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, 2020

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

225 Binney Street, Cambridge, MA 02142
(617) 679-2000

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

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 x 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 x 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	x	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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 x

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of October 20, 2020, was 153,881,597 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2020

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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 potential impact of increased product competition in the markets in which we compete, including increased competition from generics, biosimilars, prodrugs and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- 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, generic or biosimilar versions of our marketed products or any other products from the same class as one of our products;
- the direct and indirect impact of COVID-19 on our business and operations, including sales, expenses, supply chain, manufacturing, research and development costs, clinical trials and employees;
- 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, activities in new or existing manufacturing facilities and the expected timeline for the Solothurn manufacturing facility to be partially operational;
- 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.) departure 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, 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®, VUMERITY® and ZINBRYTA® are registered 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,	
	2020	2019	2020	2019
Revenues:				
Product, net	$ 2,690.3	$ 2,894.7	$ 8,390.6	$ 8,455.0
Revenues from anti-CD20 therapeutic programs	560.1	595.8	1,558.8	1,689.6
Other	125.7	109.6	642.6	562.0
Total revenues	3,376.1	3,600.1	10,592.0	10,706.6
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	449.1	430.0	1,314.6	1,508.3
Research and development	1,140.9	540.4	2,264.8	1,588.9
Selling, general and administrative	573.1	554.5	1,698.3	1,709.8
Amortization and impairment of acquired intangible assets	82.6	283.9	215.6	422.2
Collaboration profit (loss) sharing	73.0	60.2	166.5	181.8
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	(17.7)	—	95.5
(Gain) loss on fair value remeasurement of contingent consideration	(29.0)	(57.8)	(23.5)	(66.3)
Restructuring charges	—	0.3	—	1.5
Acquired in-process research and development	—	—	75.0	—
Total cost and expenses	2,289.7	1,793.8	5,711.3	5,441.7
Income from operations	1,086.4	1,806.3	4,880.7	5,264.9
Other income (expense), net	(128.6)	(27.3)	(186.1)	132.6
Income before income tax expense and equity in loss of investee, net of tax	957.8	1,779.0	4,694.6	5,397.5
Income tax expense	240.8	211.3	979.0	881.9
Equity in (income) loss of investee, net of tax	**13.1**	**21.8**	**12.7**	**66.8**
Net income	703.9	1,545.9	3,702.9	4,448.8
Net income (loss) attributable to noncontrolling interests, net of tax	2.4	—	60.2	—
Net income attributable to Biogen Inc.	$ 701.5	$ 1,545.9	$ 3,642.7	$ 4,448.8
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 4.47	$ 8.40	$ 22.29	$ 23.38
Diluted earnings per share attributable to Biogen Inc.	$ 4.46	$ 8.39	$ 22.25	$ 23.35
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	156.9	184.0	163.4	190.3
Diluted earnings per share attributable to Biogen Inc.	157.2	184.2	163.7	190.5

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,	
	2020	2019	2020	2019
Net income attributable to Biogen Inc.	$ 701.5	$ 1,545.9	$ 3,642.7	$ 4,448.8
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	0.1	0.1	1.0	10.3
Unrealized gains (losses) on cash flow hedges, net of tax	(83.7)	59.1	(101.1)	38.1
Gains (losses) on net investment hedges	(11.3)	21.2	5.5	46.9
Unrealized gains (losses) on pension benefit obligation, net of tax	(0.5)	0.8	0.4	1.5
Currency translation adjustment	50.9	79.4	3.9	51.3
Total other comprehensive income (loss), net of tax	(44.5)	160.6	(90.3)	148.1
Comprehensive income attributable to Biogen Inc.	657.0	1,706.5	3,552.4	4,596.9
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	1.5	—	61.1	(0.4)
Comprehensive income	$ 658.5	$ 1,706.5	$ 3,613.5	$ 4,596.5

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, 2020	As of December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,224.8	$ 2,913.7
Marketable securities	1,355.0	1,562.2
Accounts receivable, net	2,024.9	1,880.5
Due from anti-CD20 therapeutic programs	527.2	590.2
Inventory	1,027.7	804.2
Other current assets	683.5	631.0
Total current assets	7,843.1	8,381.8
Marketable securities	1,009.8	1,408.1
Property, plant and equipment, net	3,359.9	3,247.3
Operating lease assets	434.2	427.0
Intangible assets, net	3,323.6	3,527.4
Goodwill	5,755.7	5,757.8
Deferred tax asset	1,372.9	3,232.1
Investments and other assets	1,834.9	1,252.8
Total assets	$ 24,934.1	$ 27,234.3
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$ —	$ 1,495.8
Taxes payable	119.4	71.4
Accounts payable	398.4	530.8
Accrued expenses and other	3,286.2	2,765.8
Total current liabilities	3,804.0	4,863.8
Notes payable	7,425.0	4,459.0
Deferred tax liability	1,123.4	2,810.8
Long-term operating lease liabilities	409.1	412.7
Other long-term liabilities	1,428.1	1,348.9
Total liabilities	14,189.6	13,895.2
Commitments and contingencies		
Equity:		
Biogen Inc. shareholders' equity:		
Preferred stock, par value $0.001 per share	—	—
Common stock, par value $0.0005 per share	0.1	0.1
Additional paid-in capital	—	—
Accumulated other comprehensive loss	(225.5)	(135.2)
Retained earnings	13,961.0	16,455.4
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	10,758.5	13,343.2
Noncontrolling interests	(14.0)	(4.1)
Total equity	10,744.5	13,339.1
Total liabilities and equity	$ 24,934.1	$ 27,234.3

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,	
	2020	2019
Cash flows from operating activities:		
Net income	$ 3,702.9	$ 4,448.8
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and impairments	366.8	567.6
Acquired in-process research and development	75.0	—
Share-based compensation	149.3	143.9
Contingent consideration	(23.5)	(66.3)
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	95.5
Deferred income taxes	211.9	28.4
Unrealized (gain) loss on strategic investments	41.8	(189.8)
Loss on equity method investment	14.7	63.5
Other	110.1	87.4
Changes in operating assets and liabilities, net:		
Accounts receivable	(135.7)	(2.4)
Due from anti-CD20 therapeutic programs	63.0	(55.4)
Inventory	(270.6)	47.3
Accrued expenses and other current liabilities	372.9	(109.1)
Income tax assets and liabilities	15.3	64.6
Other changes in operating assets and liabilities, net	(97.0)	(5.6)
Net cash flows provided by operating activities	4,596.9	5,118.4
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	5,240.7	3,867.6
Purchases of marketable securities	(4,649.1)	(4,052.1)
Contingent consideration paid related to Fumapharm AG acquisition	—	(300.0)
Acquisition of Nightstar Therapeutics plc, net of cash acquired	—	(744.4)
Purchase of Sangamo Therapeutics, Inc. stock	(141.8)	—
Purchase of Denali Therapeutics Inc. stock	(423.7)	—
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	—	923.7
Purchases of property, plant and equipment	(338.8)	(404.1)
Acquired in-process research and development	(75.0)	—
Acquisitions of intangible assets	(37.0)	—
Proceeds from sales of strategic investments	0.5	476.0
Other	(18.0)	(4.6)
Net cash flows provided by (used in) investing activities	(442.2)	(237.9)
Cash flows from financing activities:		
Purchases of treasury stock	(6,279.1)	(3,775.2)
Payments related to issuance of stock for share-based compensation arrangements, net	(11.8)	(16.9)
Proceeds from borrowings	2,967.3	—
Repayment of borrowings	(1,500.0)	—
Net distribution to noncontrolling interest	(70.9)	4.3
Other	22.9	43.8
Net cash flows used in financing activities	(4,871.6)	(3,744.0)
Net increase (decrease) in cash and cash equivalents	(716.9)	1,136.5
Effect of exchange rate changes on cash and cash equivalents	28.0	(17.2)
Cash and cash equivalents, beginning of the period	2,913.7	1,224.6
Cash and cash equivalents, end of the period	$ 2,224.8	$ 2,343.9

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, June 30, 2020	—	$ —	182.1	$ 0.1	$ —	$ (181.0)	$ 14,466.7	(23.8)	$ (2,977.1)	$ 11,308.7	$ (19.5)	$ 11,289.2
Net income	—	—	—	—	—	—	701.5	—	—	701.5	2.4	703.9
Other comprehensive income (loss), net of tax	—	—	—	—	—	(44.5)	—	—	—	(44.5)	(0.9)	(45.4)
Capital contribution by noncontrolling interest	—	—	—	—	—	—	—	—	—	—	4.0	4.0
Repurchase of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	(4.5)	—	—	—	—	(4.5)	(1,250.0)	(1,250.0)	—	(1,250.0)
Retirement of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	—	—	(45.1)	—	(1,204.9)	4.5	1,250.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	9.7	—	—	—	—	9.7	—	9.7
Issuance of common stock under stock award plan	—	—	—	—	—	—	(2.3)	—	—	(2.3)	—	(2.3)
Compensation related to share-based payments	—	—	—	—	35.4	—	—	—	—	35.4	—	35.4
Balance, September 30, 2020	—	$ —	177.7	$ 0.1	$ —	$ (225.5)	$ 13,961.0	(23.8)	$ (2,977.1)	$ 10,758.5	$ (14.0)	$ 10,744.5

See accompanying notes to these unaudited condensed consolidated financial statements.

BIOGEN 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, 2019	—	$ —	198.0	$ 0.1	$ —	$ (135.2)	$ 16,455.4	(23.8)	$ (2,977.1)	$ 13,343.2	$ (4.1)	$ 13,339.1
Net income	—	—	—	—	—	—	3,642.7	—	—	3,642.7	60.2	3,702.9
Other comprehensive income (loss), net of tax	—	—	—	—	—	(90.3)	—	—	—	(90.3)	0.9	(89.4)
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(75.0)	(75.0)
Capital contribution by noncontrolling interest	—	—	—	—	—	—	—	—	—	—	4.0	4.0
Repurchase of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(4.1)	(1,279.1)	(1,279.1)	—	(1,279.1)
Retirement of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	(4.1)	—	(71.0)	—	(1,208.1)	4.1	1,279.1	—	—	—
Repurchase of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(16.7)	(5,000.0)	(5,000.0)	—	(5,000.0)
Retirement of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	(16.7)	—	(121.3)	—	(4,878.7)	16.7	5,000.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	38.8	—	—	—	—	38.8	—	38.8
Issuance of common stock under stock award plan	—	—	0.3	—	—	—	(50.3)	—	—	(50.3)	—	(50.3)
Compensation related to share-based payments	—	—	—	—	154.2	—	—	—	—	154.2	—	154.2
Other	—	—	—	—	(0.7)	—	—	—	—	(0.7)	—	(0.7)
Balance, September 30, 2020	—	$ —	177.7	$ 0.1	$ —	$ (225.5)	$ 13,961.0	(23.8)	$ (2,977.1)	$ 10,758.5	$ (14.0)	$ 10,744.5

See accompanying notes to these unaudited condensed consolidated financial statements.

BIOGEN 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, 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
Repurchase of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(3.1)	(717.9)	(717.9)	—	(717.9)
Retirement of common stock pursuant to the March 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.

BIOGEN 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 March 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(7.0)	(1,627.8)	(1,627.8)	—	(1,627.8)
Retirement of common stock pursuant to the March 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.

1. Summary of Significant Accounting Policies

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

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology; Alzheimer's disease and dementia; neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS); movement disorders, including Parkinson's disease; 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, VUMERITY, 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 and relapsing MS; 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 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 (2019 Form 10-K).

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduces 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 certain countries in Europe and have exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11 referencing LUCENTIS and SB15 referencing EYLEA, in major markets worldwide, including the United States (U.S.), Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements 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 statement 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 2019 Form 10-K. Our accounting policies are described in the *Notes to Consolidated Financial Statements* in our 2019 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, 2020, 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 innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies.

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 a variable interest 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.

The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, depends on future developments that are highly uncertain, subject to change and are difficult to predict, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19 as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our condensed consolidated financial statements and there may be changes to those estimates in future periods.

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.

Credit Losses

In June 2016 the FASB issued Accounting Standards Update (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. This standard requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases.

This standard became effective for us on January 1, 2020, and based on the composition of our trade receivables, investment portfolio and other financial assets, current economic conditions and historical credit loss activity, the adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures. During the three and nine months ended September 30, 2020, we recorded an immaterial amount associated with expected credit losses related to outstanding trade receivables in certain foreign countries that have been disproportionately impacted by the COVID-19 pandemic.

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 became effective for us on January 1, 2020, and did not have a material impact on our disclosures. For the new disclosures regarding our Level 3 instruments, please read *Note 7, Fair Value Measurements,* to these condensed consolidated financial statements.

Internal Use Software

In August 2018 the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This standard clarifies the accounting for implementation costs in cloud computing arrangements. This standard, which became effective for us on January 1, 2020, and was adopted on a prospective basis, resulted in an immaterial amount of additional assets being recorded on our condensed consolidated balance sheets.

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 Accounting Standards Codification (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 became effective for us on January 1, 2020, and did not have a material impact on our condensed consolidated financial statements and related disclosures.

2. Acquisitions

BIIB118 Acquisition

In March 2020 we acquired BIIB118 (formerly known as PF-05251749), a novel CNS-penetrant small molecule inhibitor of casein kinase 1, for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). We plan to develop this Phase 1 asset for the potential treatment of sundowning in Alzheimer's disease and irregular sleep wake rhythm disorder in Parkinson's disease.

In connection with this acquisition, we made an upfront payment of $75.0 million to Pfizer, which was accounted for as an asset acquisition and recorded as acquired in-process research and development (IPR&D) in our condensed consolidated statements of income as BIIB118 has not yet reached technological feasibility. We may also pay Pfizer up to $635.0 million in potential additional development and commercialization milestone payments as well as tiered royalties in the high single digits to sub-teens.

Acquisition of Nightstar Therapeutics plc

In June 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 (timrepigene emparvovec), 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 (RPGR gene therapy), 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 was 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. We finalized purchase accounting for this acquisition in the fourth quarter of 2019.

For additional information on our acquisition of NST, please read *Note 2, Acquisitions,* to our consolidated financial statements included in our 2019 Form 10-K.

3. Divestitures

Divestiture of Hillerød, Denmark Manufacturing Operations

In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation (FUJIFILM) to sell all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark. We determined that the assets and liabilities related to our Hillerød, Denmark manufacturing operations met the criteria to be classified as held for sale. For the nine months ended September 30, 2019, we recorded a loss of approximately $160.2 million in our condensed consolidated statements of income. This estimated loss included a pre-tax loss of $95.5 million, which reflected a $17.7 million decrease to our previously recorded pre-tax loss, reflecting our estimated fair value of the assets and liabilities held for sale as of September 30, 2019, adjusted for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately $11.2 million and included our initial 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. In addition, we recorded a tax expense of $64.7 million related to the transaction during the nine months ended September 30, 2019.

In August 2019 this transaction closed and we received approximately $881.9 million in cash, which may be adjusted based on the contractual terms 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 provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Our estimate of the adverse commitment obligation is approximately $74.0 million as of September 30, 2020 and December 31, 2019. We developed this estimate using a probability-weighted estimate of future manufacturing activity and may adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods. 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. Our estimate of the fair value of the adverse commitment obligation is a Level 3 measurement and is based on forecasted batch production at the Hillerød facility.

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. Consistent with our assessment as of the transaction date, 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 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 in the third quarter of 2019. These materials were sold at cost, which approximated fair value.

4. Revenues

Product Revenues

Revenues by product are summarized as follows:

	For the Three Months Ended September 30,					
	2020			2019		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	$ 684.2	$ 283.3	$ 967.5	$ 842.0	$ 280.4	$ 1,122.4
Interferon**	327.3	146.8	474.1	360.3	169.7	530.0
TYSABRI	304.2	212.3	516.5	263.0	220.6	483.6
FAMPYRA	—	26.8	26.8	—	24.2	24.2
Subtotal: MS product revenues	1,315.7	669.2	1,984.9	1,465.3	694.9	2,160.2
Spinal Muscular Atrophy:						
SPINRAZA	182.5	311.9	494.4	236.7	310.4	547.1
Biosimilars:						
BENEPALI	—	124.2	124.2	—	115.9	115.9
IMRALDI	—	56.2	56.2	—	49.3	49.3
FLIXABI	—	27.5	27.5	—	18.4	18.4
Subtotal: Biosimilar product revenues	—	207.9	207.9	—	183.6	183.6
Other:						
FUMADERM	—	3.1	3.1	—	3.8	3.8
Total product revenues	$ 1,498.2	$ 1,192.1	$ 2,690.3	$ 1,702.0	$ 1,192.7	$ 2,894.7

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
**Interferon includes AVONEX and PLEGRIDY.

	For the Nine Months Ended September 30,					
	2020			2019		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	$ 2,383.4	$ 875.2	$ 3,258.6	$ 2,429.5	$ 841.9	$ 3,271.4
Interferon**	965.5	456.0	1,421.5	1,067.3	518.0	1,585.3
TYSABRI	826.0	644.9	1,470.9	772.3	647.0	1,419.3
FAMPYRA	—	78.1	78.1	—	71.2	71.2
Subtotal: MS product revenues	4,174.9	2,054.2	6,229.1	4,269.1	2,078.1	6,347.2
Spinal Muscular Atrophy:						
SPINRAZA	628.2	925.8	1,554.0	690.6	863.2	1,553.8
Biosimilars:						
BENEPALI	—	363.9	363.9	—	360.2	360.2
IMRALDI	—	162.6	162.6	—	132.3	132.3
FLIXABI	—	71.8	71.8	—	49.9	49.9
Subtotal: Biosimilar product revenues	—	598.3	598.3	—	542.4	542.4
Other:						
FUMADERM	—	9.2	9.2	—	11.6	11.6
Total product revenues	$ 4,803.1	$ 3,587.5	$ 8,390.6	$ 4,959.7	$ 3,495.3	$ 8,455.0

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
**Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 31.2% and 15.6% of gross product revenues for the three months ended September 30, 2020, and 30.9% and 16.0% of gross product revenues for the nine months ended September 30, 2020.

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.

An analysis of the change in reserves for discounts and allowances is summarized as follows:

(In millions)	Discounts	Contractual Adjustments	Returns	Total
Balance, December 31, 2019	$ 131.1	$ 1,027.3	$ 40.5	$ 1,198.9
Current provisions relating to sales in current year	589.6	2,465.8	14.8	3,070.2
Adjustments relating to prior years	(1.0)	(41.6)	1.8	(40.8)
Payments/credits relating to sales in current year	(457.9)	(1,704.5)	—	(2,162.4)
Payments/credits relating to sales in prior years	(120.3)	(658.4)	(15.4)	(794.1)
Balance, September 30, 2020	$ 141.5	$ 1,088.6	$ 41.7	$ 1,271.8

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

(In millions)	As of September 30, 2020	As of December 31, 2019
Reduction of accounts receivable, net	$ 227.9	$ 197.8
Component of accrued expenses and other	1,043.9	1,001.1
Total revenue-related reserves	$ 1,271.8	$ 1,198.9

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs are summarized below. For the purposes of this footnote we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$ 275.0	$ 393.2	$ 873.8	$ 1,161.2
Other revenues from anti-CD20 therapeutic programs	285.1	202.6	685.0	528.4
Total revenues from anti-CD20 therapeutic programs	$ 560.1	$ 595.8	$ 1,558.8	$ 1,689.6

For additional information on our collaboration arrangements with Genentech, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

Other Revenues

Other revenues are summarized as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Revenues from collaborative and other relationships:				
Profit (loss) earned under our 50% share of the co-promotion losses on ZINBRYTA in the U.S. with AbbVie Inc.	$ —	$ 0.3	$ 0.7	$ (0.2)
Revenues earned under our technical development agreement, manufacturing services agreements and royalty revenues on biosimilar products with Samsung Bioepis	5.4	12.9	13.6	89.9
Other royalty and corporate revenues:				
Royalty	10.3	3.3	28.8	9.9
Other corporate	110.0	93.1	599.5	462.4
Total other revenues	$ 125.7	$ 109.6	$ 642.6	$ 562.0

During the third quarter of 2019, we amended our agreement with a contract manufacturing customer pursuant to which we licensed certain of our manufacturing-related intellectual property to the customer. In the second quarter of 2020, the customer received regulatory approval for its product that is being manufactured using certain of our manufacturing-related intellectual property. As a result, we are entitled to $500.0 million in a series of three payments. The first payment became due upon regulatory approval of such product and was received during the second quarter of 2020. Subsequent payments are due on the first and second anniversaries of the regulatory approval.

