*, to our condensed consolidated financial statements included in this report.

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.

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 products, products of our collaborators and pipeline product candidates may negatively impact

future sales of our existing 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.

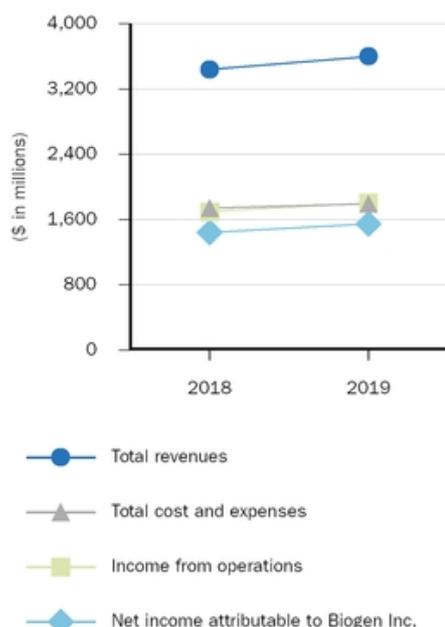
The potential impact on our results of operations and liquidity resulting from Brexit remains unclear. The actual effects of Brexit will depend upon many factors and significant uncertainty remains with respect to the ultimate resolution of the Brexit negotiations. The final outcome of these negotiations 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 3.3% and 3.4% of our total product revenues for the three and nine months ended September 30, 2019, respectively, and 3.2% and 3.3% for the prior year comparative periods, respectively, were derived from U.K. sales.

We have implemented measures to meet E.U. legal and regulatory 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.

Financial Highlights

For the Three Months ended September 30, 2019 and 2018



Diluted earnings per share attributable to Biogen Inc. was \$8.39 for the three months ended September 30, 2019, representing an increase of 17.3% over \$7.15 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 September 30, 2019, compared to the three months ended September 30, 2018, reflects the following:

- Total revenues were \$3,600.1 million for the third quarter of 2019, representing an increase of 4.7% over \$3,439.0 million in the same period in 2018.
- Product revenues, net totaled \$2,894.7 million for the third quarter of 2019, representing an increase of 4.1% over \$2,780.1 million in the same period in 2018. This increase was primarily due to a 36.2% increase in revenues from our biosimilar products and a 17.0% increase in revenues from SPINRAZA.
- Revenues from anti-CD20 therapeutic programs totaled \$595.8 million for the third quarter of 2019, representing an increase of 16.4% over \$511.7 million in the same period in 2018. This increase was primarily

due to a 37.3% increase in royalty revenues on sales of OCREVUS.

- Other revenues totaled \$109.6 million for the third quarter of 2019, representing a decrease of 25.5% from \$147.2 million in the same period in 2018. This decrease was primarily due to lower revenues from our contract manufacturing agreements.
- Total cost and expenses were \$1,793.8 million for the third quarter of 2019, representing an increase of 3.0% over \$1,741.4 million in the same period in 2018. This increase was primarily due to a 11.4% increase in selling, general and administrative expense, a 6.4% increase in research and development expense and a 34.2% decrease in net (gain) loss on fair value remeasurement of contingent consideration. The increase to cost and expenses was partially offset by a 6.7% decrease in cost of sales.
- Net income attributable to Biogen Inc. was favorably impacted by a decrease in our effective tax rate to 11.9% for the third quarter of 2019, from 20.4% for the same period in 2018, due in part to an internal reorganization of certain intellectual property rights and the impact of the enactment of a new taxing regime in the country and certain cantons of Switzerland, which we refer to as Swiss Tax Reform.

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

- Cash, cash equivalents and marketable securities totaled approximately \$6.3 billion and \$4.9 billion as of September 30, 2019 and December 31, 2018, respectively.
- We repurchased and retired approximately 3.1 million shares of our common stock at a cost of approximately \$717.9 million during the third quarter of 2019 under a program authorized by our Board of Directors in March 2019 to repurchase up to \$5.0 billion of our common stock (2019 Share Repurchase Program).

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.

Acquisition of Nightstar Therapeutics plc

On June 7, 2019, we completed our acquisition of all of the outstanding shares of Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus (AAV) treatments for inherited retinal disorders. As a result of this acquisition, we added two mid-to late-stage clinical assets, as well as preclinical programs, in ophthalmology. These assets include BIIB111 (formerly known as NSR-REP1), which is in Phase 3 development for the potential treatment of choroideremia, a rare, degenerative, X-linked inherited retinal disorder that leads to blindness and currently has no approved treatments, and BIIB112 (formerly known as NSR-RPGR), which is in Phase 2/3 development for the potential treatment of X-linked retinitis pigmentosa (XLRP), which is a rare inherited retinal disease with no currently approved treatments.

Under the terms of this acquisition, we paid NST shareholders \$25.50 in cash for each issued and outstanding NST share, which totaled \$847.6 million.

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

Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM Corporation (FUJIFILM). Upon the closing of this transaction, we received approximately \$881.9 million in cash, which is subject to the finalization of certain working capital adjustments and may be further adjusted based on

other contractual terms. In addition, we sold to FUJIFILM \$41.8 million of raw materials.

For additional information on the 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. In October 2019 the FDA issued a tentative approval for diroximel fumarate. 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 final approval.

Aducanumab (AB mAb)

On October 22, 2019, we and Eisai Co., Ltd. (Eisai) announced that we plan to pursue regulatory approval for aducanumab in the U.S. and that the Phase 3 EMERGE study met its primary endpoint showing a significant reduction in clinical decline. We believe that results from a subset of patients in the Phase 3 ENGAGE study who received sufficient exposure to high dose aducanumab support the findings from EMERGE. The decision to file is based on a new analysis, conducted by Biogen in close consultation with the FDA, of a larger dataset from the Phase 3 EMERGE and ENGAGE trials that were discontinued in March 2019 following a futility analysis.

Elenbecestat

In September 2019 we and Eisai announced the decision to discontinue the global Phase 3 trials, MISSION AD1 and MISSION AD2, designed to assess the efficacy and safety of elenbecestat, the oral BACE (base amyloid cleaving enzyme) inhibitor, in patients with mild cognitive impairment and mild AD.

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 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.

Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2019		2018		2019		2018	
Product revenues, net:								
United States	\$ 1,702.0	47.3%	\$ 1,740.5	50.6%	\$ 4,959.7	46.3%	\$ 5,020.3	50.6%
Rest of world	1,192.7	33.1%	1,039.6	30.2%	3,495.3	32.6%	3,040.8	30.6%
Total product revenues, net	2,894.7	80.4%	2,780.1	80.8%	8,455.0	79.0%	8,061.1	81.2%
Revenues from anti-CD20 therapeutic programs	595.8	16.5%	511.7	14.9%	1,689.6	15.8%	1,445.3	14.6%
Other revenues	109.6	3.0%	147.2	4.3%	562.0	5.2%	420.2	4.2%
Total revenues	\$ 3,600.1	100.0%	\$ 3,439.0	100.0%	\$ 10,706.6	100.0%	\$ 9,926.6	100.0%

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2019		2018		2019		2018	
Multiple Sclerosis:								
TECFIDERA	\$ 1,122.4	38.8%	\$ 1,090.0	39.2%	\$ 3,271.4	38.7%	\$ 3,163.7	39.2%
Interferon*	530.0	18.3%	590.1	21.2%	1,585.3	18.7%	1,765.9	21.9%
TYSABRI	483.6	16.7%	470.2	16.9%	1,419.3	16.8%	1,399.5	17.4%
FAMPYRA	24.2	0.8%	22.5	0.8%	71.2	0.8%	69.9	0.9%
ZINBRYTA	—	—%	—	—%	—	—%	1.4	—%
Subtotal: MS product revenues	2,160.2	74.6%	2,172.8	78.2%	6,347.2	75.1%	6,400.4	79.4%
Spinal Muscular Atrophy:								
SPINRAZA	547.1	18.9%	467.7	16.8%	1,553.8	18.4%	1,254.3	15.6%
Biosimilars:								
BENEPALI	115.9	4.0%	123.4	4.4%	360.2	4.3%	359.9	4.5%
IMRALDI	49.3	1.7%	—	—%	132.3	1.6%	—	—%
FLIXABI	18.4	0.6%	11.4	0.4%	49.9	0.6%	29.2	0.4%
Subtotal: Biosimilar product revenues	183.6	6.3%	134.8	4.8%	542.4	6.4%	389.1	4.8%
Other:								
FUMADERM	3.8	0.1%	4.8	0.2%	11.6	0.1%	17.3	0.2%
Total product revenues	\$ 2,894.7	100.0%	\$ 2,780.1	100.0%	\$ 8,455.0	100.0%	\$ 8,061.1	100.0%

*Interferon includes AVONEX and PLEGRIDY.

Multiple Sclerosis (MS)

TECFIDERA



TECFIDERA revenues were consistent with price increases, offset by a decrease in unit sales volume of 4% and higher rates in discounts and allowances.

For the nine months ended September 30, 2019, compared to the same period in 2018, the increase of 1.4% in U.S. TECFIDERA revenues was primarily due to price increases, partially offset by a decrease in unit sales volume of 3% and higher rates in discounts and allowances.

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases of 13.1% and 9.8%, respectively, in rest of world TECFIDERA revenues were primarily due to increases in unit sales volumes of 10% and 13%, respectively, primarily related to our European and Japanese 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

For the three months ended September 30, 2019, compared to the same period in 2018, U.S.

declines in the U.S. We also expect price reductions in certain European countries.

We are currently involved in 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, related to TECFIDERA. These parties have, or are seeking, regulatory approval of Abbreviated New Drug Applications for generic versions of TECFIDERA or NDAs filed under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. If we are unsuccessful in these patent infringement actions, generic versions of TECFIDERA or other bioequivalent products could be introduced into the market prior to our patents' expiry dates.

Interferon



For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the decreases of 14.5% and 13.8%, respectively, in U.S. Interferon revenues were primarily due to decreases in Interferon unit sales volumes of 11% and 12%, respectively, which were primarily attributable to patients transitioning to other MS therapies and price decreases.

For the three months ended September 30, 2019, compared to the same period in 2018, the increase of 0.7% in rest of world Interferon revenues was primarily due to an increase in Interferon unit sales volumes of 13%, partially offset by pricing reductions in certain European countries.

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease of 2.0% in rest of world Interferon revenues was primarily due to pricing reductions in certain European countries, partially offset by an increase in Interferon unit sales volumes of 15%.

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.

TYSABRI



For the three months ended September 30, 2019, compared to the same period in 2018, the increase of 4.0% in U.S. TYSABRI revenues was primarily due to price increases, partially offset by higher rates in discounts and allowances and a decrease in unit sales volumes of 1%.

For the nine months ended September 30, 2019, compared to the same period in 2018, the increase of 0.5% in U.S. TYSABRI revenues was primarily due to price increases, partially offset by a decrease in unit sales volumes of 4%.

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases of 1.6% and 2.5%, respectively, in rest of world TYSABRI revenues were primarily due to increases in unit sales volumes of 14% and 7%, respectively.

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 and nine months ended September 30, 2019, compared to the same periods in 2018, the increases of 5.7% and 11.8%, respectively, in U.S. SPINRAZA revenues were primarily due to increases in unit sales volumes of 6% and 12%, respectively.

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases of 27.3% and 35.6%, respectively, in rest of world SPINRAZA revenues were primarily due to increases in unit sales volumes of 71% and 68%, respectively, partially offset by the unfavorable impact of foreign currency exchange of \$9.2 million and \$36.3 million, respectively.

For the nine months ended September 30, 2019, rest of world SPINRAZA revenues were 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 from August 2017, the date upon which we began to sell SPINRAZA in France, until 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.

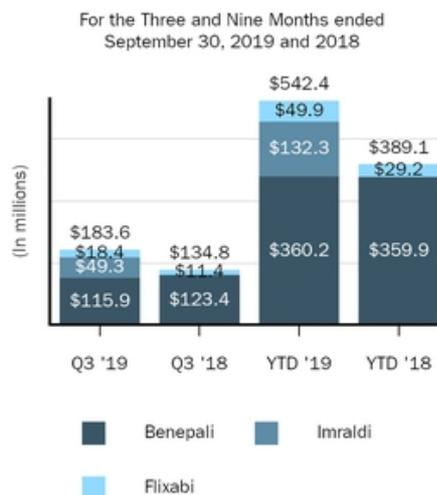
We face competition from a new gene therapy product, which was approved in the U.S. in May 2019

for the treatment of SMA. Additionally, we are aware of other products in development that, if successfully developed and approved, may compete with SPINRAZA in the SMA market. Future sales of SPINRAZA may be adversely affected by the commercialization of these competing products.

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, IMRALDI and FLIXABI



For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases of 36.2% and 39.4%, respectively, in biosimilar revenues were primarily due to the launch of IMRALDI in the fourth quarter of 2018, partially offset by the unfavorable impact of foreign currency exchange of \$6.5 million and \$23.7 million, respectively.

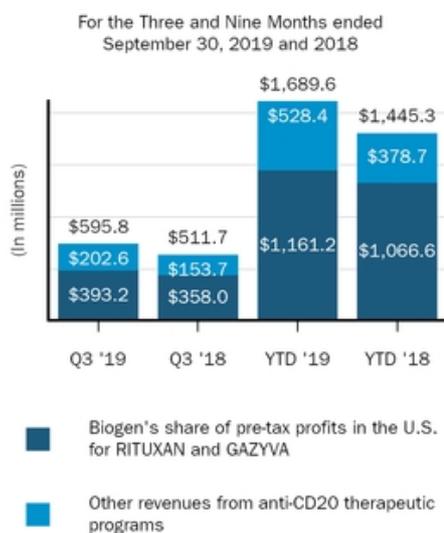
In 2019 we expect strong revenue growth for our biosimilar business, primarily driven by the continued launch of IMRALDI.