Other corporate revenues for the nine months ended September 30, 2020, reflect $333.2 million related to the delivery of the license for certain of our manufacturing-related intellectual property under the amended agreement discussed above and the performance of manufacturing product supply services for such customer. We have allocated the remaining $166.8 million of the $500.0 million transaction price to the performance of manufacturing product supply services for the customer, which we expect to perform through 2026. The value allocated to the manufacturing services was based on expected demand for supply and the fair value of comparable manufacturing and development services.

5. Inventory

The components of inventory are summarized as follows:

(In millions)	**As of September 30, 2020**	**As of December 31, 2019**
Raw materials	$ 288.4	$ 169.7
Work in process	539.9	460.0
Finished goods	199.4	174.5
Total inventory	$ 1,027.7	$ 804.2

6. Intangible Assets and Goodwill

Intangible Assets

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

		As of September 30, 2020			As of December 31, 2019		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,394.3	$ (5,077.7)	$ 2,316.6	$ 7,379.3	$ (4,881.4)	$ 2,497.9
In-process research and development	Indefinite until commercialization	943.0	—	943.0	965.5	—	965.5
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 8,401.3	$ (5,077.7)	$ 3,323.6	$ 8,408.8	$ (4,881.4)	$ 3,527.4

For the three and nine months ended September 30, 2020, amortization and impairment of acquired intangible assets totaled $82.6 million and $215.6 million, respectively, compared to $283.9 million and $422.2 million, respectively, in the prior year comparative periods.

For the three and nine months ended September 30, 2020, amortization and impairment of acquired intangible assets reflects the impact of a $19.3 million impairment charge related to one of our IPR&D intangible assets.

For the three and nine months ended September 30, 2019, amortization and impairment of acquired intangible assets 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, which was discontinued in the third quarter of 2019.

For the three and nine months ended September 30, 2020, amortization of acquired intangible assets, excluding impairment charges, totaled $63.3 million and $196.3 million, respectively, compared to $68.0 million and $206.3 million, respectively, in the prior year comparative periods.

Completed Technology

Completed technology primarily relates to our acquisition of all remaining rights to TYSABRI from Elan Pharma International Ltd., an affiliate of Elan Corporation plc, and milestone payments made to Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, following the approval of VUMERITY in the U.S. in October 2019, net of accumulated amortization.

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. Included in IPR&D balances are adjustments related to foreign currency exchange rate fluctuations. 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. The carrying value associated with our IPR&D assets as of September 30, 2020, relates to the various IPR&D programs we acquired in connection with our acquisitions of NST, Convergence Pharmaceuticals Holdings Ltd. (Convergence) and Biogen International Neuroscience GmbH (BIN). The majority of the balance relates to our acquisition of NST in June 2019 whereby we acquired IPR&D programs with an estimated fair value of approximately $700.0 million.

Vixotrigine

In the periods since we acquired vixotrigine (BIIB074), there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of trigeminal neuralgia (TGN) as we engaged with the U.S. Food and Drug Administration (FDA) regarding the design of the Phase 3 studies and awaited data and insights from mid-stage clinical trials of vixotrigine in other indications that have since been completed. The fair value of the TGN asset is not significantly in excess of carrying value. As of September 30, 2020, the carrying value associated with our vixotrigine IPR&D assets was $167.6 million.

Estimated Future Amortization of Intangible Assets

The estimated future amortization of finite-lived intangible assets for the next five years is expected to be as follows:

(In millions)	As of September 30, 2020
2020 (remaining three months)	$ 60.0
2021	205.0
2022	215.0
2023	215.0
2024	225.0
2025	220.0

Goodwill

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

(In millions)	As of September 30, 2020
Goodwill, December 31, 2019	$ 5,757.8
Other	(2.1)
Goodwill, September 30, 2020	$ 5,755.7

As of September 30, 2020, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

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, 2020			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 1,570.3	$ —	$ 1,570.3	$ —
Marketable debt securities:				
Corporate debt securities	1,443.8	—	1,443.8	—
Government securities	767.4	—	767.4	—
Mortgage and other asset backed securities	153.6	—	153.6	—
Marketable equity securities	868.5	276.5	592.0	—
Derivative contracts	26.0	—	26.0	—
Plan assets for deferred compensation	26.4	—	26.4	—
Total	$ 4,856.0	$ 276.5	$ 4,579.5	$ —
Liabilities:				
Derivative contracts	$ 99.6	$ —	$ 99.6	$ —
Contingent consideration obligations	322.6	—	—	322.6
Total	$ 422.2	$ —	$ 99.6	$ 322.6

	As of December 31, 2019			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 2,541.1	$ —	$ 2,541.1	$ —
Marketable debt securities:				
Corporate debt securities	1,695.1	—	1,695.1	—
Government securities	1,013.9	—	1,013.9	—
Mortgage and other asset backed securities	261.3	—	261.3	—
Marketable equity securities	337.5	7.9	329.6	—
Derivative contracts	43.8	—	43.8	—
Plan assets for deferred compensation	27.7	—	27.7	—
Total	$ 5,920.4	$ 7.9	$ 5,912.5	$ —
Liabilities:				
Derivative contracts	$ 8.3	$ —	$ 8.3	$ —
Contingent consideration obligations	346.1	—	—	346.1
Total	$ 354.4	$ —	$ 8.3	$ 346.1

There have been no material impairments of our assets measured and carried at fair value during the three and nine months ended September 30, 2020. In addition, there were no changes in valuation techniques during the three and nine months ended September 30, 2020. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities was determined through third-party pricing services. The fair value of Level 2 instruments classified as marketable equity securities represents our investments in Sangamo Therapeutics, Inc. (Sangamo) common stock and Denali Therapeutics Inc. (Denali) common stock and are valued using an option pricing valuation model as the investments are each subject to certain holding period restrictions. For additional information on our investments in Sangamo and Denali common stock, please read *Note 8, Financial Instruments,* to these condensed consolidated financial statements.

Our investments in marketable equity securities also include shares of Ionis Pharmaceuticals, Inc. (Ionis) common stock acquired in June 2018. Our shares of Ionis common stock were initially subject to certain holding period restrictions that expired during the first quarter of 2020. The fair value of this investment was a Level 1 measurement as of September 30, 2020.

For a description of our validation procedures related to prices provided by third-party pricing 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 2019 Form 10-K.

The following table summarizes the significant unobservable inputs in the fair value measurement of our contingent consideration obligations as of September 30, 2020:

	As of September 30, 2020				
(In millions)	Fair Value	Valuation Technique	Unobservable Input	Range	Weighted Average
Liabilities:					
Contingent consideration obligation	$ 322.6	Discounted cash flow	Discount rate	0.57% to 0.89%	0.63%
			Expected timing of achievement of development milestones	2021 to 2027	—

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. In addition, we apply various probabilities of technological and regulatory success, ranging from high single digits to certain probability, to the valuation models to estimate the fair values of our contingent consideration obligations.

Debt Instruments

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

	As of September 30, 2020		As of December 31, 2019	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
2.900% Senior Notes due September 15, 2020[1]	$ —	$ —	$ 1,509.6	$ 1,495.8
3.625% Senior Notes due September 15, 2022	1,058.4	997.5	1,038.9	996.6
4.050% Senior Notes due September 15, 2025	1,988.5	1,740.7	1,897.2	1,739.5
2.250% Senior Notes due May 1, 2030	1,532.8	1,491.0	—	—
5.200% Senior Notes due September 15, 2045	2,286.3	1,723.3	2,107.9	1,722.9
3.150% Senior Notes due May 1, 2050	1,470.0	1,472.5	—	—
Total	$ 8,336.0	$ 7,425.0	$ 6,553.6	$ 5,954.8

[1] Our 2.900% Senior Notes due September 15, 2020, were redeemed in full in May 2020 using the net proceeds from the issuance on April 30, 2020, of our senior unsecured notes for an aggregate principal amount of $3.0 billion. For additional information, please read *Note 11, Indebtedness,* to these condensed consolidated financial statements.

The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. For additional information related to our Senior Notes issued on September 15, 2015, please read *Note 12, Indebtedness,* to our consolidated financial statements included in our 2019 Form 10-K. For additional information related to our Senior Notes issued on April 30, 2020, please read *Note 11, Indebtedness,* to these condensed consolidated financial statements.

Contingent Consideration Obligations

In connection with our acquisitions of Convergence and BIN, 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:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Fair value, beginning of period	$ 351.6	$ 401.3	$ 346.1	$ 409.8
Changes in fair value	(29.0)	(57.8)	(23.5)	(66.3)
Payments	—	—	—	—
Fair value, end of period	$ 322.6	$ 343.5	$ 322.6	$ 343.5

As of September 30, 2020 and December 31, 2019, approximately $173.2 million and $197.7 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, 2020, changes in the fair value of our contingent consideration obligations were primarily due to changes in the probability and the expected timing of the achievement of certain remaining developmental milestones as well as changes in the interest rates used to revalue our contingent consideration liabilities and the passage of time.

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 idiopathic pulmonary fibrosis 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.

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, 2020	As of December 31, 2019
Commercial paper	$ 649.2	$ 384.4
Overnight reverse repurchase agreements	465.4	368.8
Money market funds	270.2	1,628.5
Short-term debt securities	185.5	159.4
Total	$ 1,570.3	$ 2,541.1

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, 2020			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities:				
Current	$ 963.5	$ 1.4	$ (0.1)	$ 964.8
Non-current	475.9	3.2	(0.1)	479.0
Government securities:				
Current	389.4	0.2	—	389.6
Non-current	376.4	1.4	—	377.8
Mortgage and other asset backed securities:				
Current	0.6	—	—	0.6
Non-current	152.6	0.6	(0.2)	153.0
Total marketable debt securities	$ 2,358.4	$ 6.8	$ (0.4)	$ 2,364.8
Marketable equity securities, non-current	$ 851.7	$ 63.6	$ (46.8)	$ 868.5

	As of December 31, 2019			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities:				
Current	$ 1,057.2	$ 1.0	$ —	$ 1,058.2
Non-current	633.9	3.0	—	636.9
Government securities:				
Current	502.9	0.4	—	503.3
Non-current	510.1	0.8	(0.3)	510.6
Mortgage and other asset backed securities:				
Current	0.7	—	—	0.7
Non-current	260.2	0.8	(0.4)	260.6
Total marketable debt securities	$ 2,965.0	$ 6.0	$ (0.7)	$ 2,970.3
Marketable equity securities, non-current	$ 218.4	$ 132.1	$ (13.0)	$ 337.5

Summary of Contractual Maturities: Available-for-Sale Debt Securities

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

	As of September 30, 2020		As of December 31, 2019	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$ 1,355.0	$ 1,353.4	$ 1,562.2	$ 1,560.8
Due after one year through five years	902.2	897.9	1,234.5	1,230.4
Due after five years	107.6	107.1	173.6	173.8
Total marketable debt securities	$ 2,364.8	$ 2,358.4	$ 2,970.3	$ 2,965.0

The average maturity of our marketable debt securities available-for-sale as of September 30, 2020 and December 31, 2019, was approximately 12 months and 14 months, respectively.

Proceeds from Marketable Debt Securities

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Proceeds from maturities and sales	$ 1,360.9	$ 611.8	$ 5,240.7	$ 3,867.6
Realized gains	1.0	0.7	12.8	2.3
Realized losses	(0.9)	(0.1)	(25.2)	(0.7)

Strategic Investments

As of September 30, 2020 and December 31, 2019, our strategic investment portfolio was comprised of investments totaling $925.1 million and $393.9 million, respectively, which are included in investments and other assets in our condensed consolidated balance sheets.

Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies, 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.

The increase in our strategic investment portfolio for the three and nine months ended September 30, 2020, was primarily due to our purchases of Denali and Sangamo common stock, as discussed below.

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali. As part of this collaboration we purchased approximately 13 million shares of Denali common stock in September 2020. This investment is classified as a Level 2 marketable equity security due to certain holding period restrictions and is remeasured each reporting period and carried at fair value. The effects of certain holding period restrictions on the investment 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 Denali's common stock and a dividend yield of zero based upon the fact that Denali and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration agreements with Denali, please read *Note 17, Collaborative and Other Relationships,* to these condensed consolidated financial statements.

Sangamo Therapeutics, Inc.

In February 2020 we entered into a collaboration and license agreement with Sangamo. In connection with the closing of this transaction in April 2020 we purchased approximately 24 million shares of Sangamo common stock. This equity method investment will be remeasured each reporting period and carried at fair value due to our election of the fair value option. The effects of certain holding period restrictions on the investment 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 Sangamo's common stock and a dividend yield of zero based upon the fact that Sangamo and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration agreement with Sangamo, please read *Note 17, Collaborative and Other Relationships,* to these condensed consolidated financial statements.

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, 2020 and December 31, 2019, had durations of 1 to 24 months and 1 to 15 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 (loss) and fair value changes of excluded portions in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.

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

	Notional Amount	
(In millions)	**As of September 30, 2020**	**As of December 31, 2019**
Euro	$ 2,717.0	$ 1,892.4
British pound	62.0	—
Swiss franc	34.5	—
Japanese yen	27.1	—
Canadian dollar	25.9	—
Total foreign currency forward contracts	$ 2,866.5	$ 1,892.4

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 losses of $114.6 million and net gains of $0.5 million as of September 30, 2020 and December 31, 2019, respectively. We expect the net losses of $114.6 million to be settled over the next 24 months, of which $94.1 million of these losses 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, 2020 and December 31, 2019, credit risk did not materially 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,			
	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized in Operating Income (in millions)	
Location	2020	2019	2020	2019
Revenues	$ (9.1)	$ 35.2	$ (8.7)	$ 0.8
Operating expenses	1.5	(0.8)	0.4	0.4

	For the Nine Months Ended September 30,			
	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized in Operating Income (in millions)	
Location	2020	2019	2020	2019
Revenues	$ 41.6	$ 79.8	$ (1.0)	$ 8.2
Operating expenses	1.4	(2.0)	(0.7)	(0.8)

Interest Rate Contracts - Hedging Instruments

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

Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes due September 15, 2020, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which were originally set to expire on September 15, 2020. The interest rate swap contracts were 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 December 31, 2019, included approximately $2.3 million related to changes in the fair value of these interest rate swap contracts. In May 2020 we settled our interest rate swap contracts, in conjunction with our early redemption of our 2.90% Senior Notes, resulting in a gain of approximately $3.3 million for the nine months ended September 30, 2020, which was 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 5.0% 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, 2020, had a remaining duration 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 $3.5 million and net losses of $1.5 million as of September 30, 2020 and December 31, 2019, 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 $0.3 million and $2.9 million as of September 30, 2020 and December 31, 2019, 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,					
	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	2020	2019	Location	2020	2019	Location	2020	2019
Gains (losses) on net investment hedge	$ (10.4)	$ 22.0	Gains (losses) on net investment hedge	$ (0.2)	$ 1.4	Other income (expense)	$ 0.9	$ 2.2

	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	2020	2019	Location	2020	2019	Location	2020	2019
Gains (losses) on net investment hedge	$ 5.0	$ 45.4	Gains (losses) on net investment hedge	$ 3.1	$ 8.1	Other income (expense)	$ 2.6	$ 6.6

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

Foreign Currency Forward Contracts - Other Derivative Instruments

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 $990.0 million and $793.8 million as of September 30, 2020 and December 31, 2019, respectively. Net gains of $7.8 million and $13.7 million related to these contracts were recorded as a component of other income (expense), net for the three and nine months ended September 30, 2020, respectively, compared to net losses of $10.3 million and $14.2 million, respectively, in the prior year comparative periods.

Summary of Derivative Instruments

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

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

(In millions)	Balance Sheet Location	As of September 30, 2020	As of December 31, 2019
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 3.4	$ 33.8
	Investments and other assets	2.3	—
Liability derivative instruments	Accrued expenses and other	70.7	2.0
	Other long-term liabilities	21.6	1.7
Net Investment Hedging Instruments:			
Asset derivative instruments	Other current assets	10.1	2.0
Fair Value Hedging Instruments:			
Liability derivative instruments	Accrued expenses and other	—	2.3
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	10.2	8.0
Liability derivative instruments	Accrued expenses and other	7.3	2.4

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 $1,734.8 million and $1,590.9 million as of September 30, 2020 and December 31, 2019, respectively. For the three and nine months ended September 30, 2020, depreciation expense totaled $51.5 million and $151.2 million, respectively, compared to $45.5 million and $145.4 million, respectively, in the prior year comparative periods.

Solothurn, Switzerland Manufacturing Facility

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially operational during the first half of 2021. Upon completion, this facility will include 393,000 square feet related to a large-scale biologics manufacturing facility, 290,000 square feet of warehouse, utilities and support space and 51,000 square feet of administrative space. As of September 30, 2020 and December 31, 2019, we had approximately $1.8 billion and $1.9 billion, respectively, capitalized as construction in progress related to this facility. For the nine months ended September 30, 2020, we placed approximately $256.8 million of fixed assets in service related to this facility. As of September 30, 2020, we had contractual commitments of approximately $14.8 million outstanding related to the construction of this facility.

11. Indebtedness

2020 Senior Notes

On April 30, 2020, we issued senior unsecured notes for an aggregate principal amount of $3.0 billion (2020 Senior Notes), consisting of the following:

- $1.5 billion of 2.25% Senior Notes due May 1, 2030, valued at 99.973% of par; and
- $1.5 billion of 3.15% Senior Notes due May 1, 2050, valued at 99.174% of par.

Our 2020 Senior Notes are senior unsecured obligations and may be redeemed at our option at any time at 100% of the principal amount plus accrued interest and, until a specified period before maturity, a specified make-whole amount. Our 2020 Senior Notes contain a change-of-control provision that, under certain circumstances, may require us to purchase our 2020 Senior Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest to the date of repurchase.

We incurred approximately $24.4 million of costs associated with this offering which have been recorded as a reduction to the carrying amount of the debt on our condensed consolidated balance sheet. These costs will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. The discounts will be amortized as additional interest expense over the period from issuance through maturity using the effective interest rate method. Interest on our 2020 Senior Notes is payable May 1 and November 1 of each year, commencing November 1, 2020.