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

(In millions)	For the Three Months Ended September 30,	
	2019	2018
Product revenues, net	\$ 1,189.8	\$ 1,112.4
Cost and expenses	141.6	157.0
Pre-tax profits in the U.S.	1,048.2	955.4
Biogen's share of pre-tax profits	\$ 393.2	\$ 358.0

(In millions)	For the Nine Months Ended September 30,	
	2019	2018
Product revenues, net	\$ 3,581.5	\$ 3,350.5
Cost and expenses	473.0	499.9
Pre-tax profits in the U.S.	3,108.5	2,850.6
Biogen's share of pre-tax profits	\$ 1,161.2	\$ 1,066.6

For the three months ended September 30, 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 6.1%. This increase in net sales of RITUXAN in the U.S. reflects an increase in unit sales volume of 2% and lower discounts and allowances.

For the nine months ended September 30, 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 6.4%. This increase in net sales of RITUXAN in the U.S. reflects an increase in unit sales volume of 3% and selling price increases, partially offset by higher discounts and allowances.

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in U.S. product revenues, net also reflects increases in GAZYVA unit sales volume of 20% and 13%, respectively.

For the three months ended September 30, 2019, compared to the same period in 2018, the decrease in collaboration costs and expenses was primarily due to lower cost of sales on RITUXAN.

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease in collaboration costs and expenses was primarily due to lower selling and marketing costs on RITUXAN and lower Branded Pharmaceutical Drug Fee expenses for RITUXAN and GAZYVA.

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 the fourth quarter of 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 and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in other revenues from anti-CD20 therapeutic programs were primarily due to sales growth of OCREVUS. Royalty revenues recognized on sales of OCREVUS for the three and nine months ended September 30, 2019, totaled

\$187.8 million and \$482.1 million, respectively, compared to \$136.8 million and \$326.5 million, respectively, in the prior year comparative periods.

OCREVUS royalty revenues are based on our estimates from third party and market research data of OCREVUS sales occurring during the corresponding period. Differences between actual and estimated royalty revenues will be adjusted for in the period in which they become known, which is expected to be the following quarter.

Other Revenues

Other revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2019		2018		2019		2018	
Revenues from collaborative and other relationships	\$ 13.2	12.0%	\$ 47.4	32.2%	\$ 89.7	16.0%	\$ 72.8	17.3%
Other royalty and corporate revenues	96.4	88.0%	99.8	67.8%	472.3	84.0%	347.4	82.7%
Total other revenues	\$ 109.6	100.0%	\$ 147.2	100.0%	\$ 562.0	100.0%	\$ 420.2	100.0%

Revenues from Collaborative and Other Relationships

Revenues from collaborative and other relationships primarily include revenues from our technical development services and manufacturing agreements with Samsung Bioepis and royalty revenues on biosimilar products from Samsung Bioepis.

Following the divestiture of our Hillerød, Denmark manufacturing operations on August 1, 2019, FUJIFILM assumed responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis. We no longer recognize revenues for the manufacturing completed after the divestiture date under our technical development services and manufacturing agreements with Samsung Bioepis.

For the three and nine months ended September 30, 2019, we recognized \$12.9 million and \$89.9 million, respectively, in revenues related to the services described above provided to Samsung Bioepis, compared to \$48.1 million and \$80.7 million, respectively, in the prior year comparative periods. Revenue recognized related to these services totaled \$96.4 million for the year ended December 31, 2018.

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.

For additional information on our collaborative and other relationships, including revenues recognized under our technical development services and manufacturing agreements with Samsung Bioepis, please read Note 17, *Collaborative and Other Relationships*, to our condensed consolidated financial statements included in this report.

Other Royalty and Corporate Revenues



We receive royalties from net sales on products related to patents that we have out-licensed and we record other corporate revenues primarily from

amounts earned under contract manufacturing agreements.

For the three months ended September 30, 2019, compared to the same period in 2018, the decrease in other royalty and corporate revenues was primarily due to the reduction in royalty revenues due to the expiration of certain of our patents, partially offset by higher contract manufacturing revenues.

For the nine months ended September 30, 2019, compared to the same period in 2018, the increase in other royalty and corporate revenues was primarily due to \$306.9 million in revenues recognized under the manufacturing and supply agreement with Bioverativ Inc. (Bioverativ) entered into in connection with the spin-off of our hemophilia business, compared to \$131.1 million recognized in the prior year comparative period. The increase in Bioverativ revenues over the prior year comparative period was due to sales of hemophilia inventory on hand. The increase in corporate revenues was partially offset by the reduction in royalty revenues due to the expiration of certain of our patents.

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 and nine months ended September 30, 2019, reserves for discounts and allowances as a percentage of gross product revenues were 24.4% and 23.5%, respectively, compared to 22.7% and 23.4%, respectively, in the prior year comparative periods.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, discounts were relatively consistent.

Contractual Adjustments

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

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in contractual adjustments were primarily due to higher managed care rebates and governmental rebates in the U.S. as well as higher governmental rebates and allowances in the rest of world, due in part to increases in SPINRAZA sales volumes worldwide.

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 and nine months ended September 30, 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:

(In millions, except percentages)	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2019	2018	Change %	2019	2018	Change %
Cost of sales, excluding amortization and impairment of acquired intangible assets	\$ 430.0	\$ 460.8	(6.7)%	\$ 1,508.3	\$ 1,327.8	13.6 %
Research and development	540.4	507.9	6.4 %	1,588.9	1,985.6	(20.0)%
Selling, general and administrative	554.5	497.7	11.4 %	1,709.8	1,515.2	12.8 %
Amortization and impairment of acquired intangible assets	283.9	281.9	0.7 %	422.2	493.2	(14.4)%
Collaboration profit (loss) sharing	60.2	47.5	26.7 %	181.8	129.2	40.7 %
Loss on divestiture of Hillerød, Denmark manufacturing operations	(17.7)	—	**	95.5	—	**
(Gain) loss on fair value remeasurement of contingent consideration	(57.8)	(87.9)	(34.2)%	(66.3)	(91.6)	(27.6)%
Restructuring charges	0.3	6.0	(95.0)%	1.5	9.2	(83.7)%
Acquired in-process research and development	—	27.5	**	—	112.5	**
Total cost and expenses	\$ 1,793.8	\$ 1,741.4	3.0 %	\$ 5,441.7	\$ 5,481.1	(0.7)%

** Percentage not meaningful.

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

Product Cost of Sales

For the three months ended September 30, 2019, compared to the same period in 2018, the decrease in product cost of sales was primarily due to lower cost of sales from contract manufacturing agreements and a decrease in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons, partially offset by an increase in sales of our biosimilar products.