2.90% Senior Notes due September 15, 2020

On September 15, 2015, we issued $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020, at 99.792% of par. Our 2.90% Senior Notes were senior unsecured obligations. We also entered into interest rate swap contracts where we received a fixed rate and paid a variable rate. In May 2020 we used the net proceeds from the sale of our 2020 Senior Notes to redeem our 2.90% Senior Notes prior to their maturity and recognized a net pre-tax charge of $9.4 million upon the extinguishment of these notes. This charge, which was recognized in interest expense in other income (expense), net in our condensed consolidated statements of income for the nine months ended September 30, 2020, reflects the payment of a $12.7 million early call premium and the write off of remaining unamortized original debt issuance costs and discount balances, partially offset by a $3.3 million gain related to the settlement of the associated interest rate swap contracts. For additional information on our interest rate swap contracts, please read *Note 9, Derivative Instruments,* to these condensed consolidated financial statements.

12. Equity

Share Repurchases

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired.

In December 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (December 2019 Share Repurchase Program) that was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 4.5 million and 16.7 million shares of our common stock at a cost of approximately $1.3 billion and $5.0 billion during the three and nine months ended September 30, 2020, respectively.

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program) that was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million shares of our common stock at a cost of approximately $1.3 billion during the nine months ended September 30, 2020.

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, 2019	$ 4.2	$ 7.8	$ 25.1	$ (32.8)	$ (139.5)	$ (135.2)
Other comprehensive income (loss) before reclassifications	(8.8)	(58.0)	8.1	0.4	3.9	(54.4)
Amounts reclassified from accumulated other comprehensive income (loss)	9.8	(43.1)	(2.6)	—	—	(35.9)
Net current period other comprehensive income (loss)	1.0	(101.1)	5.5	0.4	3.9	(90.3)
Balance, September 30, 2020	$ 5.2	$ (93.3)	$ 30.6	$ (32.4)	$ (135.6)	$ (225.5)

(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)

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

		Amounts Reclassified from Accumulated Other Comprehensive Income			
		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	Income Statement Location	2020	2019	2020	2019
Gains (losses) on securities available for sale	Other income (expense)	$ 0.1	$ 0.6	$ (12.4)	$ 1.6
	Income tax benefit (expense)	—	(0.1)	2.6	(0.3)
Gains (losses) on cash flow hedges	Revenues	(9.1)	35.2	41.6	79.8
	Operating expenses	1.5	(0.8)	1.4	(2.0)
	Other income (expense)	—	0.1	0.2	0.2
	Income tax benefit (expense)	0.1	(0.1)	(0.1)	(0.3)
Gains (losses) on net investment hedge	Other income (expense)	0.8	2.2	2.6	6.6
Total reclassifications, net of tax		$ (6.6)	$ 37.1	$ 35.9	$ 85.6

13. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Numerator:				
Net income attributable to Biogen Inc.	$ 701.5	$ 1,545.9	$ 3,642.7	$ 4,448.8
Denominator:				
Weighted average number of common shares outstanding	156.9	184.0	163.4	190.3
Effect of dilutive securities:				
Time-vested restricted stock units	0.1	0.1	0.1	0.1
Market stock units	0.1	0.1	0.1	0.1
Performance stock units settled in stock	0.1	—	0.1	—
Dilutive potential common shares	0.3	0.2	0.3	0.2
Shares used in calculating diluted earnings per share	157.2	184.2	163.7	190.5

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:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Research and development	$ 14.6	$ 15.4	$ 63.1	$ 65.2
Selling, general and administrative	25.0	34.2	98.4	116.8
Subtotal	39.6	49.6	161.5	182.0
Capitalized share-based compensation costs	(1.9)	(1.7)	(4.9)	(7.8)
Share-based compensation expense included in total cost and expenses	37.7	47.9	156.6	174.2
Income tax effect	(5.4)	(8.1)	(25.7)	(29.1)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 32.3	$ 39.8	$ 130.9	$ 145.1

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Market stock units	$ 5.5	$ 9.3	$ 32.0	$ 24.8
Time-vested restricted stock units	35.3	37.9	107.3	104.4
Cash settled performance units	—	0.3	(1.7)	(0.3)
Performance units	—	0.2	(0.1)	1.0
Performance stock units settled in stock	(8.4)	(1.1)	4.0	13.0
Performance stock units settled in cash	4.1	1.3	9.0	3.2
Employee stock purchase plan	3.1	1.7	11.0	9.7
NST stock options	—	—	—	26.2
Subtotal	39.6	49.6	161.5	182.0
Capitalized share-based compensation costs	(1.9)	(1.7)	(4.9)	(7.8)
Share-based compensation expense included in total cost and expenses	$ 37.7	$ 47.9	$ 156.6	$ 174.2

We estimate the fair value of our obligations associated with our performance 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.

15. Income Taxes

Coronavirus Aid, Relief and Economic Security Act

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law in the U.S. in March 2020. The CARES Act adjusted a number of provisions of the tax code, including the calculation and eligibility of certain deductions and the treatment of net operating losses and tax credits. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the three and nine months ended September 30, 2020, or to our net deferred tax assets as of September 30, 2020.

TECFIDERA

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 19, Litigation,* to these condensed consolidated financial statements.

Multiple TECFIDERA generic entrants are now in the U.S. market, some of which have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the third quarter of 2020 and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

As of September 30, 2020, we have assessed the realizability of our deferred tax assets that are dependent on future expected sales of TECFIDERA in the U.S. and reduced the value of certain deferred tax assets by approximately $1,627.9 million and reduced the value of deferred tax liabilities associated with global intangible low-taxed income (GILTI) and tax credits by approximately $1,538.6 million. For the three and nine months ended September 30, 2020, the income tax expense associated with these reductions was approximately $33.3 million and $89.3 million, respectively.

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,	
	2020	2019	2020	2019
Statutory rate	21.0 %	21.0 %	21.0 %	21.0 %
State taxes	0.9	0.9	0.6	0.7
Taxes on foreign earnings	(3.0)	(5.0)	(3.6)	(4.7)
Tax credits	(2.3)	(1.5)	(1.3)	(1.0)
Purchased intangible assets	2.9	0.4	0.8	0.4
Divestiture of Denmark manufacturing operations	—	—	—	1.5
Internal reorganization of certain intellectual property rights	—	(1.5)	—	(2.1)
TECFIDERA impairment	3.5	—	1.9	—
GILTI	2.2	1.6	1.3	1.6
Swiss tax reform	—	(3.1)	—	(1.0)
Other permanent items	(0.6)	(0.1)	—	0.2
Other	0.5	(0.8)	0.2	(0.3)
Effective tax rate	25.1 %	11.9 %	20.9 %	16.3 %

Changes in Tax Rate

For the three months ended September 30, 2020, compared to the same period in 2019, the increase in our effective tax rate was primarily due to an internal reorganization of certain intellectual property rights related to the intercompany sale of such intellectual property in 2019, the enactment of a new taxing regime in the country and certain cantons of Switzerland in 2019 (Swiss Tax Reform) and the net $33.3 million income tax expense related to the establishment of a valuation allowance against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S., as discussed above.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in our effective tax rate was primarily due to the $89.3 million impact from the valuation allowance described above, the internal reorganization of certain intellectual property rights and Swiss Tax Reform, partially offset by the $64.7 million tax expense recognized in September 30, 2019, related to the divestiture of our Hillerød, Denmark manufacturing operations. Although we recognized a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture required us to write off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions. 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.

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

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 2012.

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.

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

We estimate that it is reasonably possible that our gross unrecognized tax benefits, exclusive of interest, could decrease by up to approximately $75.0 million in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations.

16. Other Consolidated Financial Statement Detail

Other Income (Expense), Net

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Interest income	$ 6.0	$ 30.5	$ 38.0	$ 90.8
Interest expense	(56.3)	(45.8)	(166.5)	(141.4)
Gain (loss) on investments, net	(82.1)	(4.1)	(52.6)	198.9
Foreign exchange gains (losses), net	3.1	(4.2)	(5.4)	(4.7)
Other, net	0.7	(3.7)	0.4	(11.0)
Total other income (expense), net	$ (128.6)	$ (27.3)	$ (186.1)	$ 132.6

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.

For the three months ended September 30, 2020, compared to the same period in 2019, the change in other income (expense), net primarily reflects net unrealized losses of approximately $82.1 million recognized on our investments related to our holdings in equity securities, compared to net unrealized losses totaling $4.1 million in the prior year comparative period. The net unrealized losses recognized during the three months ended September 30, 2020, primarily reflect a decrease in the fair value of Ionis common stock of approximately $66.2 million and a decrease in the fair value of Denali common stock of approximately $29.6 million, partially offset by an increase in the fair value of Sangamo common stock of approximately $15.2 million.

For the nine months ended September 30, 2020, compared to the same period in 2019, the change in other income (expense), net primarily reflects net unrealized losses of approximately $40.3 million recognized on our investments related to our holdings in equity securities, compared to net unrealized gains totaling $198.9 million in the prior year comparative period. The net unrealized losses recognized during the nine months ended September 30, 2020, primarily reflect a decrease in the fair value of Ionis common stock of approximately $56.7 million and a decrease in the fair value of Denali common stock of approximately $29.6 million, partially offset by an increase in the fair value of Sangamo common stock of approximately $56.1 million.

The following table summarizes our gain (loss) on investments, net that relates to our equity securities held as of September 30, 2020 and 2019:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Net gains (losses) recognized during the period on equity securities	$ (82.3)	$ (4.6)	$ (40.3)	$ 197.3
Less: Net gains (losses) recognized during the period on equity securities sold during the period	—	4.4	—	46.8
Unrealized gains (losses) recognized during the period on equity securities	$ (82.3)	$ (9.0)	$ (40.3)	$ 150.5

Accrued Expenses and Other

Accrued expenses and other consists of the following:

(In millions)	As of September 30, 2020	As of December 31, 2019
Revenue-related reserves for discounts and allowances	$ 1,043.9	$ 1,001.1
Employee compensation and benefits	279.0	309.1
Royalties and licensing fees	222.8	220.9
Collaboration expenses	277.9	281.6
Current portion of contingent consideration obligations	164.4	148.4
Construction in progress	23.4	78.0
Other	1,274.8	726.7
Total accrued expenses and other	$ 3,286.2	$ 2,765.8

Other Long-term Liabilities

Other long-term liabilities were $1,428.1 million and $1,348.9 million as of September 30, 2020 and December 31, 2019, respectively, and included accrued income taxes totaling $729.3 million and $803.3 million, respectively. Included within accrued taxes as of September 30, 2020 and December 31, 2019, is an accrual for a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) of approximately $635.0 million and approximately $697.0 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 Alzheimer's disease (the BAN2401 and Elenbecestat Collaboration). In September 2019 we and Eisai discontinued the global Phase 3 studies of elenbecestat in early Alzheimer's disease.

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. If BAN2401 receives marketing approval, we and Eisai will co-promote BAN2401 and share profits equally. In addition, the BAN2401 and Elenbecestat Collaboration provides both parties with certain rights and obligations in the event of a change in control of either party.

The BAN2401 and Elenbecestat Collaboration also provided Eisai with an option to jointly develop and commercialize aducanumab, our anti-amyloid beta antibody candidate for Alzheimer's disease (Aducanumab Option), and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). In October 2017 Eisai exercised its Aducanumab Option and we entered into a new collaboration agreement for the joint development and commercialization of aducanumab (Aducanumab Collaboration Agreement). Eisai has not exercised its Anti-Tau Option.

Under the Aducanumab Collaboration Agreement, the two companies will continue to jointly develop BAN2401 in accordance with the BAN2401 and Elenbecestat Collaboration; however, we are no longer required to pay Eisai any milestone payments in relation to BAN2401 and we are no longer entitled to any potential development and commercial milestone payments from Eisai in relation to aducanumab. For additional information on our BAN2401 and Elenbecestat Collaboration, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**	**2020**	**2019**
Total development expense incurred by the collaboration related to the advancement of BAN2401 and elenbecestat	$ 75.7	$ 168.7	$ 153.2	$ 305.3
Biogen's share of BAN2401 and elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	37.9	84.3	76.6	152.6
Total sales and marketing expense incurred by the collaboration	nm	10.2	6.3	24.8
Biogen's share of BAN2401 and elenbecestat sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	nm	5.1	3.2	12.4

[nm] - For the three months ended September 30, 2020, sales and marketing expense related to the BAN2401 and Elenbecestat Collaboration was immaterial.

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. Beginning January 1, 2019, Eisai is reimbursing us for 45% of development costs incurred by the collaboration for the advancement of aducanumab (aducanumab development expense).

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 Alzheimer's disease. 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. 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 45% Eisai reimbursement of development costs incurred under the Aducanumab Collaboration Agreement.

In July 2020 we completed the submission of a Biologics License Application (BLA) to the FDA for the approval of aducanumab. For the nine months ended September 30, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45% share of the $75.0 million milestone expense related to the submission of the BLA to the FDA for the approval of aducanumab.

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 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Total aducanumab development expense	$ 37.5	$ 4.7	$ 92.5	$ 170.5
Biogen's share of aducanumab development expense reflected in research and development expense in our condensed consolidated statements of income	20.6	2.6	50.9	93.8
Total aducanumab sales and marketing expense incurred by the collaboration	90.9	0.1	158.8	21.3
Biogen's share of aducanumab sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	51.3	—	88.8	11.7
Total aducanumab collaboration third party milestone expense	—	—	75.0	—
Eisai's share of aducanumab milestone expense reflected in collaboration profit sharing in our condensed consolidated statements of income	—	—	33.8	—

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.

UCB Pharma S.A.

We have a collaboration agreement with UCB Pharma S.A. (UCB) to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of systemic lupus erythematosus and other future agreed indications. Either we or UCB may propose development of dapirolizumab pegol in additional indications. If the parties do not agree to add an indication as an agreed indication to the collaboration, we or UCB may, at the sole expense of the applicable party, pursue development in such excluded indication(s), subject to an opt-in right of the non-pursuing party after proof of clinical activity.

All costs incurred for agreed indications, including research, development, sales and marketing expenses, are shared equally between us and UCB. Upon marketing approval, we and UCB will co-promote dapirolizumab pegol and share profits equally. A summary of development expense related to the UCB collaboration agreement is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2020	2019	2020	2019
Total UCB development expense	$ 10.2	$ 5.4	$ 35.7	$ 21.6
Biogen's share of UCB development expense reflected in research and development expense in our condensed consolidated statements of income	5.2	2.7	17.9	10.8

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.

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. In addition to the LRRK2 program, we also received an exclusive option to license two preclinical programs from Denali's Transport Vehicle (TV) platform, including its Antibody Transport Vehicle: Abeta program, and a second program utilizing its TV technology. Further, we have the right of first negotiation on two additional TV-enabled therapeutics, currently at a preclinical stage, should Denali decide to seek a collaboration for such programs.

As part of this collaboration we purchased approximately $465.0 million of Denali common stock in September 2020, or approximately 13 million shares at approximately $34.94 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Denali common stock acquired and a charge of approximately $41.3 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Denali common stock. We also made an upfront payment of $560.0 million that was recorded as research and development expense.

We may also pay development and commercial milestone payments that could total up to approximately $1.1 billion if the milestones related to LRRK2 are achieved as well as tiered royalties on potential net commercial sales of LRRK2 licensed products.

Sangamo Therapeutics, Inc.

In February 2020 we entered into a collaboration and license agreement with Sangamo to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. The companies are leveraging Sangamo's proprietary zinc finger protein technology delivered via AAV with the aim to modulate the expression of key genes involved in neurological diseases.

In connection with the closing of this transaction in April 2020 we purchased $225.0 million of Sangamo common stock, or approximately 24 million shares at approximately $9.21 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately $83.0 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Sangamo common stock. We also made an upfront payment of $125.0 million that was recorded as research and development expense.

We may also pay research, development, regulatory and commercial milestone payments that could total up to approximately $2.4 billion if we select all of the targets allowed under this agreement and all the specified milestones set forth in this agreement are achieved. Of this amount, up to $80.0 million relates to the selection of targets, $1.9 billion relates to the achievement of specified research, clinical development, regulatory and first commercial sale milestones and $380.0 million relates to the achievement of specified sales-based milestones if annual worldwide net sales of licensed products reach specified levels. In addition, we may pay tiered royalties on potential net commercial sales of any products developed under this collaboration in the high single digit to double digit sub-teen percentages.

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 are leveraging Skyhawk's SkySTAR technology platform with the goal of discovering innovative small molecule treatments for patients with neurological diseases, including MS and SMA. We are 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 $2.4 billion in 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. These prepaid research and development services are

expensed as the services are provided. In October 2019 we amended this agreement to add an additional discovery program. In connection with this amendment, we made a payment to Skyhawk of $15.0 million.

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 5.0% 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, 2020, 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 basis differences are amortized over their economic life. The total basis difference was approximately $675 million and relates to inventory, developed technology, IPR&D and deferred tax balances. The basis differences related to inventory were amortized, net of tax, over their estimated useful lives of 1.5 years, and the basis differences related to developed technology and IPR&D for marketed products will be amortized, net of tax, over their estimated useful lives of 15 years.

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, 2020, we recognized net losses on our investment of $13.1 million and $12.7 million, respectively, reflecting our share of Samsung Bioepis' operating results and amortization of basis differences.

As of September 30, 2020 and December 31, 2019, the carrying value of our investment in Samsung Bioepis totaled 652.4 billion South Korean won ($557.8 million) and 670.8 billion South Korean won ($580.2 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets.

2019 Transaction

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11 referencing LUCENTIS and SB15 referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. Samsung Bioepis will be responsible for development and will supply both products to us.

In connection with this transaction, we made an upfront payment of $100.0 million to Samsung Bioepis in January 2020, of which $63.0 million was recorded as research and development expense in 2019 and $37.0 million was recorded as an intangible asset in 2019. Additionally, during the third quarter of 2020, we paid Samsung Bioepis a $15.0 million development milestone, which was included in research and development expense in our consolidated statements of income. We may pay Samsung Bioepis up to $195.0 million in additional development, regulatory and sales-based milestones.

We also acquired an option to extend the term of our 2013 commercial agreement for BENEPALI, IMRALDI and FLIXABI by an additional five years, subject to payment of an option exercise fee of $60.0 million, and obtained exclusive rights to commercialize these products in China.

2013 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, 2020, we recognized net profit-sharing expense of $72.9 million and $200.1 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits, compared to $60.1 million and $181.6 million, respectively, in the prior year comparative periods. As discussed above, we have an option to extend this agreement by an additional five years, subject to the payment of an option exercise fee of $60.0 million.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a technical development services agreement, a manufacturing agreement and a license agreement with Samsung Bioepis. For the three and nine months ended September 30, 2020, we recognized $5.4 million and $13.6 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 $12.9 million and $89.9 million, respectively, in the prior year comparative periods.

Following the divestiture of our Hillerød, Denmark manufacturing operations in August 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 Hillerød, Denmark manufacturing operations 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.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were $4.3 million and $85.0 million as of September 30, 2020 and December 31, 2019, respectively. Amounts payable to Samsung Bioepis were $26.4 million as of September 30, 2020. Amounts payable to Samsung Bioepis as of December 31, 2019, consisted of the $100.0 million upfront payment related to the 2019 transaction, as discussed above.

For additional information on our collaboration arrangements with Samsung Bioepis and our other significant collaboration arrangements, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

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 Alzheimer's disease, including aducanumab (as amended, the Neurimmune Agreement). We are responsible for the development, manufacturing and commercialization of all collaboration products. The Neurimmune 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 a licensed product.