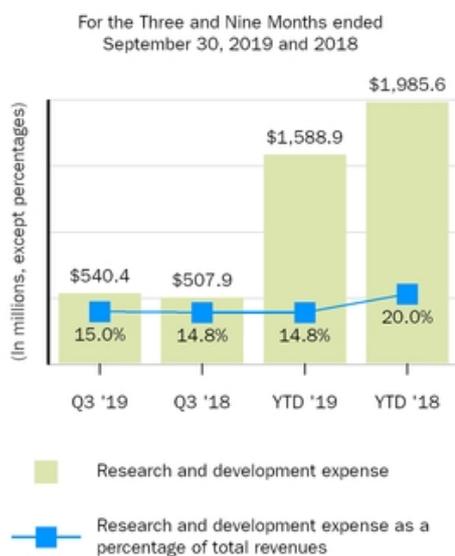


For the nine months ended September 30, 2019, compared to the same period in 2018, the increase in product cost of sales was primarily due to our sale to Bioverativ of hemophilia-related inventory on hand with a cost basis totaling \$173.5 million in the first quarter of 2019, pursuant to the terms of the manufacturing and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business, an increase in sales of our biosimilar products and an increase in inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons, partially offset by lower cost of sales from our contract manufacturing agreements, except Bioverativ, as noted above.

Royalty Cost of Sales

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the decreases in royalty cost of sales were primarily due to a decrease in royalties payable on sales of TYSABRI resulting from the expiration of certain third party royalties, partially offset by increased royalties payable on higher sales of SPINRAZA and IMRALDI.

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

For the three months ended September 30, 2019, compared to the same period in 2018, the increase in research and development expense was primarily due to increases in costs incurred in connection with our early and late stage programs, partially offset by a decrease in costs incurred in connection with milestones and upfront expenses and research and discovery.

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease in research and development expense was primarily due to a decrease in milestone and upfront expenses and a decrease in research and discovery. These decreases were partially offset by increases in costs incurred in connection with our early and late stage programs.

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

Milestone and Upfront Expenses

Milestone and upfront expenses for the nine months ended September 30, 2019, reflected 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. The decrease compared to the same period in 2018 was primarily due to the prior year recognition of a \$486.2 million net charge to research and development expense related to the closing of a 10-year exclusive agreement with Ionis to

develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases (the 2018 Ionis Agreement).

Early Stage Programs

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in spending related to our early stage programs were primarily due to an increase in costs associated with:

- our decision in September 2019 to discontinue the Phase 2b study of BG00011 (STX-100) for the potential treatment of idiopathic pulmonary fibrosis (IPF);
- BIIB092 (gosuranemab) in PSP and AD pursuant to our license agreement with Bristol-Myers Squibb Company;
- BIIB054 (α -synuclein mAb) in Parkinson's disease;
- BIIB104 in cognitive impairment associated with schizophrenia (CIAS); and
- BIIB110 (ActRIIA/B ligand trap) in SMA.

These increases were partially offset by a decrease in costs associated with:

- the development of vixotrigine (BIIB074) in trigeminal neuralgia (TGN);
- BIIB067 (tofersen) in ALS, which was advanced to a late stage program in the first quarter of 2019;
- our decision in December 2018 to discontinue development of BIIB087, an investigational AAV-based gene therapy for the treatment of X-linked retinoschisis, and BIIB088, an investigational AAV-based gene therapy for the treatment of XLRP, upon the termination of our collaboration agreement with Applied Genetic Technologies Corporation; and
- BAN2401 (A β mAb) in early AD pursuant to our collaboration arrangement with Eisai, which was advanced to a late stage program in the first quarter of 2019.

Late Stage Programs

For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in spending associated with our late stage programs were primarily due to:

- our share of the termination costs related to the discontinuation of the global Phase 3 trials of elenbecestat in AD;

- BAN2401 in early AD pursuant to our collaboration arrangement with Eisai, which was advanced to a late stage program in the first quarter of 2019;
- tofersen in ALS, which was advanced to a late stage program in the first quarter of 2019; and
- BIIB093 (glibenclamide IV) in large hemispheric infarction (LHI), which was advanced to a late stage program in the third quarter of 2018.

These increases were partially offset by a decrease in spending related to the discontinuation of the global Phase 3 trials of aducanumab, net of Eisai reimbursement.

In the first quarter of 2019, as a result of the decision to discontinue the Phase 3 EMERGE and ENGAGE trials following the futility analysis, 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. On October 22, 2019, we and Eisai announced that, based on a new analysis, conducted by Biogen in close consultation with the FDA, of a larger dataset from the Phase 3 EMERGE and ENGAGE trials that were discontinued in March 2019 following the futility analysis, we plan to pursue regulatory approval for aducanumab in the U.S.

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.

In September 2019 we and Eisai announced the decision to discontinue the global Phase 3 trials, MISSION AD1 and MISSION AD2, designed to assess the efficacy and safety of elenbecestat in patients with mild cognitive impairment and mild AD. As a result of this decision, in the third quarter of 2019, we accrued approximately \$48.0 million related to our share of the termination of various clinical trials and research and development contracts incurred under the collaboration arrangement with 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.

Selling, General and Administrative

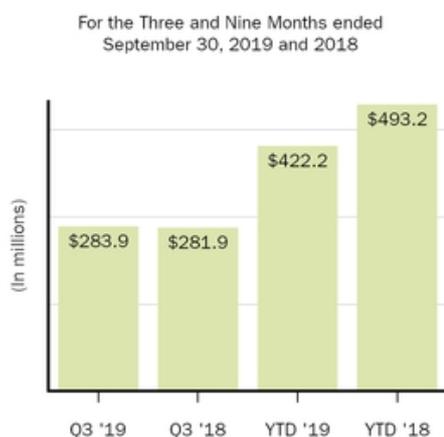
For the Three and Nine Months ended
September 30, 2019 and 2018



For the three and nine months ended September 30, 2019, compared to the same periods in 2018, the increases in selling, general and administrative expense were primarily due to an increase in corporate giving, an increase in commercialization costs, primarily related to SPINRAZA, as we continued to expand into new international markets, an increase in incentive compensation and an increase in legal and patent fees. These increases were partially offset by a decrease in operational spending associated with our pre-commercialization costs related to our AD programs following the discontinuation of the global Phase 3 trials of aducanumab in March 2019.

Selling, general and administrative expense for the nine months ended September 30, 2019, also reflects an increase due to acquisition related charges incurred in connection with our acquisition of NST totaling \$33.4 million, including \$18.4 million of stock-based compensation expense associated with the accelerated vesting of stock options previously granted to NST employees for post-combination services performed, partially offset by a decrease in operational spend on ZINBRYTA subsequent to the voluntary worldwide withdrawal of ZINBRYTA for RMS, which we and AbbVie Inc. announced in March 2018.