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

In October 2017 we amended the terms of the Neurimmune Agreement and made a $150.0 million payment to Neurimmune in exchange for a 15% reduction in the previously negotiated royalty rates payable on products developed under the Neurimmune Agreement, including royalties payable on potential commercial sales of aducanumab. In May 2018 we made an additional $50.0 million payment to Neurimmune to further reduce the previously negotiated royalty rates payable on products developed under the Neurimmune Agreement, including royalties payable on potential commercial sales of aducanumab, by an additional 5%. Our royalty rates payable on products developed under the Neurimmune Agreement, including royalty rates payable on potential commercial sales of aducanumab, now range from the high single digits to sub-teens. As we consolidate the results of Neurimmune, we treated these payments as distributions and recognized them as charges to noncontrolling interests in the fourth quarter of 2017 and the second quarter of 2018, as applicable.

Additionally, under the terms of the Neurimmune Agreement, we are required to pay Neurimmune a milestone payment of $75.0 million upon the regulatory filing with the FDA for approval of aducanumab and a milestone payment of $100.0 million if aducanumab is launched in the U.S. In July 2020 we completed the submission of a BLA to the FDA for the approval of aducanumab. During the third quarter of 2020, we paid Neurimmune $75.0 million upon the completed submission of the BLA for aducanumab with the FDA, which was recognized as a charge to noncontrolling interests for the nine months ended September 30, 2020. In addition, for the nine months ended September 30, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45% share of the $75.0 million milestone payment.

Research and development costs for which we reimburse Neurimmune are reflected in research and development expense in our condensed consolidated statements of income. During the three and nine months ended September 30, 2020 and 2019, 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.

Under the Aducanumab Collaboration Agreement, Eisai had an option to share in the benefit and cost associated with the royalty reductions discussed above; however, Eisai did not elect to share in the benefit and cost with respect to either the October 2017 or May 2018 royalty reductions, which will impact the amount of profits (losses) on potential commercial sales of aducanumab to be shared with Eisai.

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

Unconsolidated Variable Interest Entities

We have relationships with various 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, 2020 and December 31, 2019, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $21.9 million and $22.7 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 19, Investments in Variable Interest Entities,* to our consolidated financial statements included in our 2019 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 2019 Form 10-K.

With respect to some loss contingencies, an estimate of the possible loss or range of loss cannot be made until management has further information, including, for example, (i) which claims, if any, will survive dispositive motion practice; (ii) information to be obtained through discovery; (iii) information as to the parties' damages claims and supporting evidence; (iv) the parties' legal theories; and (v) the parties' settlement positions.

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

Loss Contingencies

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 has commercialized 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 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 Danish Utility Models. In June 2019 the Danish court denied Fresenius Kabi's request for a preliminary injunction. Fresenius Kabi has appealed that decision and a hearing has been set for January 2021. In July 2020 the Danish Patent Board of Appeal revoked the Utility Models that were the subject of Fresenius Kabi's October 2018 request for a preliminary injunction and Fresenius Kabi has appealed those revocations.

In June 2020 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 another Danish Utility Model. A hearing has been scheduled for May 2021.

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. In Italy, Fresenius Kabi has surrendered the Italian counterpart of the '510 Patent and the court dismissed its infringement action in October 2020. A hearing in the proceeding in Germany has been set for August 2021.

In July 2019 Gedeon Richter PLC (Gedeon Richter) 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. The November 2020 hearing has been postponed and a new hearing date has not been set.

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. Gedeon Richter filed a separate action for infringement in the same court. A hearing was held in May 2020 and in July 2020 the court revoked the Dutch counterpart of the '667 Patent.

An estimate of the possible loss or range of loss in the pending IMRALDI patent litigation described above cannot be made at this time.

Qui Tam Litigation

In July 2015 a qui tam action filed by Michael Bawduniak on behalf of the U.S. and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. 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.

Dispute with Former Convergence Shareholders

In November and December 2019 Shareholder Representative Services LLC, on behalf of the former shareholders of Convergence, sent us correspondence asserting claims of $200.0 million for alleged breach of the contract under which we acquired Convergence. We dispute the claims.

Dispute with Jacobs Switzerland GmbH

Jacobs Switzerland GmbH, the general contractor for the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland, claims approximately 31.0 million Swiss Francs (approximately $33.0 million) relating to construction costs. We dispute the claim.

Other Matters

Petition for Inter Partes Review

In July 2018 Mylan Pharmaceuticals, Inc. (Mylan) filed a petition that was granted by the U.S. Patent Trial and Appeal Board (PTAB) for *inter partes* review of our U.S. Patent No. 8,399,514 (the '514 Patent). The '514 Patent includes claims covering treatment of MS with 480 mg of dimethyl fumarate per day as provided for in our TECFIDERA label. In February 2020 the PTAB issued a final written decision upholding the patentability of the ‘514 Patent and in April 2020 Mylan filed an appeal in the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit), which is pending. Oral argument has been scheduled for December 8, 2020.

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

In 2017, 2018 and 2019 we filed patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (the Delaware Actions), against Accord Healthcare Inc., Alkem Laboratories Ltd., Amneal Pharmaceuticals LLC, Aurobindo Pharma U.S.A., Inc., Cipla Limited, Glenmark Pharmaceuticals Ltd., Graviti Pharmaceuticals Pvt. Ltd., Hetero USA, Inc., Lupin Atlantis Holdings SA, Macleods Pharmaceuticals, Ltd., MSN Laboratories Pvt. Ltd., Pharmathen S.A., Prinston Pharmaceutical Inc., Sandoz Inc., Sawai USA, Inc., Shilpa Medicare Limited, Slayback Pharma LLC, Torrent Pharmaceuticals Ltd., TWi Pharmaceuticals, Inc., Windlas Healthcare Pvt. Ltd. and Zydus Pharmaceuticals (USA) Inc. (the Delaware Defendants) in the U.S. District Court for the District of Delaware (the Delaware Court) and against Mylan in the U.S. District Court for the Northern District of West Virginia (the West Virginia Court). The litigation against Aurobindo Pharma U.S.A., Inc., Glenmark Pharmaceuticals Ltd. and Sawai USA, Inc. was dismissed in the fourth quarter of 2019.

On June 22, 2020, the West Virginia Court entered judgment for Mylan that the asserted claims of the ‘514 Patent are invalid for lack of written description. We appealed the judgment to the Federal Circuit and the appeal is pending. Oral argument has been scheduled for December 8, 2020.

On September 22, 2020, the Delaware Court entered judgment for the Delaware Defendants on the grounds that the judgment of the West Virginia Court applies to the Delaware Actions under principles of collateral estoppel. We have appealed the judgment and the appeal is pending. Multiple generic versions of TECFIDERA have entered the U.S. market prior to resolution of the appeals.

On August 31, 2020, we filed a patent infringement action under the Hatch-Waxman Act against Sun Pharmaceutical Industries Limited, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global SZE in the Delaware Court. No trial has been scheduled in this action.

European Patent Office Oppositions

In 2016 the European Patent Office (EPO) revoked our European Patent No. 2 137 537, which covers 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 a hearing has been set for January 2021.

In March 2018 the EPO revoked Forward Pharma A/S' (Forward Pharma) 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 a hearing has been set for February 2021.

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 No. 215263 (the Polish '263 Patent), which corresponds to our European Patent No. 1 485 127 (the E.U. '127 Patent) and covers administration of natalizumab (TYSABRI) to treat MS. The Polish '263 Patent expires in February 2023. No hearing 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, respectively, of the E.U. '127 Patent, which also cover administration of natalizumab (TYSABRI) to treat MS and expire in February 2023. The Dutch and German counterparts were ruled invalid. The decision in the Dutch action was affirmed on appeal and the German appeal has been withdrawn. No hearing 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 (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, among other things, the use of interferon beta for immunomodulation. The complaint seeks monetary damages, including lost profits and royalties.

Bayer, Pfizer, Novartis and EMD Serono all 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. Bayer has also requested *ex parte* reexamination by the U.S. Patent and Trademark Office of Claim 1 of the ‘755 Patent, which request was granted in January 2020 and is pending.

In September 2020 the Federal Circuit reversed the trial court's judgment against EMD Serono and Pfizer that the '755 patent is valid. We intend to file a petition for panel rehearing and rehearing en banc.

Annulment Proceeding in General Court of the European Union relating to TECFIDERA

In October 2018 Pharmaceutical Works Polpharma SA (Polpharma) filed an application in the General Court of the European Union seeking to annul a decision of the European Medicines Agency (EMA) in which the EMA refused to validate Polpharma’s application to market a generic version of TECFIDERA on the grounds that TECFIDERA benefits from regulatory data protection (RDP). Polpharma disputes that TECFIDERA benefits from RDP. Biogen and the European Commission were granted leave to intervene in the case in support of the EMA and the case is pending. A hearing was held on July 13, 2020, and we are awaiting a decision.

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 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 have reached an agreement in principle with the government to resolve this matter. We have accrued the amount of our best estimate of the minimum probable loss in this matter.

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, 2019 (2019 Form 10-K).

Executive Summary

Introduction

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology; Alzheimer's disease and dementia; neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS); movement disorders, including Parkinson's disease; 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, VUMERITY, 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 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 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduces 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 certain countries in Europe and have exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11 referencing LUCENTIS and SB15 referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 17, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

We are committed to ensuring an uninterrupted supply of medicines to patients around the world. To that end, we continually review our manufacturing capacity, capabilities, processes and facilities. In order to support our future growth and drug development pipeline, we are expanding our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which we expect to be partially operational during the first half of 2021. We believe that the Solothurn manufacturing facility will provide us with the ability to further expand if our future growth and drug development plans increase.

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.

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.

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 and revenue streams continue to face increasing competition in many markets from generic versions, prodrugs and biosimilars of existing products as well as products approved under abbreviated regulatory pathways. Such products 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 are able to charge for our products and the volume of products we sell, which will negatively impact our revenues. In addition, when a generic version of one of our products is commercialized, it may, in some cases, be automatically substituted for our product and reduce our revenues in a short period of time.

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 public health epidemics, such as the COVID-19 pandemic, on employees, the global economy and the delivery of healthcare treatments, foreign currency exchange fluctuations, changes in intellectual property legal protections and changes in trade regulations and procedures.

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.

TECFIDERA

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 19, Litigation,* to our condensed consolidated financial statements included in this report.

Multiple TECFIDERA generic entrants are now in the U.S. market, some of which have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the third quarter of 2020 and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition. For additional information, please read the discussion under *Results of Operations - Product Revenues - Multiple Sclerosis (MS) - Fumarate* below.

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 its withdrawal and outline the future relationship between the U.K. and the E.U. upon exit, which occurred on January 31, 2020. Following the U.K.'s departure, there is now a transition period during which existing arrangements will remain in place until the end of 2020, allowing detailed discussions on the future relationship between the U.K. and the E.U. to take place.

The actual effects of Brexit will depend upon many factors and significant uncertainty remains with respect to the future relationship between the U.K. and the E.U. The final outcome of the discussions during the transition period 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 expect Brexit to have a material impact on our consolidated results of operations as less than 4.0% of our total product revenues for the three and nine months ended September 30, 2020, were derived from U.K. sales, which is consistent with full year product sales in 2019.

We have implemented measures to meet E.U. legal and regulatory requirements and continue to modify our business operations to prepare for the end of the transition period and the finalization of the terms of 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.

Business Update Regarding COVID-19

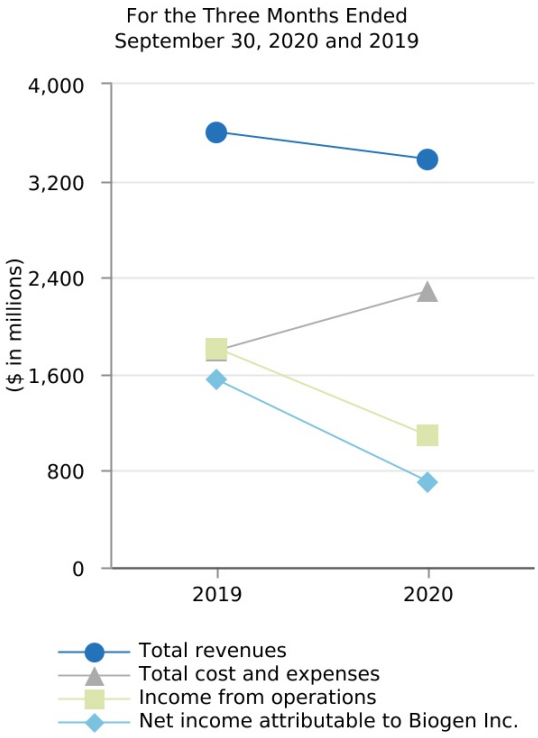
The COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts our business, results of operations and financial condition depends on future developments that are highly uncertain, subject to change and are difficult to predict, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19 as well as the economic impact on local, regional, national and international customers and markets.

We are monitoring the demand for our products, including the duration and degree to which we may see delays in starting new patients on a product due to hospitals diverting the resources that are necessary to administer certain of our products to care for COVID-19 patients, including products, such as TYSABRI and SPINRAZA, that are administered in a physician's office or hospital setting. We may also see reduced demand for immunosuppressant therapies during the COVID-19 pandemic.

While we are currently continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have impacted the timeline for some of our clinical trials and these precautions may, directly or indirectly, have a further impact on timing in the future. For example, our Phase 3 study of BIIB093 (glibenclamide IV) for large hemispheric infarction, a severe form of ischemic stroke, has been delayed as this study involves administration of BIIB093 in an acute hospital setting. To help mitigate the impact of the COVID-19 pandemic to our clinical trials, we are pursuing innovative approaches such as remote monitoring, remote patient visits and supporting home infusions. These alternative measures have resulted in an immaterial increase to the cost of the clinical trials underway.

For additional information on the various risks posed by the COVID-19 pandemic, please read *Item 3. Quantitative and Qualitative Disclosures About Market Risk* and *Item 1A. Risk Factors* included in this report.

Financial Highlights



Diluted earnings per share attributable to Biogen Inc. was $4.46 for the three months ended September 30, 2020, representing a decrease of 46.8% compared to $8.39 in the same period in 2019.

As further 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, 2020, compared to the three months ended September 30, 2019, reflects the following:

- Total revenues were $3,376.1 million for the third quarter of 2020, representing a $224.0 million, or 6.2%, decrease compared to $3,600.1 million in the same period in 2019.
- Product revenues, net totaled $2,690.3 million for the third quarter of 2020, representing a $204.4 million, or 7.1%, decrease compared to $2,894.7 million in the same period in 2019. This decrease was primarily due to a $52.7 million, or 9.6%, decrease in SPINRAZA and a $175.3 million, or 8.1%, decrease in MS product revenues, partially offset by a $24.3 million, or 13.2%, increase in revenues from our biosimilar products.
    - The decrease in MS product revenues was primarily due to a decrease in TECFIDERA demand and pricing as a result of multiple TECFIDERA generic entrants entering the U.S. market during the third quarter of 2020.
- Revenues from anti-CD20 therapeutic programs (our share of RITUXAN, including RITUXAN HYCELA, and GAZYVA collaboration operating profits) totaled $560.1 million for the third quarter of 2020, representing a $35.7 million, or 6.0%, decrease compared to $595.8 million in the same period in 2019. This decrease was primarily due to a $129.8 million, or 33.0%, decrease in RITUXAN revenues, partially offset by a $84.6 million, or 45.1%, increase in royalty revenues on sales of OCREVUS. We believe that sales of RITUXAN have been adversely affected by the onset of biosimilars competition.
- Other revenues totaled $125.7 million for the third quarter of 2020, representing a 14.7% increase from $109.6 million in the same period in 2019.
- Total cost and expenses were $2,289.7 million for the third quarter of 2020, representing a $495.9 million increase compared to $1,793.8 million in the same period in 2019. This increase was primarily due to a $600.5 million increase in research and development expense.
    - The increase in research and development expense was primarily due to $601.3 million in charges recognized in connection with our collaboration with Denali Therapeutics Inc. (Denali) in the third quarter of 2020.

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

- Cash, cash equivalents and marketable securities totaled approximately $4.6 billion and $5.9 billion as of September 30, 2020 and December 31, 2019, respectively.
- We repurchased and retired approximately 4.5 million shares of our common stock at a cost of approximately $1.3 billion during the third quarter of 2020 under a program authorized by our Board of Directors in December 2019 to repurchase up to $5.0 billion of our common stock (December 2019 Share Repurchase Program). Our December 2019 Share Repurchase Program was completed as of September 30, 2020.

Acquisitions and Collaborative and Other Relationships

BIIB118 Acquisition

In March 2020 we acquired BIIB118 (formerly known as PF-05251749), a novel CNS-penetrant small molecule inhibitor of casein kinase 1, for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). We plan to develop this Phase 1 asset for the potential treatment of sundowning in Alzheimer's disease and irregular sleep wake rhythm disorder in Parkinson’s disease.

For additional information on our acquisition of BIIB118, please read *Note 2, Acquisitions,* to our condensed consolidated financial statements included in this report.

Sangamo Therapeutics, Inc.

In April 2020 we closed a collaboration and license agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including, Parkinson’s disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period.

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

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. In addition to the LRRK2 program, we also received an exclusive option to license two preclinical programs from Denali’s Transport Vehicle (TV) platform, including its Antibody Transport Vehicle: Abeta program, and a second program utilizing its TV technology. Further, we have the right of first negotiation on two additional TV-enabled therapeutics, currently at a preclinical stage, should Denali decide to seek a collaboration for such programs.

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

Other Key Developments

Aducanumab (AB mAb)

In July 2020 we completed the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the approval of aducanumab, an anti-amyloid beta antibody candidate for the potential treatment of Alzheimer's disease that we are developing in collaboration with Eisai Co., Ltd. (Eisai). The completed submission followed ongoing collaboration with the FDA and includes clinical data from the Phase 3 EMERGE and ENGAGE studies as well as the Phase 1b PRIME study. In August 2020 the FDA accepted the BLA and granted Priority Review with a Prescription Drug User Fee Act action date on March 7, 2021.

During the first quarter of 2020, we initiated the EMBARK global re-dosing clinical study, which is designed to evaluate aducanumab in eligible Alzheimer's disease patients who were actively enrolled in aducanumab studies (PRIME, EVOLVE, EMERGE and ENGAGE) in March 2019.

SB11 (referencing LUCENTIS)

In October 2020 we and Samsung Bioepis announced that the European Medicines Agency accepted for review the Marketing Authorization Application for SB11, a proposed biosimilar referencing LUCENTIS (ranibizumab).

Healthy Climate, Healthy Lives

In September 2020 we announced *Healthy Climate, Healthy Lives*, a $250.0 million, 20-year initiative to eliminate our fossil fuels across our operations and collaborate with renowned institutions with the aim to improve health, especially for the world's most vulnerable populations.

2020 Share Repurchase Program

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 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, 2020		2019		For the Nine Months Ended September 30, 2020		2019	
Product revenues, net:								
United States	$ 1,498.2	44.4 %	$ 1,702.0	47.3 %	$ 4,803.1	45.3 %	$ 4,959.7	46.4 %
Rest of world	1,192.1	35.3	1,192.7	33.1	3,587.5	33.9	3,495.3	32.6
Total product revenues, net	2,690.3	79.7	2,894.7	80.4	8,390.6	79.2	8,455.0	79.0
Revenues from anti-CD20 therapeutic programs	560.1	16.6	595.8	16.5	1,558.8	14.7	1,689.6	15.8
Other revenues	125.7	3.7	109.6	3.0	642.6	6.1	562.0	5.2
Total revenues	$ 3,376.1	100.0 %	$ 3,600.1	100.0 %	$ 10,592.0	100.0 %	$ 10,706.6	100.0 %

Product Revenues

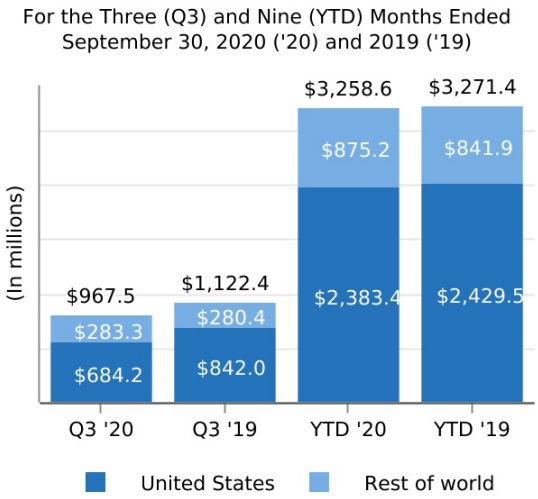
Product revenues are summarized as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2020		2019		For the Nine Months Ended September 30, 2020		2019	
Multiple Sclerosis:								
Fumarate*	$ 967.5	36.0 %	$ 1,122.4	38.8 %	$ 3,258.6	38.9 %	$ 3,271.4	38.7 %
Interferon**	474.1	17.6	530.0	18.3	1,421.5	17.0	1,585.3	18.7
TYSABRI	516.5	19.2	483.6	16.7	1,470.9	17.5	1,419.3	16.8
FAMPYRA	26.8	1.0	24.2	0.8	78.1	0.9	71.2	0.8
Subtotal: MS product revenues	1,984.9	73.8	2,160.2	74.6	6,229.1	74.3	6,347.2	75.1
Spinal Muscular Atrophy:								
SPINRAZA	494.4	18.4	547.1	18.9	1,554.0	18.5	1,553.8	18.4
Biosimilars:								
BENEPALI	124.2	4.6	115.9	4.0	363.9	4.3	360.2	4.3
IMRALDI	56.2	2.1	49.3	1.7	162.6	1.9	132.3	1.6
FLIXABI	27.5	1.0	18.4	0.6	71.8	0.9	49.9	0.6
Subtotal: Biosimilar product revenues	207.9	7.7	183.6	6.3	598.3	7.1	542.4	6.4
Other:								
FUMADERM	3.1	0.1	3.8	0.1	9.2	0.1	11.6	0.1
Total product revenues	$ 2,690.3	100.0 %	$ 2,894.7	100.0 %	$ 8,390.6	100.0 %	$ 8,455.0	100.0 %

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
**Interferon includes AVONEX and PLEGRIDY.

Multiple Sclerosis (MS)

Fumarate



Fumarate revenues include sales from TECFIDERA and VUMERITY. In October 2019 the FDA approved VUMERITY for the treatment of RMS and VUMERITY became commercially available in the U.S. in November 2019.

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases of 18.7% and 1.9%, respectively, in U.S. Fumarate revenues were primarily due to a decrease in TECFIDERA demand and pricing as a result of multiple TECFIDERA generic entrants entering the U.S. market during the third quarter of 2020. Decreases were also due to unfavorable pricing, driven by discounts and allowances.

For the three months ended September 30, 2020, compared to the same period in 2019, the increase in rest of world Fumarate revenues was primarily due to an increase in sales volume of 5.9%, partially offset by unfavorable foreign currency impact.

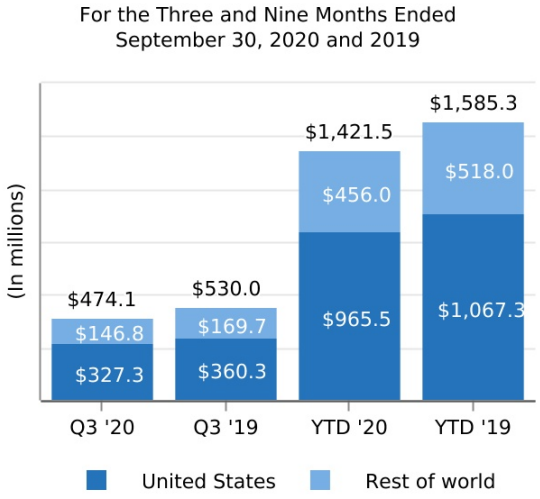
For the nine months ended September 30, 2020, compared to the same period in 2019, the increase of 4.0% in rest of world Fumarate revenues was primarily due to an increase in sales volumes of 10.0%, which was primarily related to our European and Japanese markets, partially offset by pricing reductions in certain European countries. The increase in volumes was primarily due to continued strong patient growth in our E.U. direct markets, including Italy, Spain and the U.K. as well as growth in Asia (Japan) and Latin America (Brazil).

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Hatch-Waxman Act in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 19, Litigation,* to our condensed consolidated financial statements included in this report.

Multiple TECFIDERA generic entrants are now in the U.S. market, some of which have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the third quarter of 2020 and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

We anticipate an increase in TECFIDERA demand in rest of world in 2020, compared to 2019, notwithstanding the increasing competition from additional treatments for MS and potential disruptions from the COVID-19 pandemic.

Interferon



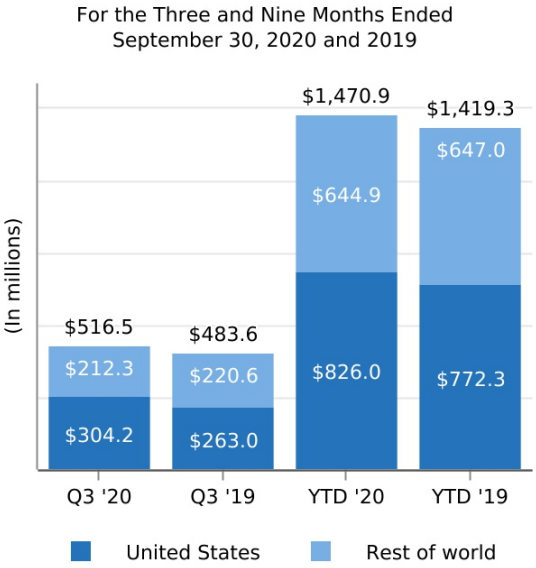
For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases of 9.2% and 9.5%, respectively, in U.S. Interferon revenues were primarily due to decreases in Interferon sales volumes of 11.8% and 10.4%, respectively. The net declines in sales volumes reflect the continued decline of the Interferon market as patients transition to other higher efficacy and oral MS therapies, which negatively impacted comparative revenues by $42.5 million and $110.7 million, respectively.

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases of 13.5% and 12.0%, respectively, in rest of world Interferon revenues were primarily due to decreases in Interferon sales volumes of 8.5% and 7.5%, respectively.

We expect that Interferon revenues will continue to decline in both the U.S. and rest of world markets

in 2020, compared to 2019, 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 and nine months ended September 30, 2020, compared to the same periods in 2019, the increases of 15.7% and 7.0%, respectively, in U.S. TYSABRI revenues were primarily due to favorable volume impacts and price increases, partially offset by higher discounts and allowance rates.

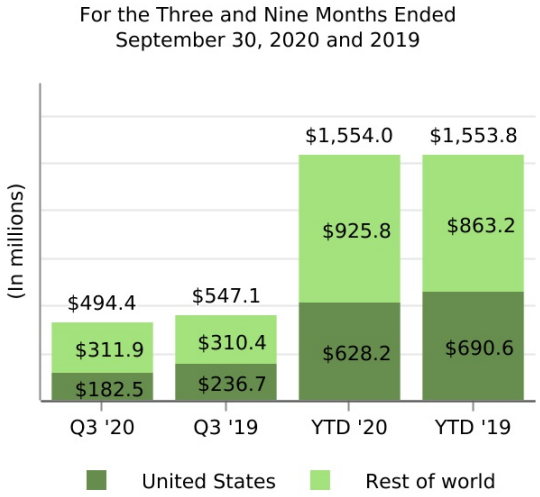
For the three months ended September 30, 2020, compared to the same period in 2019, the decrease of 3.8% in rest of world TYSABRI revenues was primarily due to an unfavorable foreign currency impact of approximately $11.5 million, partially offset by a favorable volume impact of approximately $3.6 million.

For the nine months ended September 30, 2020, compared to the same period in 2019, rest of world TYSABRI revenues remained flat.

We anticipate TYSABRI demand to be stable on a global basis in 2020, compared to 2019, despite increasing competition from additional treatments for MS, including OCREVUS. We believe that some TYSABRI infusions may be delayed due, directly or indirectly, to the COVID-19 pandemic.

Spinal Muscular Atrophy

SPINRAZA



For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases of 22.9% and 9.0%, respectively, in U.S. SPINRAZA revenues were primarily due to a decreases in sales volumes of 22.4% and 7.6%, respectively, resulting from increased competition as well as lower loading and maintenance doses and site of care closures as a result of the COVID-19 pandemic.

For the three months ended September 30, 2020, compared to the same period in 2019, rest of world SPINRAZA revenues remained flat.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase of 7.3% in rest of world SPINRAZA revenues was primarily due to an increase in sales volumes of 18.2%, partially offset by the impact of a shift from loading to maintenance doses, lower net prices and the unfavorable impact of foreign currency exchange.

We expect that the rate at which SPINRAZA revenues will grow will be modest in 2020, compared to 2019, 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, lower prices in certain rest of world countries and the potential impact of the COVID-19 pandemic. We are evaluating the impact of the COVID-19 pandemic on the ability of hospitals to provide SPINRAZA dosing to patients. We believe that some SPINRAZA doses may be delayed due, directly or indirectly, to the COVID-19 pandemic.

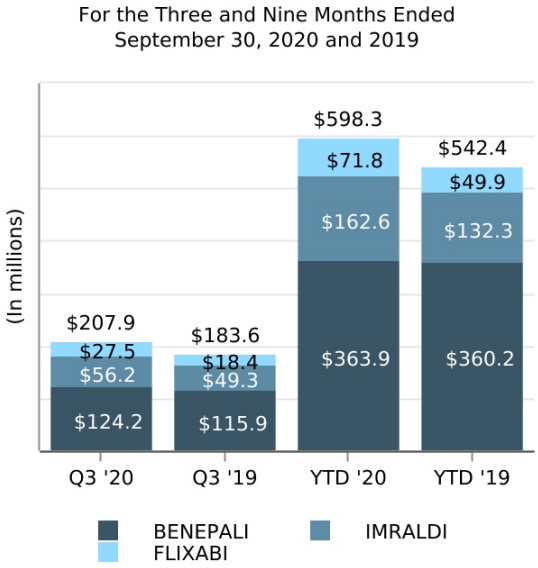
We face competition from a new gene therapy product that was approved in the U.S. in May 2019 and in the E.U. in May 2020 for the treatment of SMA as well as a new oral product for the treatment of

SMA that was approved in the U.S. in August 2020. Additionally, we are aware of other products now in development that, if launched, may compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products.

For information on our collaboration arrangements with Ionis Pharmaceuticals, Inc. (Ionis), please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

Biosimilars

BENEPALI, IMRALDI and FLIXABI



For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the increases of 13.2% and 10.3%, respectively, in biosimilar revenues were primarily due to higher volumes and favorable foreign currency impact, partially offset by the unfavorable impact of price decreases.

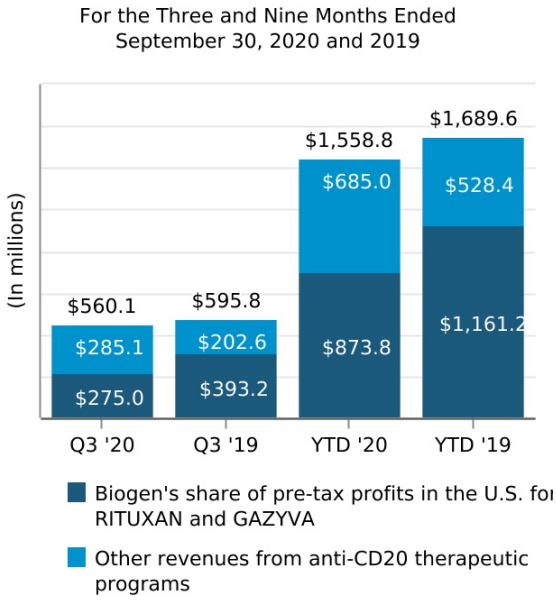
In 2020 we expect modest to moderate revenue growth for our biosimilars business depending on the impact of the COVID-19 pandemic. We expect growth to be primarily driven by the continued launch of IMRALDI in Europe, partially offset by price reductions in certain European countries.

For additional information on our collaboration arrangements 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:

	For the Three Months Ended September 30,	
(In millions)	**2020**	**2019**
Product revenues, net	$ 814.4	$ 1,189.8
Cost and expenses	81.1	141.6
Pre-tax profits in the U.S.	733.3	1,048.2
Biogen's share of pre-tax profits	$ 275.0	$ 393.2

	For the Nine Months Ended September 30,	
(In millions)	**2020**	**2019**
Product revenues, net	$ 2,700.5	$ 3,581.5
Cost and expenses	350.0	473.0
Pre-tax profits in the U.S.	2,350.5	3,108.5
Biogen's share of pre-tax profits	$ 873.8	$ 1,161.2

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases in U.S. product revenues, net were primarily due to decreased sales volume of RITUXAN in the U.S. of 26.0% and 21.5%, respectively, due to the onset of competition from multiple biosimilars and, we believe, the adverse impacts due, directly or indirectly, to the COVID-19 pandemic.

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, product revenues, net also reflects increases in GAZYVA sales volume of 25.4% and 32.5%, respectively.

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases in collaboration costs and expenses were primarily due to lower cost of sales on RITUXAN.

We are aware of anti-CD20 molecules, including biosimilar products, in development that if successfully developed and approved, could compete with RITUXAN and GAZYVA in the oncology market. The introduction of one or more competitive products can result in significant reduction in net sales for the relevant product, as other manufacturers typically offer their versions at lower prices. In November 2019 and January 2020 biosimilar products referencing RITUXAN were launched in the U.S. An additional biosimilar entrant is possible. This competition has adversely affected the pre-tax profits of our collaboration arrangements with Genentech and could have a significant adverse affect on 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, 2020, compared to the same periods in 2019, 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, 2020, totaled $272.5 million and $643.0 million, respectively, compared to $187.8 million and $482.1 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 generally expected to be the following quarter.

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 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

Other Revenues

Other revenues are summarized as follows:

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
(In millions, except percentages)	**2020**		**2019**		**2020**		**2019**	
Revenues from collaborative and other relationships	$ 5.4	4.3 %	$ 13.2	12.0 %	$ 14.3	2.2 %	$ 89.7	16.0 %
Other royalty and corporate revenues	120.3	95.7	96.4	88.0	628.3	97.8	472.3	84.0
Total other revenues	$ 125.7	100.0 %	$ 109.6	100.0 %	$ 642.6	100.0 %	$ 562.0	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 in August 2019, FUJIFILM Corporation (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 Hillerød, Denmark manufacturing operations divestiture date under our technical development services and manufacturing agreements with Samsung Bioepis.

For additional information on our collaborative and other relationships, including revenues recognized under our technical development services and manufacturing agreements with Samsung Bioepis, please read *Note 17, Collaborative and Other Relationships,* 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.

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.

During the third quarter of 2019, we amended our agreement with a contract manufacturing customer pursuant to which we licensed certain of our manufacturing-related intellectual property to the customer. In the second quarter of 2020, the customer received regulatory approval for its product that is being manufactured using certain of our manufacturing-related intellectual property. As a result, we are entitled to $500.0 million in a series of three payments. The first payment became due upon regulatory approval of such product and was received during the second quarter of 2020. Subsequent payments are due on the first and second anniversaries of the regulatory approval.

Other corporate revenues for the nine months ended September 30, 2020, reflect $333.2 million related to the delivery of the license for certain of our manufacturing-related intellectual property under the amended agreement discussed above and the performance of manufacturing product supply services for such customer. We have allocated the remaining $166.8 million of the $500.0 million transaction price to the performance of manufacturing product supply services for the customer, which we expect to perform through 2026. The value allocated to the manufacturing services was based on expected demand for supply and the fair value of comparable manufacturing and development services.

For the three months ended September 30, 2020, compared to the same period in 2019, the increase in other royalty and corporate revenues was primarily due to an increase in royalty revenues and higher contract manufacturing revenues.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in other royalty and corporate revenues was due to higher contract manufacturing revenues, primarily resulting from $333.2 million in revenues related to the delivery of the license for certain of our manufacturing-related intellectual property to a contract manufacturing customer, as discussed above. The increase was partially offset by revenues recognized in 2019 under the manufacturing and supply agreement with Bioverativ Inc. (Bioverativ) entered into in connection with the spin-off of our hemophilia business as well as revenues recognized in 2019 under our technical development services and manufacturing agreements with Samsung Bioepis prior to the divestiture of our Hillerød, Denmark manufacturing operations.

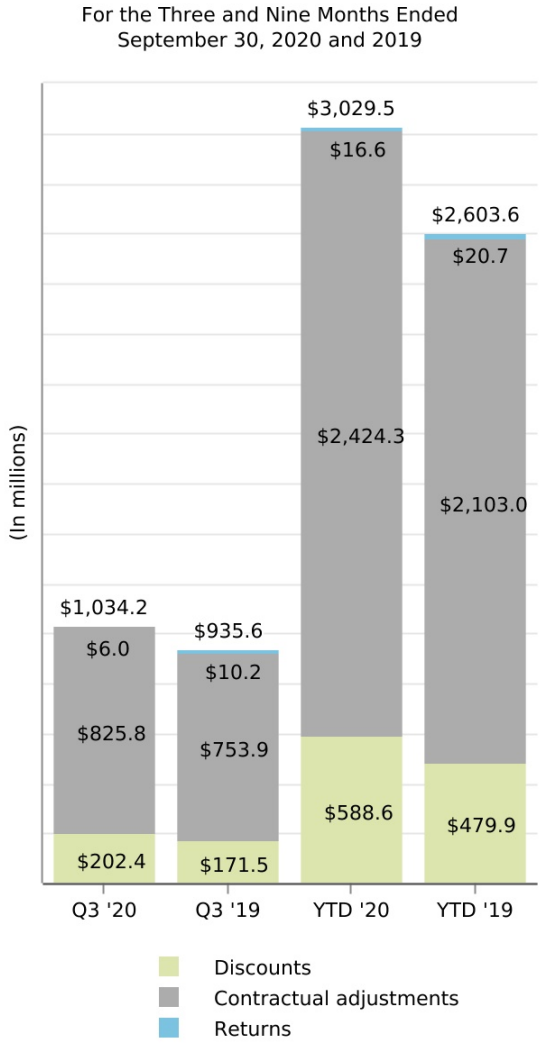
Reserves for Discounts and Allowances

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, 2020, reserves for discounts and allowances as a percentage of gross product revenues were 27.3% and 26.3%, respectively, compared to 24.4% and 23.5%, 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, 2020, compared to the same periods in 2019, the increases in discounts were primarily driven by increases in gross sales.

Contractual Adjustments

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

For the three months ended September 30, 2020, compared to the same period in 2019, the decrease in contractual adjustments was primarily due to a favorable change in estimates.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in contractual adjustments was 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, 2020, compared to the same periods in 2019, 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.