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 second quarter of 2019. 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 and nine months ended September 30, 2019, reflects the impact of a \$215.9 million impairment charge related to certain in-process research and development (IPR&D) assets associated with the Phase 2b study of BG00011 for the potential treatment of IPF, which was discontinued in the third quarter of 2019, as discussed below.

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

Amortization of acquired intangible assets, excluding impairment charges, totaled approximately \$68.0 million and \$206.3 million for the three and nine months ended September 30, 2019, respectively, compared to \$92.6 million and \$303.9 million, respectively, in the prior year comparative periods.

The decrease in amortization of acquired intangible assets, excluding impairment charges, was primarily due to a net overall decrease in our expected rate of amortization for acquired intangible assets. This decrease 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.

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.

IPR&D related to Business Combinations

IPR&D represents the fair value assigned to research and development assets that we acquired as part of a business combination 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.

BG00011

During the third quarter of 2019 we discontinued the Phase 2b study of BG00011 for the potential treatment of IPF due to safety concerns. As a result, we recognized an impairment charge of approximately \$215.9 million during the third quarter of 2019 to reduce the fair value of the IPR&D

intangible asset to zero. We also adjusted the value of our contingent consideration obligations related to this asset resulting in a gain of \$61.2 million in the third quarter of 2019.

Vixotrigine

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

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

Overall, the value of our acquired IPR&D assets is dependent upon many 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, research and development priorities and development risk, changes in program and portfolio economics and related impact of foreign currency exchange rates and economic trends and evaluating industry and company data regarding the productivity of clinical research and the development process. Changes in our estimates and prioritization of these items may result in a significant change to our valuation of our IPR&D assets.

For example, the TGN program has experienced numerous delays in development in the periods since we acquired the TGN program and the fair value of this asset is not significantly in excess of carrying value. In addition, we are currently testing vixotrigine in another mid-stage clinical trial, in a different neuropathic pain indication, for which we also have an IPR&D asset. Data from that trial may affect the economic value of vixotrigine and the IPR&D assets for one or both programs could be impaired if assumptions used in determining their fair value change.

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 primarily includes our partner's 50% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis.

For the three and nine months ended September 30, 2019, we recognized net profit-sharing expense of \$60.1 million and \$181.6 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to \$47.7 million and \$131.2 million, respectively, in the prior year comparative periods. The increases in profit-sharing expense were 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.

Loss on Divestiture of Hillerød, Denmark Manufacturing Operations

For the Three and Nine Months ended September 30, 2019 and 2018



Divestiture of Hillerød, Denmark Manufacturing Operations

On August 1, 2019, we completed the sale of all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. Upon the closing of this transaction, we received approximately \$881.9 million in cash, which is subject to the finalization of certain working capital adjustments and may be further adjusted based on other contractual terms, which are discussed below. We determined that the operations disposed of in this transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

As part of this 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 \$114.0 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 also may be obligated to indemnify FUJIFILM for liabilities that existed relating to certain business activities incurred prior to the closing of this 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 did not include these contingent payments in our calculation of the fair value of the operations.

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

In connection with this transaction we recognized a total net loss of approximately \$160.2 million in our condensed consolidated statements of income. This loss included a pre-tax loss of \$95.5 million, which reflects a decrease of \$17.7 million to our previously recorded pre-tax loss. The loss recognized was based on exchange rates and business conditions on the closing date of this transaction, and included costs to sell our Hillerød, Denmark manufacturing operations of approximately \$11.2 million and our estimate of the fair value of an adverse commitment of approximately \$114.0 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. We also recorded a tax expense of \$64.7 million related to this transaction.

Our estimate of the fair value of the adverse commitment is a Level 3 measurement and is based on forecasted batch production at the Hillerød facility.

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

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

For the Three and Nine Months ended September 30, 2019 and 2018



Consideration payable for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular

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

For the three and nine months ended September 30, 2019, changes in the fair value of our contingent consideration obligations were primarily due to the discontinuation of our BG00011 program for the potential treatment of IPF, partially offset by a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

For the three and nine months ended September 30, 2018, changes in the fair value of our contingent consideration obligations were primarily due to lower cumulative probabilities of success related to our vixotrigine program for the potential treatment of TGN, an increase in interest rates used to revalue our contingent consideration liabilities and the passage of time.

For additional information on our IPR&D intangible assets related to our discontinued BG00011 program for the potential treatment of IPF and our vixotrigine program for the potential treatment of TGN, please read Note 6, *Intangible Assets and Goodwill*, to our condensed consolidated financial statements included in this report.

Acquired In-Process Research and Development

For the Three and Nine Months ended September 30, 2019 and 2018



BIIB110 Acquisition

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

BIIB104 Acquisition

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

BIIB100 Acquisition

In January 2018 we acquired BIIB100 from Karyopharm Therapeutics Inc. (Karyopharm). BIIB100 is a Phase 1 investigational oral compound for the treatment of certain neurological and neurodegenerative diseases, primarily in ALS. In connection with the closing of this transaction, we made an upfront payment of \$10.0 million to Karyopharm, which was recorded as acquired IPR&D in our condensed consolidated statements of income as BIIB100 has not yet reached technological feasibility.

For additional information on our acquisitions of BIIB110, BIIB104 and BIIB100, please read Note 2, *Acquisitions*, to our consolidated financial statements included in our 2018 Form 10-K.

Other Income (Expense), Net

For the Three and Nine Months ended September 30, 2019 and 2018



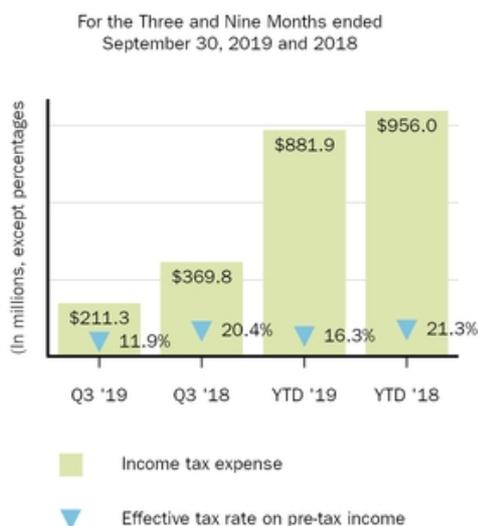
For the three months ended September 30, 2019, compared to the same period in 2018, the change in other income (expense), net primarily reflects net losses totaling \$4.1 million recognized on our investments related to our holdings in equity and debt securities, compared to net gains totaling \$141.1 million in the prior year comparative period. The net losses recognized during the three months ended September 30, 2019, primarily reflects a decrease in the fair value in our investment in Ionis common stock from June 30, 2019, partially offset by a gain recognized on our sale of a portion of our investment in Ionis common stock during the third quarter of 2019 reflecting an increase in fair value of the shares sold from June 30, 2019.

Proceeds from our sale of a portion of our investment in Ionis common stock during the three and nine months ended September 30, 2019, totaled approximately \$168.7 million and \$382.0 million, respectively. The original cost basis upon acquisition in June 2018 for the shares sold during the three and nine months ended September 30, 2019, totaled approximately \$138.9 million and \$312.5 million, respectively.

For the nine months ended September 30, 2019, compared to the same period in 2018, the change in other income (expense), net primarily reflects net gains totaling \$198.9 million recognized on our investments related to our holdings in equity and debt securities, compared to net gains totaling \$132.0 million in the prior year comparative period. The net gains recognized during the nine months ended September 30, 2019, primarily reflect an increase in the fair value in our investment in Ionis common stock from December 31, 2018, partially offset by the net loss recognized on our sale of a portion of our investment in Ionis common stock during the second quarter of 2019 and third quarter of 2019 reflecting a decrease in fair value of the shares sold from March 31, 2019.

Other income (expense), net for the nine months ended September 30, 2019, also reflects an increase in the fair value of an investment in a non-marketable equity security from December 31, 2018, that was realized for a net gain of approximately \$87.7 million upon sale in the second quarter of 2019.

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 September 30, 2019, compared to the same period in 2018, the decrease in our effective tax rate was primarily due to Swiss Tax Reform. As a result of the impact of Swiss Tax Reform, in the three months ended September 30, 2019, we recorded an income tax benefit of approximately \$54.3 million, resulting from a remeasurement of our deferred tax assets and liabilities. In addition, in the three months ended September 30, 2019, we recognized a net benefit for the impact of the internal reorganization of certain intellectual property rights and a net benefit of \$15.8 million resulting from the finalization of tax returns in various jurisdictions related to the 2018 fiscal year. We also had a higher effective tax rate in 2018 resulting from our sale of inventory, the tax effect of which had been included within prepaid taxes at January 1, 2018, at a higher effective tax rate than the 2018 statutory tax rate.

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease in our effective tax rate was primarily due to the combination of the internal reorganization of certain intellectual property rights and the impact of Swiss Tax Reform. This decrease was partially offset

by a \$64.7 million tax expense related to the divestiture of our subsidiary that owned our Hillerød, Denmark manufacturing operations. We also had a higher effective tax rate in 2018 resulting from our sale of inventory, the tax effect of which had been included within prepaid taxes at January 1, 2018, at a higher effective tax rate than the 2018 statutory tax rate.

Although we are recognizing a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture requires us to write off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions.

As a result of the internal reorganization of certain intellectual property rights, as of September 30, 2019, we recorded a deferred tax asset of \$754.2 million and a deferred tax liability of \$603.4 million.

For additional information on the 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 and nine months ended September 30, 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

For the Three and Nine Months ended
September 30, 2019 and 2018



In February 2012 we entered into a joint venture agreement with Samsung BioLogics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar 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 September 30, 2019, our ownership percentage remained at approximately 49.9%.

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. In the first quarter of 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.

Our joint venture partner, Samsung BioLogics, is currently subject to an ongoing criminal investigation that we continue to monitor. While this investigation could impact the operations of Samsung Bioepis and its business, we have assessed the value of our investment in Samsung Bioepis and continue to believe that the fair value of the investment is in excess of its net book value.

For the three and nine months ended September 30, 2019, losses reflect our share of losses totaling \$0.8 million and \$9.3 million, respectively, and amortization of basis differences totaling \$21.1 million and \$57.6 million, respectively.

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 September 30, 2019	As of December 31, 2018	Change %
Financial assets:			
Cash and cash equivalents	\$ 2,343.9	\$ 1,224.6	91.4 %
Marketable securities — current	2,093.5	2,313.4	(9.5)%
Marketable securities — non-current	1,813.9	1,375.9	31.8 %
Total cash, cash equivalents and marketable securities	<u>\$ 6,251.3</u>	<u>\$ 4,913.9</u>	<u>27.2 %</u>
Borrowings:			
Current portion of notes payable	\$ 1,495.3	\$ —	100.0 %
Notes payable	4,458.2	5,936.5	(24.9)%
Total borrowings	<u>\$ 5,953.5</u>	<u>\$ 5,936.5</u>	<u>0.3 %</u>
Working capital:			
Current assets	\$ 8,448.2	\$ 7,640.9	10.6 %
Current liabilities	(4,432.2)	(3,295.2)	34.5 %
Total working capital	<u>\$ 4,016.0</u>	<u>\$ 4,345.7</u>	<u>(7.6)%</u>

For the nine months ended September 30, 2019, certain significant cash flows were as follows:

- \$5.1 billion in net cash flows provided by operating activities, net of:
 - \$788.5 million in total payments for income taxes;
 - \$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;
- \$3.8 billion used for share repurchases;
- \$923.7 million in proceeds received on the divestiture of our Hillerød, Denmark manufacturing operations;
- \$744.4 million payment made for our acquisition of NST, net of cash acquired;
- \$476.0 million in proceeds received on sales of strategic investments;
- \$404.1 million used for purchases of property, plant and equipment; and
- \$300.0 million for the final contingent payment made to former shareholders of Fumapharm AG and holders of their rights.

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

- \$4.3 billion in net cash flows provided by operating activities, net of:
 - \$698.8 million in total payments for income taxes; and
 - \$375.0 million upfront payment made to Ionis upon the closing of the 2018 Ionis Agreement and a \$162.1 million charge reflecting the premium paid for the purchase of Ionis common stock;
- \$3.0 billion used for share repurchases;
- \$1.2 billion in contingent payments made to former shareholders of Fumapharm AG and holders of their rights;
- \$544.7 million used for purchases of property, plant and equipment;
- \$462.9 million payment made to Ionis reflecting the fair value of the Ionis common stock purchased upon the closing of the 2018 Ionis Agreement; and
- \$112.5 million in upfront payments made for our acquisitions of BIIB100, BIIB104 and BIIB110.

Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned from our operations. We expect to continue funding our current and planned operating requirements principally through our cash flows from

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

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. Under our 2019 Share Repurchase Program, we repurchased and retired approximately 3.1 million and 7.0 million shares of our common stock at a cost of approximately \$717.9 million and \$1.6 billion during the three and nine months ended September 30, 2019, respectively.

From October 1, 2019 through October 21, 2019, we repurchased and retired approximately 2.3 million shares of our common stock at a cost of approximately \$508.6 million under our 2019 Share Repurchase Program. Approximately \$2.9 billion remained available under our 2019 Share Repurchase Program as of October 21, 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), which was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million shares of our common stock at a cost of approximately \$2.1 billion during the nine months ended September 30, 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 10.5 million shares of our common stock at a cost of approximately \$3.0 billion during the nine months ended September 30, 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 September 30, 2019, we had cash, cash equivalents and marketable securities totaling approximately \$6.3 billion compared to approximately \$4.9 billion as of December 31, 2018. The net increase in cash, cash equivalents and marketable securities at September 30, 2019 from December 31, 2018, was primarily due to cash flows from operations, cash received upon the divestiture of our Hillerød, Denmark manufacturing operations and proceeds from sales of strategic investments, partially offset by cash used for share repurchases, cash used for our acquisition of NST, net purchases of property, plant and equipment, contingent payments made to former shareholders of Fumapharm AG and holders of their rights, net purchases of marketable securities and upfront payments made to Skyhawk and C4T.