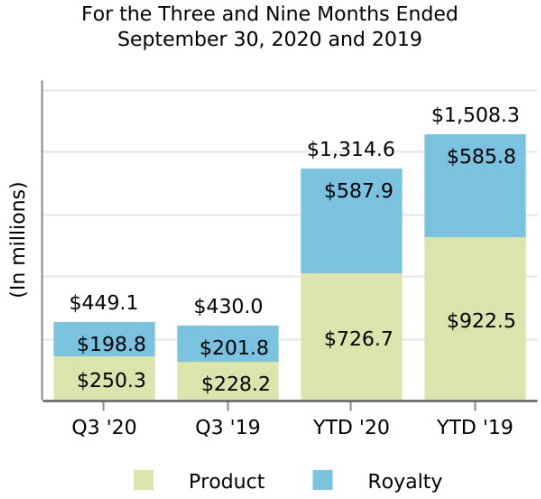
Cost and Expenses

A summary of total cost and expenses is as follows:

(In millions, except percentages)	For the Three Months Ended September 30, 2020	2019	Change %	For the Nine Months Ended September 30, 2020	2019	Change %
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 449.1	$ 430.0	4.4 %	$ 1,314.6	$ 1,508.3	(12.8)%
Research and development	1,140.9	540.4	111.1	2,264.8	1,588.9	42.5
Selling, general and administrative	573.1	554.5	3.4	1,698.3	1,709.8	(0.7)
Amortization and impairment of acquired intangible assets	82.6	283.9	(70.9)	215.6	422.2	(48.9)
Collaboration profit (loss) sharing	73.0	60.2	21.3	166.5	181.8	(8.4)
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	(17.7)	**	—	95.5	**
(Gain) loss on fair value remeasurement of contingent consideration	(29.0)	(57.8)	(49.8)	(23.5)	(66.3)	(64.6)
Restructuring charges	—	0.3	(100.0)	—	1.5	(100.0)
Acquired in-process research and development	—	—	**	75.0	—	**
Total cost and expenses	$ 2,289.7	$ 1,793.8	27.6 %	$ 5,711.3	$ 5,441.7	5.0 %

** 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, 2020, compared to the same period in 2019, the increase in product cost of sales was primarily due to higher cost of sales associated with higher revenues from contract manufacturing agreements.

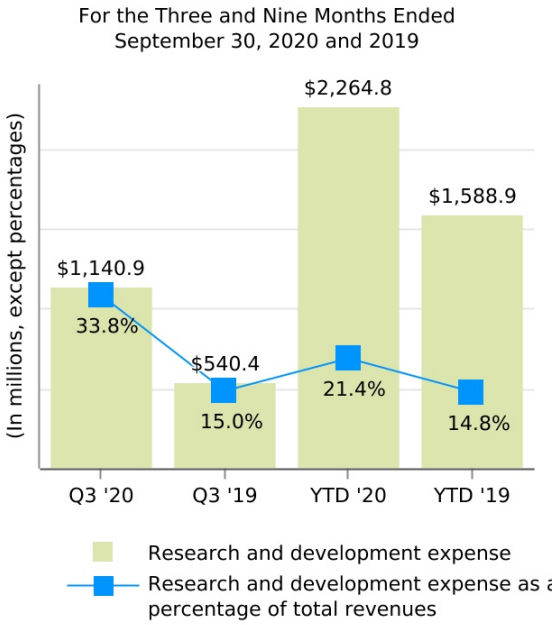
For the nine months ended September 30, 2020, compared to the same period in 2019, the decrease in product cost of sales was primarily due to lower cost of sales from contract manufacturing agreements, primarily resulting from the sale of hemophilia inventory, with a cost basis of $173.5 million, to Bioverativ in the first quarter of 2019 and FUJIFILM assuming responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis.

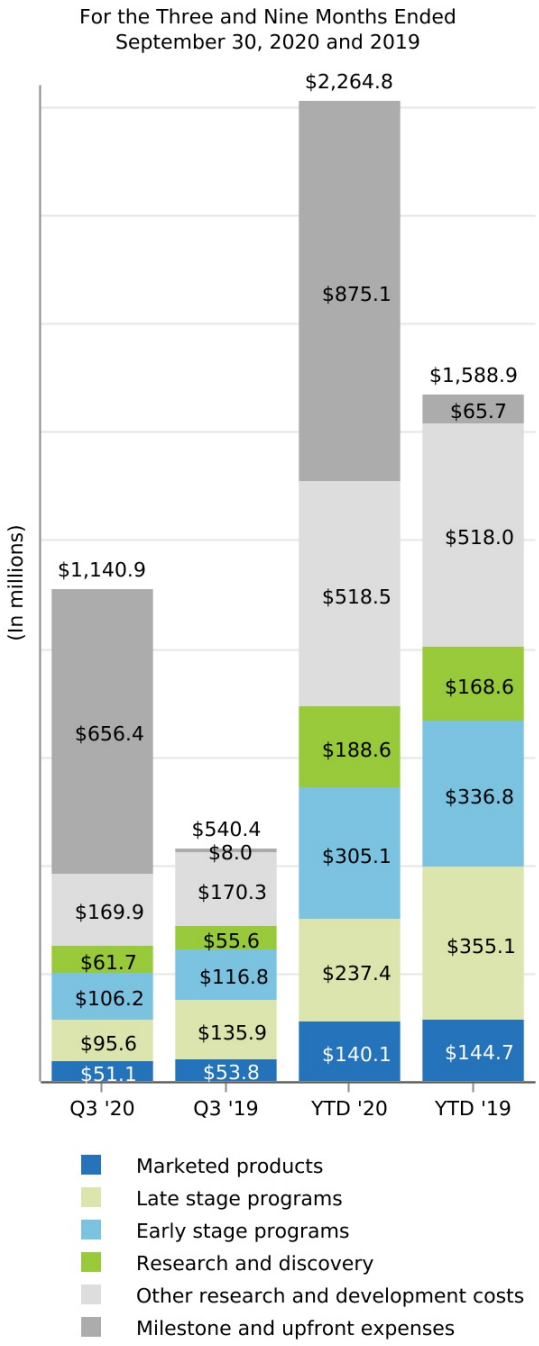
Royalty Cost of Sales

For the three months ended September 30, 2020, compared to the same period in 2019, the decrease in royalty cost of sales was primarily due to lower royalties payable on lower sales of SPINRAZA.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in royalty cost of sales was primarily due to higher royalties payable on higher sales of TYSABRI and VUMERITY.

Research and Development





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

A significant amount of our research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as

management costs, as well as depreciation, information technology and facility-based expenses. These costs are considered other research and development costs in the table above and are not allocated to a specific program or stage.

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

For the three months ended September 30, 2020, compared to the same period in 2019, the increase in research and development expense was primarily due to approximately $601.3 million in charges recognized in connection with our collaboration with Denali in the third quarter of 2020.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in research and development expense was primarily due to approximately $601.3 million and $208.0 million in charges recognized upon the closing of our collaborations with Denali and Sangamo, respectively.

While we are currently continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have impacted the timeline for some of our clinical trials and these precautions may, directly or indirectly, have a further impact on timing in the future. For example, our Phase 3 study of BIIB093 for large hemispheric infarction has been delayed as this study involves administration of BIIB093 in an acute hospital setting.

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

Milestone and Upfront Expenses

For the three months ended September 30, 2020, compared to the same period in 2019, the increase in milestone and upfront expenses was primarily due to a $601.3 million charge to research and development expense related to our collaboration with Denali in the third quarter of 2020.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in milestone and upfront expenses was primarily due to approximately $601.3 million and $208.0 million in charges to research and development expense related to our collaboration and license agreements with Denali and Sangamo, respectively.

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

Early Stage Programs

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases in spending related to our early stage programs were primarily due to decreases in costs associated with:

- the discontinuation of gosuranemab (BIIB092) in progressive supraneuclear palsy; and
- the advancement of toferson (BIIB067) in ALS into late stage.

The decreases were partially offset by increases in costs associated with:

- spending in the development of BIIB112 (RPGR gene therapy) in X-linked retinitis pigmentosa; and
- the discontinuation of the Phase 2b study of BG00011 (STX-100) for the potential treatment of idiopathic pulmonary fibrosis (IPF).

Late Stage Programs

For the three and nine months ended September 30, 2020, compared to the same periods in 2019, the decreases in spending associated with our late stage programs were primarily due to:

- a decrease in spending related to the discontinuation of the global Phase 3 trials of aducanumab, net of reimbursement from our collaboration partner Eisai in the first quarter of 2019;
- a decrease in spending related to the discontinuation of the global Phase 3 trials, MISSION AD1 and MISSION AD2, of elenbecestat (development code: E2609) in patients with early Alzheimer's disease in the third quarter of 2019; and

- a decrease in spending related to VUMERITY, which was approved by the FDA in the fourth quarter of 2019.

These decreases were partially offset by an increase in spending due to the advancement of toferson in ALS into late stage, an increase in spending related to BAN2401, a monoclonal antibody that targets amyloid beta aggregates, in early Alzheimer's disease that we are developing in collaboration with Eisai, our EMBARK redosing study for aducanumab and BIIB111 (timrepigene emparvovec) in choroideremia.

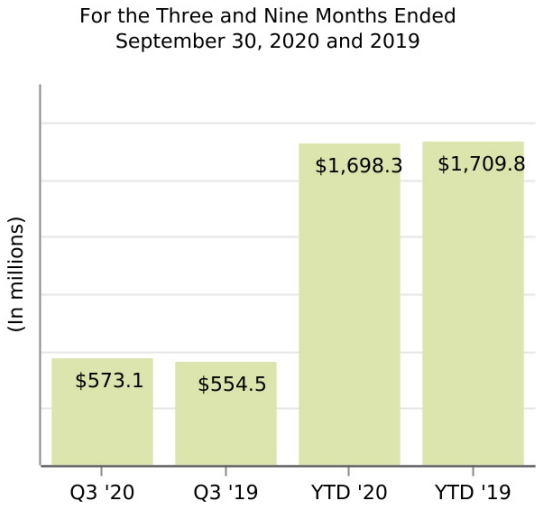
In the first quarter of 2019, as a result of the decision to discontinue the Phase 3 EMERGE and ENGAGE trials following a futility analysis, we accrued approximately $45.0 million related to the termination of various clinical trials and research and development contracts net of the expected 45% Eisai reimbursement of development costs incurred by the collaboration for the advancement of aducanumab.

In October 2019 we and Eisai announced that, based on a new analysis, conducted by Biogen in consultation with the FDA, of a larger dataset from the Phase 3 EMERGE and ENGAGE trials that were discontinued in March 2019, we plan to pursue regulatory approval for aducanumab in the U.S. In July 2020 we completed the submission of a BLA to the FDA for the approval of aducanumab.

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

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

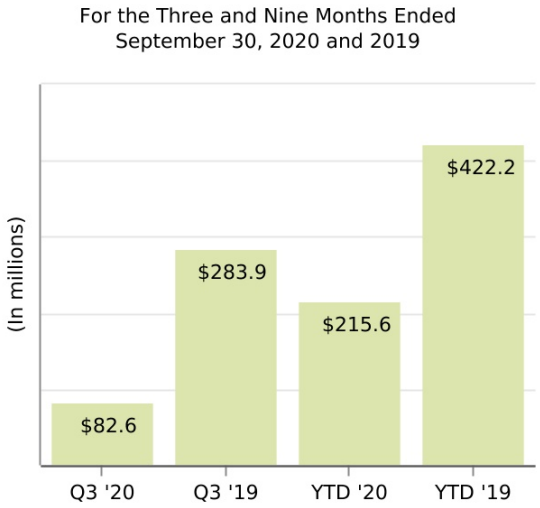
Selling, General and Administrative



For the three months ended September 30, 2020, compared to the same period in 2019, selling, general and administrative expense increased 3.4%, primarily due to increases in personnel in support of the potential launch of aducanumab.

For the nine months ended September 30, 2020, compared to the same period in 2019, selling, general and administrative expense remained flat.

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, VUMERITY and TECFIDERA (rest of world) products and other programs acquired through business combinations.

For the three and nine months ended September 30, 2020, amortization and impairment of acquired intangible assets reflects the impact of a $19.3 million impairment charge related to one of our in-process research and development (IPR&D) intangible assets.

For the three and nine months ended September 30, 2019, amortization and impairment of acquired intangible assets 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 IPF, which was discontinued in the third quarter of 2019.

For the three and nine months ended September 30, 2020, amortization of acquired intangible assets, excluding impairment charges, totaled $63.3 million and $196.3 million, respectively, compared to $68.0 million and $206.3 million, respectively, in the prior year comparative periods.

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.

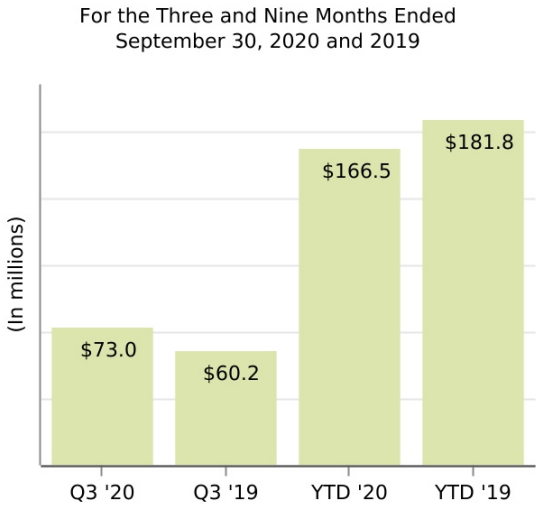
Overall, the value of our acquired IPR&D assets is dependent upon several variables, including estimates of future revenues and the effects of competition, our ability to secure sufficient pricing in a competitive market, our ability to confirm safety and efficacy based on data from clinical trials and regulatory feedback, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from one clinical trial phase to the next. We are continually reevaluating our estimates concerning these and other variables, including our life cycle management strategies, 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 programs may result in a significant change to our valuation of our IPR&D assets.

Vixotrigine

In the periods since we acquired vixotrigine (BIIB074), there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of trigeminal neuralgia (TGN) as we engaged with the FDA regarding the design of the Phase 3 studies and awaited data and insights from mid-stage clinical trials of vixotrigine in other indications that have since been completed. The fair value of the TGN asset is not significantly in excess of carrying value. As of September 30, 2020, the carrying value associated with our vixotrigine IPR&D assets was $167.6 million.

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

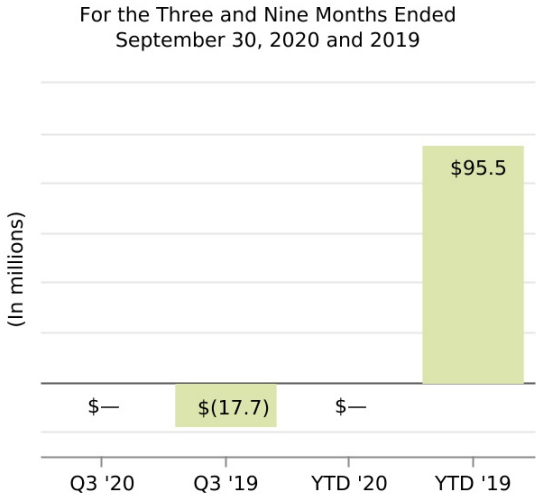
For the three and nine months ended September 30, 2020, we recognized net profit-sharing expense of $72.9 million and $200.1 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits compared to $60.1 million and

$181.6 million, respectively, in the prior year comparative periods.

For the nine months ended September 30, 2020, we also recognized net profit-sharing income of $33.8 million to reflect Eisai's 45% share of the $75.0 million milestone expense related to the completed submission of the BLA to the FDA for approval of aducanumab.

For additional information on our collaboration arrangements with Samsung Bioepis and Eisai, 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

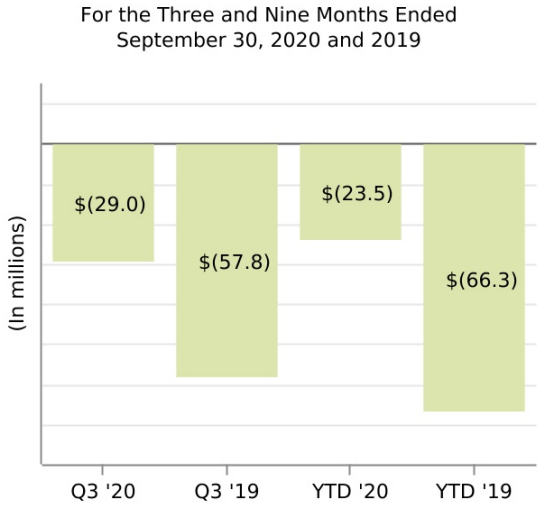


In March 2019 we entered into a share purchase agreement with FUJIFILM to sell all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark. The transaction closed in August 2019.

For the nine months ended September 30, 2019, we recorded a loss of approximately $160.2 million in our condensed consolidated statements of income. This estimated loss included a pre-tax loss of $95.5 million, which reflected a $17.7 million decrease to our previously recorded pre-tax loss, reflecting our estimated fair value of the assets and liabilities held for sale as of September 30, 2019, adjusted for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately $11.2 million and included our initial 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. In addition, we recorded a tax expense of $64.7 million related to the transaction during the nine months ended September 30, 2019.

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

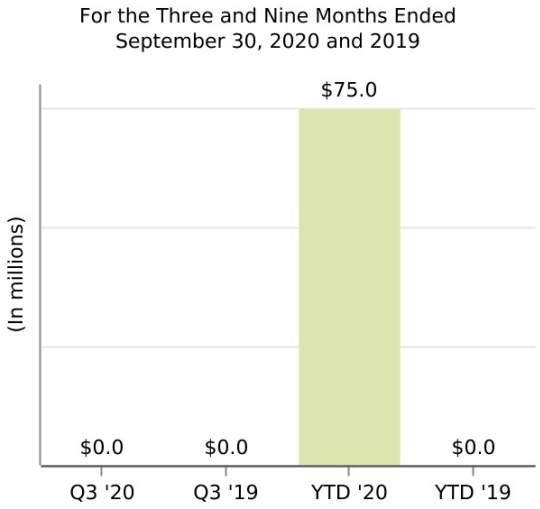


Consideration payable for certain of our business combinations includes future payments that are contingent upon the occurrence of a particular event or events. We record an obligation for such contingent consideration payments at fair value on the acquisition date. We then revalue our contingent consideration 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, 2020, changes in the fair value of our contingent consideration obligations were primarily due to changes in the probability and the expected timing of the achievement of certain remaining developmental milestones as well as changes in the interest rates used to revalue our contingent consideration liabilities and the passage of time.

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.

Acquired In-Process Research and Development

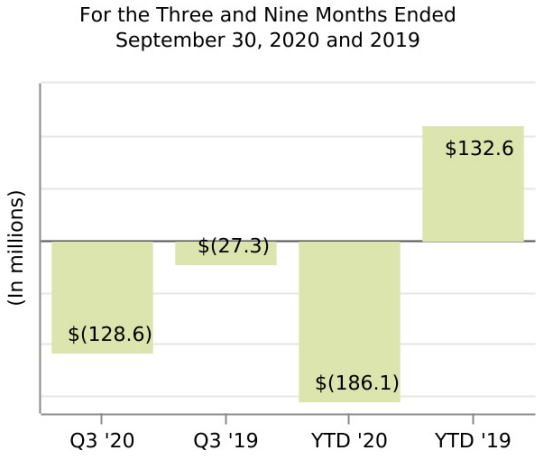


BIIB118 Acquisition

In March 2020 we acquired BIIB118 from Pfizer for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases. In connection with this acquisition, we made an upfront payment of $75.0 million to Pfizer, which was accounted for as an asset acquisition and recorded as acquired IPR&D in our condensed consolidated statements of income as BIIB118 has not yet reached technological feasibility.