Investments and other assets in our condensed consolidated balance sheet as of September 30, 2019 and December 31, 2018, includes the carrying value of our investment in Samsung Bioepis of \$572.8 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 September 30, 2019 and December 31, 2018, also includes the fair value of our investment in Ionis common stock of \$318.2 million and \$563.8 million, respectively, which is subject to certain holding period restrictions.

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

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

Cash Flows

The following table summarizes our cash flow activity:

(In millions, except percentages)	For the Nine Months Ended September 30,		
	2019	2018	% Change
Net cash flows provided by operating activities	\$ 5,118.4	\$ 4,292.3	19.2 %
Net cash flows used in investing activities	\$ (237.9)	\$ (421.0)	(43.5)%
Net cash flows used in financing activities	\$ (3,744.0)	\$ (3,035.0)	23.4 %

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.

September 30, 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 September 30, 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 September 30, 2019, from December 31, 2018, reflects an increase in total current assets of approximately \$807.3 million and an increase in total current liabilities of approximately \$1.1 billion.

The net increase in total current assets was primarily driven by an increase in net cash, cash equivalents and marketable securities, as described above, offset by a decrease in inventory resulting from our sale of hemophilia-related inventory to Bioverativ.

The net increase in current liabilities was primarily due to the reclassification of \$1.5 billion of our Senior Notes to current liabilities from notes payable, as the Senior Notes are due within one year. This increase was partially offset by a reduction in accrued expenses and other. 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, a decrease in the accrual for construction in progress and the \$45.0 million upfront payment made to C4T, which was accrued as of December 31, 2018.

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

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

For the nine months ended September 30, 2019, compared to the same period in 2018, net cash flows provided by operating activities increased primarily due to higher net income, the changes in working capital, as discussed above, the \$375.0 million upfront payment made to Ionis upon the closing of the 2018 Ionis Agreement and a \$162.1 million charge reflecting the premium paid for the purchase of Ionis common stock in the prior year comparative period.

Investing Activities

For the nine months ended September 30, 2019, compared to the same period in 2018, the decrease in net cash flows used in investing activities was primarily due to a decrease in net proceeds related to marketable securities and the cash used for our acquisition of NST. These amounts were partially offset by a decrease in contingent payments made to former shareholders of Fumapharm AG and holders of their rights, the proceeds received upon the divestiture of our Hillerød, Denmark manufacturing operations, the proceeds received on our sales of strategic investments and the \$462.9 million payment made to Ionis reflecting the fair value of the Ionis common stock purchased upon the closing of the 2018 Ionis Agreement in the prior year comparative period.

Financing Activities

For the nine months ended September 30, 2019, compared to the same period in 2018, the increase in net cash flows used in financing activities was primarily due to the 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 \$0.7 billion in remaining milestones related to these acquisitions.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of September 30, 2019, we could make potential future

milestone payments to third parties of up to approximately \$6.3 billion, including approximately \$0.9 billion in development milestones, approximately \$1.7 billion in regulatory milestones and approximately \$3.7 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of September 30, 2019, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval or commercial milestones.

Provided various development, regulatory or commercial milestones are achieved, we anticipate that we may pay approximately \$172.0 million of milestone payments during the remainder of 2019.

Other Funding Commitments

As of September 30, 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 \$37.0 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2019. We have approximately \$466.0 million in cancellable future commitments based on existing CRO contracts as of September 30, 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 September 30, 2019, we have approximately \$128.0 million of liabilities associated with uncertain tax positions.

As of both September 30, 2019 and December 31, 2018, included in other long-term liabilities 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 September 30, 2019, no amounts are expected to be paid within one year due to a \$87.0 million carryforward of taxes paid in relation to the company's 2017 tax return. 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 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, 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 September 30, 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 15 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read Note 9, *Derivative Instruments*, to our condensed consolidated financial statements included in this report.

Our ability to mitigate the impact of foreign currency exchange rate changes on revenues and net

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

Balance Sheet Risk Management Hedging Program

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

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of September 30, 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 \$284.0 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 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 one month. As of September 30, 2019 and December 31, 2018, a hypothetical adverse 10% movement would result in a hypothetical decrease in fair value of approximately \$50.0 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 September 30, 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 \$27.0 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 September 30, 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 limited due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale and other third-party distributors, public hospitals, pharmacies and other government entities. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We operate in certain countries where weakness in economic conditions can result in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

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

receivable and greater collection risk in certain countries.

We believe that our allowance for doubtful accounts was adequate as of September 30, 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 September 30, 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 September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

For a discussion of legal proceedings as of September 30, 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 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;
- the introduction of a new gene therapy product that was approved in the U.S. in May 2019 for the treatment of SMA, and other products in development that, if successfully developed and approved, may compete with SPINRAZA in the SMA market, including potential oral products;
- our limited marketing experience within certain SMA markets, which may impact our ability to develop additional relationships with the associated medical and scientific community; and
- the lack of readiness of healthcare providers to treat patients with SMA.

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.

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 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

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.

In the SMA market, we face competition from a gene therapy product that was approved in the U.S. in May 2019 for the treatment of SMA. Future sales of SPINRAZA may be adversely affected by the commercialization of this competing product.

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.

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 to operate our business. Our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data. A breakdown, invasion, corruption, destruction or breach of our technology systems and/or unauthorized access to our data and information could subject us to liability or negatively impact the operation of our business. Our technology 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. Cyber-attacks could also include supply chain attacks, which could cause a delay in the manufacturing of our products or products produced for contract manufacturing. 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, operational or reputational harm to us, loss of competitive advantage or loss of consumer confidence. 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 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, joint venture partners 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, including joint venture partners, 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, including joint venture partners, subjects us to a number of risks, including:

- we may be unable to control the resources our collaborators, joint venture partners 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, joint venture partners or other third parties, and the underlying agreement with our collaborators, joint venture partners or other third parties may fail to provide us with significant protection or may fail to be effectively enforced if the collaborators, joint ventures partners or third parties fail to perform;
- the interests of our collaborators, joint venture partners 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, joint ventures 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, joint venture partners 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, joint venture partners 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, joint venture partners 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 and/or joint ventures.