For additional information on our acquisition of BIIB118, please read *Note 2, Acquisitions,* to our condensed consolidated financial statements included in this report.

Other Income (Expense), Net



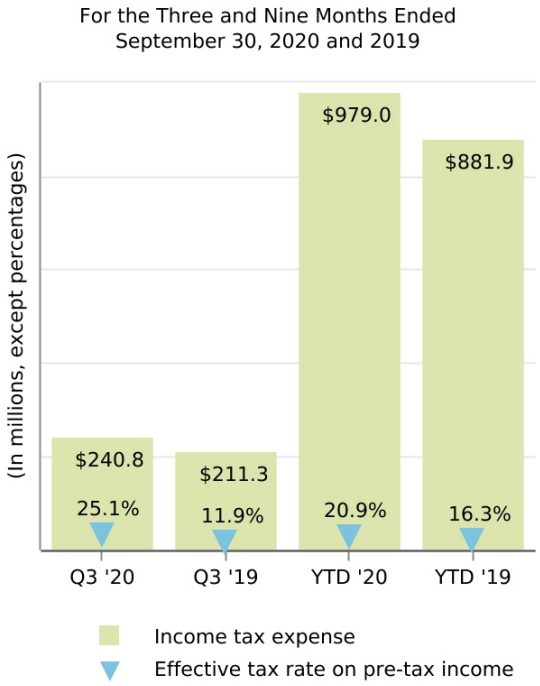
For the three months ended September 30, 2020, compared to the same period in 2019, the change in other income (expense), net primarily

reflects net unrealized losses of approximately $82.1 million recognized on our investments related to our holdings in equity securities, compared to net unrealized losses totaling $4.1 million in the prior year comparative period. The net unrealized losses recognized during the three months ended September 30, 2020, primarily reflect a decrease in the fair value of Ionis common stock of approximately $66.2 million and a decrease in the fair value of Denali common stock of approximately $29.6 million, partially offset by an increase in the fair value of Sangamo common stock of approximately $15.2 million.

For the nine months ended September 30, 2020, compared to the same period in 2019, the change in other income (expense), net primarily reflects net unrealized losses of approximately $40.3 million recognized on our investments related to our holdings in equity securities, compared to net unrealized gains totaling $198.9 million in the prior year comparative period. The net unrealized losses recognized during the nine months ended September 30, 2020, primarily reflect a decrease in the fair value of Ionis common stock of approximately $56.7 million and a decrease in the fair value of Denali common stock of approximately $29.6 million, partially offset by an increase in the fair value of Sangamo common stock of approximately $56.1 million.

We expect interest expense will continue to increase as a result of the issuance of our senior unsecured notes for an aggregate principal amount of $3.0 billion (2020 Senior Notes). For additional information on our 2020 Senior Notes, please read *Note 11, Indebtedness,* to our condensed consolidated financial statements included in this report.

Income Tax Provision



Our effective tax rate fluctuates from year to year due to the global nature of our operations. The factors that most significantly impact our effective tax rate include 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, 2020, compared to the same period in 2019, the increase in our effective tax rate was primarily due to an internal reorganization of certain intellectual property rights related to the intercompany sale of such intellectual property in 2019, the enactment of a new taxing regime in the country and certain cantons of Switzerland in 2019 (Swiss Tax Reform) and the net $33.3 million income tax expense related to the establishment of a valuation allowance against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S.

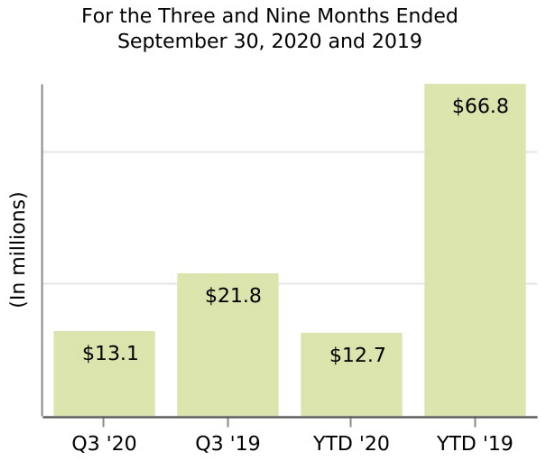
For additional information, please read *Note 19, Litigation,* to our condensed consolidated financial statements included in this report.

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in our effective tax rate was primarily due to the $89.3 million impact from the valuation allowance described above, the internal reorganization of certain intellectual property rights and Swiss Tax Reform,

partially offset by the $64.7 million tax expense recognized in September 30, 2019, related to the divestiture of our Hillerød, Denmark manufacturing operations. Although we recognized a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture required us to write off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions. 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 income taxes please read *Note 15, Income Taxes,* to our condensed consolidated financial statements included in this report.

Equity in (Income) Loss of Investee, Net of Tax



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

In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5.0% 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, 2020, our ownership percentage remained at approximately 49.9%.

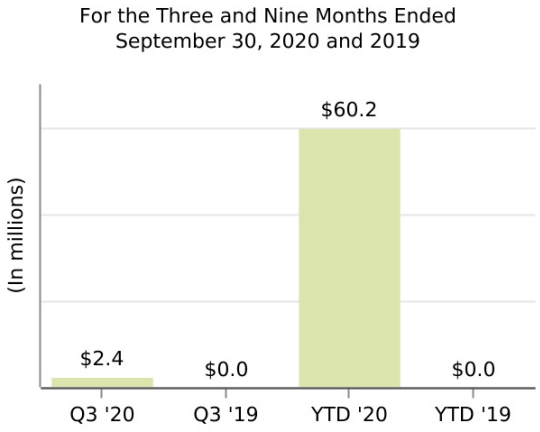
We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in (income) loss of investee, net of tax in our condensed consolidated statements of income. During 2015, as our share of losses exceeded the carrying value of our 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, 2020, we recognized net losses on our investment of $13.1 million and $12.7 million, respectively, reflecting our share of Samsung Bioepis' operating results and amortization of basis differences.

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

Noncontrolling Interest



For the three and nine months ended September 30, 2020, the change in net income (loss) attributable to noncontrolling interests, net of tax was primarily due to the $75.0 million milestone payment related to the completed submission of the BLA to the FDA for the approval of aducanumab.

For additional information, please read *Note 18, Investments in Variable Interest Entities,* 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, 2020	As of December 31, 2019	Change %
Financial assets:			
Cash and cash equivalents	$ 2,224.8	$ 2,913.7	(23.6)%
Marketable securities — current	1,355.0	1,562.2	(13.3)
Marketable securities — non-current	1,009.8	1,408.1	(28.3)
Total cash, cash equivalents and marketable securities	$ 4,589.6	$ 5,884.0	(22.0)%
Borrowings:			
Current portion of notes payable	$ —	$ 1,495.8	(100.0)%
Notes payable	7,425.0	4,459.0	66.5
Total borrowings	$ 7,425.0	$ 5,954.8	24.7 %
Working capital:			
Current assets	$ 7,843.1	$ 8,381.8	(6.4)%
Current liabilities	(3,804.0)	(4,863.8)	(21.8)
Total working capital	$ 4,039.1	$ 3,518.0	14.8 %

For the nine months ended September 30, 2020, certain significant cash flows were as follows:

- $6.3 billion used for share repurchases;
- $4.6 billion in net cash flows provided by operating activities;
- $3.0 billion in net proceeds received from the issuance of our 2020 Senior Notes;
- $1.5 billion payment made for the redemption of our 2.90% Senior Notes due September 15, 2020, prior to their maturity;
- $752.7 million in total payments for income taxes;
- $423.7 million used to purchase the Denali common stock;
- $338.8 million used for purchases of property, plant and equipment;
- $141.8 million used to purchase the Sangamo common stock;
- $75.0 million milestone payment to Neurimmune SubOne AG (Neurimmune);
- $75.0 million payment related to our acquisition of BIIB118 from Pfizer; and
- $37.0 million payment to Samsung Bioepis in connection with the 2019 transaction.

Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. On April 30, 2020, we issued our 2020 Senior Notes for an aggregate principal amount of $3.0 billion. We expect our operating expenditures, particularly those related to research and development, clinical trials, commercialization of new products and international expansion to continue to grow. However, we expect to continue funding our current and planned operating requirements primarily through cash flows earned from our operations as well as our existing cash resources and proceeds received from the issuance of our 2020 Senior Notes. Generic competition for TECFIDERA in the U.S. has begun and we believe that this competition will reduce our cash flow from operations in 2020 and will have a significant adverse impact on our future cash flows from operations. 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.

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. In March 2020 there was a severe liquidity crisis in the capital markets, particularly with respect to securities with maturities of less than one year, due to the COVID-19 pandemic. This issue impacted pricing of securities in our portfolio as we attempted to decrease our marketable securities level and increase cash, leading to approximately $12.4 million in realized losses for the nine months ended September 30, 2020. We believe that recent actions taken by the U.S. Federal Reserve to enhance liquidity have stabilized the capital markets for the time being.

As of September 30, 2020, we had cash, cash equivalents and marketable securities totaling approximately $4.6 billion compared to approximately $5.9 billion as of December 31, 2019. The net decrease in cash, cash equivalents and marketable securities at September 30, 2020, from December 31, 2019, was primarily due to cash used for share repurchases, the redemption of our 2.90% Senior Notes due September 15, 2020, the purchases of Sangamo and Denali common stock, net purchases of property, plant and equipment and payments made to Neurimmune, Pfizer and Samsung Bioepis, partially offset by cash flows from operations and net proceeds from the issuance of our 2020 Senior Notes.

Investments and other assets in our condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, include the carrying value of our investment in Samsung Bioepis of $557.8 million and $580.2 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. This investment is also subject to foreign currency exchange fluctuations. Investments and other assets, as of September 30, 2020 and December 31, 2019, also include the fair value of our investment in Ionis common stock of $272.9 million and $329.6 million, respectively.

In connection with our collaboration and license agreement with Sangamo, we purchased approximately 24 million shares of Sangamo common stock in April 2020. As of September 30, 2020, the fair value of this investment was $197.9 million. In connection with our collaboration with Denali, we purchased approximately 13 million shares of Denali common stock in September 2020. As of September 30, 2020, the fair value of this investment was $394.1 million.

For additional information on our acquisition of BIIB118 from Pfizer, please read *Note 2, Acquisitions,* to our condensed consolidated financial statements included in this report. For additional information on our collaboration arrangements with Samsung Bioepis, Sangamo and Denali, please read *Note 17, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Borrowings

In April 2020 we issued our 2020 Senior Notes for an aggregate principal amount of $3.0 billion, consisting of the following:

- $1.5 billion aggregate principal amount of 2.25% Senior Notes due May 1, 2030; and
- $1.5 billion aggregate principal amount of 3.15% Senior Notes due May 1, 2050.

The following is a summary of our currently outstanding senior secured notes issued in 2015 (2015 Senior Notes):

- $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.

Our 2020 Senior Notes and our 2015 Senior Notes were issued at a discount, which are amortized as additional interest expense over the period from issuance through maturity.

In May 2020 we redeemed our 2.90% Senior Notes due September 15, 2020, with an aggregate principal amount of $1.5 billion.

For a summary of the fair and carrying values of our outstanding borrowings as of September 30, 2020 and December 31, 2019, please read *Note 7, Fair Value Measurements,* to our condensed consolidated financial statements included in this report.

2020 Credit Facility

In January 2020 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. This revolving credit facility replaced the revolving credit facility that we entered into in August 2015. As of September 30, 2020, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Working Capital

Working capital is defined as current assets less current liabilities. The change in working capital at September 30, 2020, from December 31, 2019, reflects a decrease in total current assets of approximately $538.7 million and a decrease in total current liabilities of approximately $1.1 billion.

The decrease in total current assets was primarily driven by a decrease in net cash, cash equivalents and marketable securities, due to the purchase of Sangamo common stock for $225.0 million, the purchase of Denali common stock for $465.0 million and $6.3 billion in purchases of our common stock, partially offset by $4.6 billion in cash flows from operations.

The net decrease in current liabilities was primarily due to the redemption of our 2.90% Senior Notes due September 15, 2020, which were classified within current liabilities as of December 31, 2019, and a reduction in accrued expenses and other, which was primarily related to the $100.0 million upfront payment made to Samsung Bioepis in connection with the 2019 transaction, which was accrued as of December 31, 2019.

Share Repurchase Programs

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired.

In December 2019 our Board of Directors authorized our December 2019 Share Repurchase Program, which was a program to repurchase up to $5.0 billion of our common stock that was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 4.5 million and 16.7 million shares of our common stock at a cost of approximately $1.3 billion and $5.0 billion during the three and nine months ended September 30, 2020, respectively.

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program) that was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million shares of our common stock at a cost of approximately $1.3 billion during the nine months ended September 30, 2020.

Cash Flows

The following table summarizes our cash flow activity:

	For the Nine Months Ended September 30,		
(In millions, except percentages)	**2020**	**2019**	**% Change**
Net cash flows provided by operating activities	$ 4,596.9	$ 5,118.4	(10.2)%
Net cash flows used in investing activities	(442.2)	(237.9)	85.9
Net cash flows used in financing activities	(4,871.6)	(3,744.0)	30.1

Operating Activities

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

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

- non-cash operating items such as depreciation and amortization, impairment charges, 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, 2020, compared to the same period in 2019, the decrease in net cash flows provided by operating activities was primarily due to lower net income as well as increases in certain working capital asset balances.

Investing Activities

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in net cash flows used in investing activities was primarily due to the purchases of the common stock of Sangamo and Denali during 2020, partially offset by higher proceeds received from the sale of investments as compared to the prior year.

Financing Activities

For the nine months ended September 30, 2020, compared to the same period in 2019, the increase in net cash flows used in financing activities was primarily due to the greater number of shares repurchased in 2020 as compared to the comparative period in 2019 and the redemption of our 2.90% Senior Notes due September 15, 2020, partially offset by the net proceeds received from the issuance of our 2020 Senior Notes.

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, 2019.

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 18.0% on annual worldwide net sales up to $2.0 billion and 25.0% 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 11.0% and 15.0%, 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 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

VUMERITY

In October 2019 the FDA approved VUMERITY for the treatment of RMS. Under our agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), we make royalty payments to Alkermes on worldwide net commercial sales of VUMERITY using a royalty rate of 15.0%, which are recorded as cost of sales in our consolidated statements of income. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval. For additional information on our collaboration arrangement with Alkermes, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2019 Form 10-K.

Contingent Consideration related to Business Combinations

In connection with our acquisitions of Convergence Pharmaceuticals Ltd. and Biogen International Neuroscience GmbH, we agreed to make additional payments based upon the achievement of certain milestone events. 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 $735.0 million in remaining milestones related to these acquisitions.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of September 30, 2020, we could trigger potential future

milestone payments to third parties of up to approximately $8.9 billion, including approximately $1.7 billion in development milestones, approximately $1.3 billion in regulatory milestones and approximately $5.9 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, 2020, 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 or commercial milestones.

Provided various development, regulatory or commercial milestones are achieved, we anticipate that we may pay approximately $4.0 million of milestone payments for the remainder of 2020. We may also pay $100.0 million if aducanumab is launched in the U.S. In July 2020 we completed the submission of a BLA to the FDA for the approval of aducanumab. During the third quarter of 2020, we paid Neurimmune SubOne AG (Neurimmune) $75.0 million upon the completed submission of the BLA for aducanumab with the FDA, which was recognized as a charge to noncontrolling interests for the nine months ended September 30, 2020. In addition, for the nine months ended September 30, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45% share of the $75.0 million milestone expense.

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.

For additional information on our collaboration arrangement with Neurimmune, please read *Note 18, Investments in Variable Interest Entities,* to our condensed consolidated financial statements included in this report.

Other Funding Commitments

As of September 30, 2020, 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 $3.5 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of September 30, 2020. We have approximately $557.8 million in cancellable future commitments based on existing CRO contracts as of September 30, 2020.

As part of the sale of our Hillerød, Denmark manufacturing operations to FUJIFILM, we provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Our estimate of the adverse commitment obligation is approximately $74.0 million as of September 30, 2020. We developed this estimate using a probability-weighted estimate of future manufacturing activity and may adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods.

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, 2020, we have approximately $154.8 million of liabilities associated with uncertain tax positions.

As of September 30, 2020 and December 31, 2019, included in other long-term liabilities we have accrued approximately $635.0 million and approximately $697.0 million, respectively, under a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). The decrease of approximately $62.0 million between September 30, 2020 and December 31, 2019, is related to the amount that is expected to be paid within one year. 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,* 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.

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 2019 Form 10-K. There have been no material changes to our critical accounting estimates since our 2019 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 and pricing pressures worldwide as well as changes in economic conditions in the markets in which we operate as a result of the COVID-19 pandemic. 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, including the impact of the COVID-19 pandemic. As a result, our 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, 2020, 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 24 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, 2020 and December 31, 2019, 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 $394.6 million and $265.0 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 our approximately 49.9% ownership percentage in Samsung Bioepis. 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, 2020 and December 31, 2019, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $42.8 million and $43.0 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, including changes resulting from the impact of the COVID-19 pandemic. 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, 2020 and December 31, 2019, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $16.6 million and $21.0 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 December 31, 2019, a 100 basis-point adverse movement (increase in LIBOR) would increase annual interest expense by approximately $6.8 million. In May 2020 we settled our interest rate swap contracts in conjunction with our early redemption of our 2.90% Senior Notes.

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 consolidated 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, impose restrictions on the coverage of certain drugs.

Our products continue to face increasing competition in many markets from generic versions, prodrugs and biosimilars of existing products as well as products approved under abbreviated regulatory pathways. Such products 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 are able to charge for our products and the volume of products we sell, which will negatively impact our revenues. In addition, when a generic version of one of our products is commercialized, it may, in some cases, be automatically substituted for our product and reduce our revenues in a short period of time.

Multiple TECFIDERA generic entrants are now in the U.S. market, some of which have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the third quarter of 2020 and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

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, including as a result of the COVID-19 pandemic, 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.

We believe that our allowance for doubtful accounts was adequate as of September 30, 2020 and December 31, 2019. 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, 2020. 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, 2020, 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, 2020, please read *Note 19, Litigation,* to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

Item 1A. Risk Factors

We are substantially dependent on revenues from our 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 and in markets affected directly and indirectly by the COVID-19 pandemic. 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:

- the introduction or greater acceptance of competing products, including generics, prodrugs, biosimilars and products approved under abbreviated regulatory pathways;
- safety or efficacy issues;
- limitations and additional pressures on product pricing or price increases, including those resulting from governmental or regulatory requirements, increased competition, including from the introduction of generic or biosimilar versions of our products, or changes in, or implementation of, reimbursement policies and practices of payors and other third parties;
- adverse legal, administrative, regulatory or legislative developments;
- our ability to maintain a positive reputation among patients, healthcare providers and others, which may be impacted by our pricing and reimbursement decisions; or
- the inability or reluctance of patients to receive a diagnosis, prescription or administration of our products or a decision to prescribe and administer competitive therapies as a direct or indirect result of the COVID-19 pandemic.

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:

- the introduction of a new gene therapy product that was approved in the U.S. in May 2019 and in the E.U. in May 2020 for the treatment of SMA as well as a new oral product for the treatment of SMA that was approved in the U.S. in August 2020 and the launch of other products now in development that may compete with SPINRAZA;
- the delay of SPINRAZA doses due, directly or indirectly, to the COVID-19 pandemic;
- the lack of readiness of healthcare providers within certain SMA markets to treat patients with SMA; or
- our limited marketing experience within certain SMA markets, which may impact our ability to develop additional relationships with the associated medical and scientific community.