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 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. The U.S. government has challenged some of our donations to third-party charities that provide patient assistance. If we, or our vendors or donation recipients, are found 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 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 or collaborate 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, prodrugs and other products approved under abbreviated regulatory pathways;
- 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
- 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 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 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, cyber-attacks 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. In addition, following the divestiture of our Hillerød, Denmark manufacturing operations, we are dependent on FUJIFILM for the manufacture of biosimilar products. If Samsung Bioepis, FUJIFILM or other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;
- *Regulatory Compliance.* Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- *Intellectual Property and Regulatory Challenges.* Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years or result in imposition of monetary damages, penalties or other civil sanctions and damage our reputation;
- *Failure to Gain Market and Patient Acceptance.* Market success of biosimilar products will be adversely affected if patients, physicians and/or payors do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- *Ability to Provide Adequate Supply.* Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet higher than anticipated demand. In addition, following the divestiture of our Hillerød, Denmark manufacturing operations, we are dependent on FUJIFILM for the manufacture of biosimilar products. FUJIFILM may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations and may be unable or unwilling to increase production capacity commensurate with demand for our existing or future biosimilar products;
- *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; and
- *Legal and Regulatory Requirements.* Any improper conduct or actions on the part of Samsung Bioepis or our joint venture partner, Samsung BioLogics, could damage our reputation and be distracting to management. In particular, Samsung BioLogics is currently subject to an ongoing criminal investigation, which may impact the operations of Samsung Bioepis and its business or divert the attention of the Samsung Bioepis management team from its ongoing operations and business.

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;
- payments in connection with acquisitions and other business development activities; and
- failure to meet certain contractual commitments, including, for example, the minimum batch production commitment guarantees we have provided as part of the transaction with FUJIFILM.

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 (including withholding taxes) 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, interpretations by tax authorities or other bodies with jurisdiction, the result of tax cases, changes in accounting for income taxes and changes in tax laws either prospectively or retrospectively (including by regulation). 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 Tax Cuts and Jobs Act of 2017 (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 immediate U.S. taxation as global intangible low-taxed income, includes base erosion prevention measures on non-U.S. earnings and the reduced effective tax rate on income that comes from U.S. exports, called Foreign Derived Intangible Income. 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.

The Swiss Federal Act on Tax Reform and AHV Financing (TRAF) will result in significant changes to the Swiss cantonal income tax system. These changes include the elimination of historic favorable cantonal tax regimes, the introduction of a patent box regime and the introduction of a research and development super deduction. The TRAF also provides for transitional rules to lessen the immediate impact of the elimination of the favorable cantonal tax regimes. These changes will become effective on January 1, 2020. In response to the TRAF, each canton must enact cantonal tax reform to comply with the framework provided by the TRAF and are also expected to lower the statutory tax rate to compensate for the elimination of the historic favorable cantonal tax regimes. We will account for the impact of the TRAF and the specific cantonal tax reform changes in the period in which each canton in which we

operate enacts the cantonal tax reform. Zug, a canton in which we operate, enacted cantonal tax reform in the third quarter of 2019 and we expect Solothurn, another canton in which we operate, to enact cantonal tax reform within the next six months. Upon the enactment of Zug cantonal tax reform, we were required to remeasure our Swiss deferred tax assets and liabilities, to account for the elimination of the historic favorable cantonal tax regimes, the impact of the transitional rules and the change in the statutory cantonal tax rate. Further remeasurement of our Swiss deferred tax assets and liabilities could have a significant impact on our income tax provision in the period of enactment.

In addition, the enactment of some or all of the recommendations set forth or that may be forthcoming in the Organization for Economic Cooperation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities and economic blocs in the countries in which we operate, could negatively impact our effective tax rate. These initiatives focus on common international principles for the entitlement to taxation of global corporate profits and minimum global tax rates.

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 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 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 2019 Share Repurchase Program could have a negative effect on our stock price. We can provide no assurance that we will repurchase shares at favorable prices, if at all.

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

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

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

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

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

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

Our business and the business of several of our strategic partners involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with state, federal and foreign standards, there will always be the risk of accidental contamination or injury. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business. Manufacturing of our products and product candidates also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, including permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

The illegal distribution and sale by third parties of counterfeit 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 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.

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 2019 Share Repurchase Program during the third 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)
July 2019	378,467	\$ 237.94	378,467	\$ 4,000.0
August 2019	—	\$ —	—	\$ 4,000.0
September 2019	2,700,000	\$ 232.52	2,700,000	\$ 3,372.2
Total	3,078,467	\$ 233.19		

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. Under our 2019 Share Repurchase Program, we repurchased and retired approximately 3.1 million and 7.0 million shares of our common stock at a cost of approximately \$717.9 million and \$1.6 billion during the three and nine months ended September 30, 2019, respectively.

In August 2018 our Board of Directors authorized our 2018 Share Repurchase Program, which was a program to repurchase up to \$3.5 billion of our common stock that was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million shares of our common stock at a cost of approximately \$2.1 billion during the nine months ended September 30, 2019.

From October 1, 2019 through October 21, 2019, we repurchased and retired approximately 2.3 million shares of our common stock at a cost of approximately \$508.6 million under our 2019 Share Repurchase Program. As of October 21, 2019, we have repurchased and retired approximately 9.3 million shares of our common stock at a cost of approximately \$2.1 billion under our 2019 Share Repurchase Program. Approximately \$2.9 billion remained available under our 2019 Share Repurchase program as of October 21, 2019.

Item 6. Exhibits

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.1*+	Annual Retainer Summary for Board of Directors (effective as of January 1, 2020).
31.1+	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in iXBRL (Inline 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, (v) the Condensed Consolidated Statements of Equity and (vi) Notes to Condensed Consolidated Financial Statements.
104	The cover page from this Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Inline XBRL.

* Management contract or compensatory plan or arrangement

+ Filed herewith

++ Furnished herewith

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)

October 22, 2019

Non-Employee Director Compensation

The following is a summary of the retainers payable to non-employee directors effective January 1, 2020:

Retainers	
Annual Board Retainer	\$125,000
Annual Retainers (in addition to Annual Board Retainer):	
Independent Chairman of the Board	\$75,000
Audit Committee Chair	\$30,000
Compensation and Management Development Committee Chair	\$30,000
Corporate Governance Committee Chair	\$30,000
Audit Committee Member (other than Chair)	\$15,000
Compensation and Management Development Committee Member (other than Chair)	\$15,000
Corporate Governance Committee Member (other than Chair)	\$15,000

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michel Vounatsos, certify that:

1. I have reviewed this quarterly report of Biogen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 22, 2019

/s/ Michel Vounatsos

Michel Vounatsos

Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey D. Capello, certify that:

1. I have reviewed this quarterly report of Biogen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 22, 2019

/s/ Jeffrey D. Capello

Jeffrey D. Capello

Executive Vice President,

Chief Financial Officer and Chief Accounting Officer

CERTIFICATION
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Biogen Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 22, 2019

/s/ Michel Vounatsos

Michel Vounatsos

Chief Executive Officer

[principal executive officer]

Dated: October 22, 2019

/s/ Jeffrey D. Capello

Jeffrey D. Capello

Executive Vice President,

Chief Financial Officer and Chief Accounting Officer

[principal financial officer]

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.