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, including our long-term viability and growth, 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 afforded to our products and processes in the U.S. and in other important markets remains uncertain and depends, in part, upon decisions of 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.

We also rely on regulatory data and market exclusivity for protection of our products. Implementation and enforcement of regulatory exclusivity 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 could affect our decision on whether to market our products in particular countries or could otherwise have an adverse impact on our revenues and results of operations.

In many markets, including the U.S., manufacturers may be allowed to rely on the safety and efficacy data of the innovator's product and not need to conduct clinical trials before marketing a competing version of a product after there is no longer patent or regulatory exclusivity. In such cases, manufacturers often charge significantly lower prices and, a major portion of the company's revenues may be reduced in a short period of time. 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.

Litigation, interferences, oppositions, *inter partes* reviews, administrative challenges or other similar types of proceedings are and may in the future be necessary in some instances to determine the validity and scope of certain of our patents, regulatory exclusivities or other 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 also face challenges to our patent and regulatory protections covering our products and processes 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 are often protracted, expensive and distracting to management. Negative outcomes of such proceedings adversely affect the validity and scope of our patent or other proprietary rights. Settlements of these proceedings often result in reducing the period of patent and other protections, accelerating reduction in revenue from affected products. Adverse outcomes in intellectual property litigation and proceedings also could 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.

The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.

Our business could be materially adversely affected, directly or indirectly, by the widespread outbreak of contagious disease, including the ongoing COVID-19 pandemic, which has spread to many of the countries in which we, our customers, our suppliers and our collaboration partners do business. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. We, other organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work. These measures are disrupting and may disrupt normal business operations both in and outside of affected areas and have significant negative impacts on businesses and financial markets worldwide.

We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic. In the U.S. and in most other key markets, our office-based employees began working from home in early March 2020, while ensuring essential staffing levels in our operations remained in place, including maintaining key personnel in our laboratories and manufacturing facilities, and many may continue to work remotely for an indefinite period of time. Prolonged remote working arrangements could impact employees' productivity and morale. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses, employee productivity and employee work culture.

Notwithstanding the protective measures we have taken to ensure the health and safety of our workers, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on taking similar measures. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able

to execute on our business strategy and/or our operations may be negatively impacted. We may also experience limitations in employee resources, including because of sickness of employees or their families or the desire of employees to avoid contact with individuals or large groups of people. In addition, we have experienced and will continue to experience disruptions to our business operations resulting from quarantines, self-isolations and other restrictions on the ability of our employees to perform their jobs.

Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment. Remote working environments may be less secure and more susceptible to hacking attacks, including phishing and social engineering attempts that seek to exploit the COVID-19 pandemic. An extended period of remote working by our employees could also strain our technology resources and introduce operational risks, including heightened cybersecurity risk.

The extent and severity of the impact of the COVID-19 pandemic on our business and clinical trials will be determined largely by the extent of disruptions in the supply chains for our products and product candidates; disruptions in access by patients to our therapies; and delays in the conduct of current and future clinical trials. For example, our Phase 3 study of BIIB093 for large hemispheric infarction has been delayed as this study involves administration of BIIB093 in an acute hospital setting. In addition, the impact of the COVID-19 pandemic on the operations of the FDA and other health authorities may delay potential approvals of our product candidates. We may also see lower new prescriptions or refills of existing prescriptions due to increased unemployment as a result of the COVID-19 pandemic.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business, operations, employees, customers, suppliers or our collaboration partners, continued spread of COVID-19, measures taken by governments, actions taken to protect employees and the broad impact of the pandemic on all business activities may materially and adversely affect our business, results of operations and financial condition.

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.

We may be required to delay the development of a product candidate or delay ongoing clinical trials as a direct or indirect result of the COVID-19 pandemic. For example, our Phase 3 study of BIIB093 for large hemispheric infarction has been delayed as this study involves administration of BIIB093 in an acute hospital setting.

We may fail to successfully obtain or preserve patent protection for the technologies incorporated into our product candidates 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. The degree of patent protection afforded to our product candidates and processes in the U.S. and in other important markets remains uncertain and depends, in part, upon decisions of the patent offices, courts, administrative bodies and lawmakers in these

countries. Furthermore, one or more of our competitors may receive patent protection that dominates, blocks or adversely affects our product development or business.

Even if we could 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 the standard of care or 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, 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. In addition, as a result of the COVID-19 pandemic, we have suspended the vast majority of our in-person interactions by our customer-facing professionals in healthcare settings, which will limit our ability to market our products and educate physicians, which, in turn, could have an adverse effect on our ability to compete in the marketing and sales of our products. Further, our ability to compete may be impacted by the inability or reluctance of patients to receive a diagnosis, prescription or administration of our products or a decision to prescribe and administer competitive therapies as a direct or indirect result of the COVID-19 pandemic.

Our products continue to face increasing competition in many markets from the introduction of generics, prodrugs and biosimilars of existing products as well as products approved under abbreviated regulatory pathways. Such products 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 are able to charge for our products and the volume of products we sell, which will negatively impact our revenues. In addition, when a generic version of one of our products is commercialized, it may, in some cases, be automatically substituted for our product and reduce our revenues in a short period of time.

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 could 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 generic versions of branded MS products, including our own products, biosimilars, follow-on products, prodrugs or products approved under 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 generic versions of branded MS products, biosimilars, follow-on products, prodrugs or products approved under 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, generic or biosimilars of our MS products or any other product from the same class as one of our 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 new gene therapy product that was approved in the U.S. in May 2019 and in the E.U. in May 2020 for the treatment of SMA as well as a new oral product for the treatment of SMA that was approved in the U.S. in August 2020. Additionally, we are aware of other products now in development that,

if launched, may compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products. In addition, future sales of SPINRAZA may also be adversely affected by the delay of SPINRAZA doses due, directly or indirectly, to the COVID-19 pandemic.

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. We have in the past made, and may continue to make, significant operating and capital expenditures for potential new products in our pipeline prior to regulatory approval with no assurance that such investment will be recouped, which may adversely affect our financial condition, business and operations.

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.

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 candidate 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.

Our ability to continue our existing clinical trials or to initiate new clinical trials may be adversely affected, directly or indirectly, by the COVID-19 pandemic. For example, our Phase 3 study of BIIB093 for large hemispheric infarction has been delayed as this study involves administration of BIIB093 in an acute hospital setting. We have open clinical trial sites in countries that have had high incident rates of COVID-19 patients. Restrictions on travel and/or transport of clinical materials, as well as diversion of hospital staff and resources to COVID-19 infected patients, could disrupt trial operations as well as recruitment, possibly resulting in a slowdown in enrollment and/or deviations from or disruptions in key clinical trial activities, such as clinical trial site monitoring. These challenges may lead to difficulties in meeting protocol-specified procedures. In addition, we may need to make certain adjustments to the operation of clinical trials in an effort to minimize risks to trial data integrity during the COVID-19 pandemic.

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, generic or biosimilar versions of our marketed products or any other products from the same class as one of our 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 (PML) 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.

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, 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.

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. Additionally, the introduction of generic versions of our products, biosimilars, follow-on products, prodrugs or products approved under abbreviated regulatory pathways, may significantly reduce both the price that we are able to charge for our products and the volume of products we sell.

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.

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. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that most of our office-based employees in the U.S. and our other key markets work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies, including Software as a Service (SaaS), Platform as a Service (PaaS) and Infrastructure as a Service (IaaS). A breakdown, invasion, corruption, destruction or breach of our technology systems, including the cloud technologies that we utilize, 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, including the cloud technologies that we utilize, 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, including the cloud technologies that we utilize, 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. In addition, our increased use of cloud technologies could heighten these and other operational risks, and any failure by cloud technology service providers to adequately safeguard their systems and prevent cyber-attacks could disrupt our operations and result in misappropriation, corruption or loss of confidential or propriety information.

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.

In addition, regulators globally are imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the E.U.’s General Data Protection Regulation, which became effective in 2018, established regulations regarding the handling of personal data, and provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20.0 million or 4% of the annual global revenues of the infringer, whichever is greater. In addition, new U.S. data privacy and security laws, such as the California Consumer Privacy Act (CCPA) that became effective in January 2020, and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with CCPA may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Failure to comply with these current and future laws could result in significant penalties and could have a material adverse effect on our business and results of operations.

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;
- delays and disruptions experienced by our collaborators, joint venture partners or third parties due to the COVID-19 pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect product sales or the clinical development or regulatory approvals of product candidates under joint control;
- 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 product candidates 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, regulatory requirements and/or applicable contractual obligations 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, impact the accuracy and timing of our financial reporting and/or 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, 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.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law in the U.S. in March 2020. The CARES Act is aimed at providing emergency assistance and health care for individuals, families and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. Due to the recent enactment of the CARES Act, there is a high degree of uncertainty around its implementation. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures. The COVID-19 pandemic may introduce temporary or permanent healthcare reform measures for which we cannot predict the financial implication of on our business.

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. In addition, 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. Further, if members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted.

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, recruitment by competitors or delays in the recruiting and hiring process as a result of the COVID-19 pandemic. 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.

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 as well as our compliance with good practice quality guidelines and regulations. 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;
- government regulations that may be imposed in response to the COVID-19 pandemic may restrict the movement of our global supply chain, divert hospital resources that are necessary to administer certain of our products and/or delay the review of product candidates;
- 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:

- the impact of public health epidemics, such as the COVID-19 pandemic, on employees, the global economy and the delivery of healthcare treatments;
- less favorable intellectual property or other applicable laws;

- the introduction or greater acceptance of competing products, including generics, biosimilars, prodrugs and 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 departure 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 U.S. 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.

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, in order to support our future growth and drug development pipeline, we are expanding 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. We expect the Solothurn manufacturing facility to be partially operational during the first half of 2021; however, there can be no assurance that we will be able to meet our expected timeline or that there will not be any direct or indirect delays resulting from the COVID-19 pandemic. We have had delays, and if there are additional delays, in bringing the Solothurn manufacturing facility online, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.

In addition, we have made 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, including the impact of the COVID-19 pandemic. 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, public health epidemics, natural disasters, power failures, cyber-attacks and numerous other factors. In addition, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which we expect to be partially operational during the first half of 2021. However, there can be no assurance that we will be able to meet our expected timeline or that there will not be any direct or indirect delays resulting from the COVID-19 pandemic. We have had delays, and if there are additional delays, in bringing the Solothurn manufacturing facility online, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.
- *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.
- *Risk Relating to Government Actions*. We and/or our third-party providers may be required by the U.S. federal government to manufacture medical supplies needed to treat COVID-19 patients under the Defense Production Act or other acts or orders of government entities, which may result in delays in the manufacturing and supply of our products.

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, including as a result of the COVID-19 pandemic, 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. In addition, as a result of the COVID-19 pandemic, we have suspended the vast majority of our in-person interactions by our customer-facing professionals in healthcare settings, which will limit our ability to market our products and educate physicians, which, in turn, could have an adverse effect on our ability to compete in the marketing and sales of our products; 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 that 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, divestitures and other business development activities;
- failure to meet certain contractual commitments, including, for example, the minimum batch production commitment guarantees we provided as part of the transaction with FUJIFILM; and
- the impact of public health epidemics, such as the COVID-19 pandemic, on employees, the global economy and the delivery of healthcare treatments.

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 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 and regulations either prospectively or retrospectively, including in response to the COVID-19 pandemic. 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 and collaborations to immediate U.S. taxation as global intangible low-taxed income (GILTI) or Subpart F income, and includes base erosion prevention measures on 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 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) resulted 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 became 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 accounted for the impact of the TRAF and the specific cantonal tax reform changes in the period in which each canton in which we operate enacted the cantonal tax reform. Zug, a canton in which we operate, enacted cantonal tax reform in the third quarter of 2019 and Solothurn, another canton in which we operate, enacted cantonal tax reform in the first quarter of 2020. Upon the enactment of 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. Final interpretation of the transitional and new regimes of the TRAF may require further adjustments and changes in our estimates, which could have a significant adverse effect on our business, results of operations or financial condition.

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 unfavorably 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. In addition, the COVID-19 pandemic could adversely affect the financial markets in some or all countries worldwide. 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 our 2020 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 2020 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 are experiencing, and have in the past experienced, extreme volatility and disruption, which leads to uncertainty and liquidity issues for both borrowers and investors. In the event of adverse capital and credit market conditions, we may be unable to obtain capital or credit market financing on favorable terms. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our cost of financing and the market price of our securities.

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 December 2019 Share Repurchase Program during the third quarter of 2020:

Period	Total Number of Shares Purchased (#)	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Programs (#)	Approximate Dollar Value of Shares That May Yet Be Purchased Under Our Programs ($ in millions)
July 2020	—	$ —	—	$ 1,250.0
August 2020	2,025,000	$ 283.69	2,025,000	$ 675.5
September 2020	2,458,413	$ 274.78	2,458,413	$ —
Total	4,483,413	$ 278.81		

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired.

In December 2019 our Board of Directors authorized our December 2019 Share Repurchase Program, which was a program to repurchase up to $5.0 billion of our common stock that was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 4.5 million and 16.7 million shares of our common stock at a cost of approximately $1.3 billion and $5.0 billion during the three and nine months ended September 30, 2020, respectively.

In March 2019 our Board of Directors authorized our March 2019 Share Repurchase Program, which was a program to repurchase up to $5.0 billion of our common stock that was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million shares of our common stock at a cost of approximately $1.3 billion during the nine months ended September 30, 2020.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1*+	Biogen Inc. Executive Severance Policy - U.S. Executive Vice President, as amended effective July 13, 2020.
10.2*+	Letter regarding employment arrangement of Michael McDonnell dated July 16, 2020.
10.3*+	Separation Agreement between Biogen Inc. and Jeffrey Capello dated July 16, 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, 2020, 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, 2020, 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/ Michael R. McDonnell
Michael R. McDonnell
Executive Vice President and
Chief Financial Officer
(principal financial officer)

October 21, 2020

Severance Plan for U.S. Executive Vice Presidents

As an Executive Vice President, you are entitled to severance benefits in the event your employment is terminated by Biogen other than For Cause or for reason of death or Disability (as these terms are defined in the Biogen Inc. 2017 Omnibus Equity Plan, as amended from time to time, or any successor plan there to ("OEP").

Benefits

Your severance benefits are comprised of (i) a lump sum payment (as calculated below), (ii) upon completion of the appropriate forms, continuation of your participation in Biogen's group medical and dental insurance plans, to the same extent permitted by COBRA and to the same extent such insurance is then provided to regular employees of Biogen, including payment by you of a portion of the insurance premiums (i.e., the "Insurance Benefit") and (iii) the reasonable cost of up to 12 months of executive-level outplacement services from a recognized provider of such services selected by Biogen, at the expense of Biogen (upon receipt of appropriate documentation). Except as otherwise prohibited by local law, any severance payments contemplated by this plan will be reduced by the number of weeks' pay corresponding to any periods during which the employee is not actively working, including statutory or contractual notice periods and any garden or other leave.

The lump sum severance payment is calculated as follows:

[12 + (A x 2)] x B = lump sum payment

where: A is the number of full years of service with Biogen (but A x 2 may not exceed 9), and B is the monthly equivalent of your target annual cash compensation at the time of your termination (i.e., one-twelfth of the sum of your then annual base salary plus target annual bonus).

The following are examples of how the lump sum payment and Insurance Benefit Period are determined:

If your employment with Biogen is terminated after 10 months of employment, you will receive a lump sum payment equal to 12 months of your target annual cash compensation and continue to participate in Biogen's group medical and dental plans for 12 months, unless you become eligible to participate in another employer's medical and dental plans before that date. COBRA continuation of medical and dental benefits is available, at your own expense, for an additional six months after this 12-month Insurance Benefit Period.

If your employment with Biogen is terminated after five years, you will receive a lump sum payment equal to 21 months [12+9] of your target annual cash compensation and continue to participate in Biogen's group medical and dental plans for 18 months, unless you become eligible to participate in another employer's medical and dental plans before that date.

If at any time within two years following a Corporate Transaction or Corporate Change in Control (as these terms are defined in Biogen's OEP) your employment is terminated by Biogen

or the succeeding corporate entity, other than For Cause or for reason of death or Disability (as these terms are defined in Biogen's OEP), or you experience an Involuntary Employment Action (defined below) and as a result you terminate your employment with Biogen or the succeeding corporate entity, then, regardless of the length of your service with Biogen and the succeeding corporate entity, and in lieu of the formula set forth above, you will receive a lump sum payment equivalent to 24 months of your target annual cash compensation at the time of your termination or at the time of a Corporate Transaction or Corporate Change in Control, whichever is higher. In addition, you will be entitled to continue participating in Biogen's group medical and dental plans for 24 months, unless you become eligible to participate in another employer's medical and dental plans before that date. The term "Involuntary Employment Action" shall have the definition set forth in Biogen's OEP, provided, however, that the term "Corporate Transaction" used in that definition shall be deemed to mean either a Corporate Transaction or Change in Control, as the case may be, and provided also that prior to your termination of employment you have notified the Chief Legal Counsel or the Head of Human Resources of Biogen in writing of the basis for your Involuntary Employment Action, you have given such notice within one year of the circumstances giving rise to your Involuntary Employment Action and Biogen does not cure such circumstances within 30 days after the date of your notice.

Delivery of Benefits

Payment and provision of all the benefits provided under this arrangement are conditioned on your execution and delivery of all necessary forms and an irrevocable general release in favor of Biogen, in form and substance reasonably acceptable to Biogen, with respect to any and all claims relating to your employment and the termination of your employment with Biogen. If you retire or voluntarily terminate your employment with Biogen, or Biogen terminates your employment For Cause or for reason of death or Disability (as these terms are defined in Biogen's OEP), or you do not provide the requisite general release, you will not be eligible to receive the severance benefits described above.

If all other conditions of this arrangement are met, a lump sum payment (less applicable taxes and other mandatory deductions as required by law) will be paid to you following the termination of your employment, no later than the first to occur of: a) 90 days following your termination of your employment with Biogen and b) March 15 of the year following the calendar year in which termination of employment occurs, unless you are a "specified employee" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (i.e., "Section 409A"). (If all preconditions to payment, including the delivery of an irrevocable general release, are not satisfied prior to the earlier of these two dates, payment to you may be delayed and you may incur additional tax liabilities under Section 409A.) If you are a "specified employee", to the extent required by Section 409A, payment will not be made to you before the date which is six months after you "separate from service" (or, if earlier, your date of death or Disability) unless the payment qualifies as excepted welfare benefits under Section 409A, does not constitute a "deferral of compensation" under Section 409A or is otherwise not subject to the requirements of Section 409A. Each payment made under this arrangement shall be treated as a separate payment and the right to receive a series of installment payments under this arrangement shall be treated as a right to a series of separate payments.

The Insurance Benefit will be paid on a monthly basis and will continue until the earlier of (i) the date you become eligible to participate in the medical and dental insurance plan of another employer or (ii) the date that is [12 + (A x 2)] months, but not more than 21 months (or 24 months in the case of a Corporate Transaction or Change in Control), following the termination of your employment with Biogen (the "Insurance Benefit Period"). You will have the right, at your own expense, to continue your participation in Biogen's group medical and dental insurance plans at the expiration of the Insurance Benefit Period, pursuant to the provisions of COBRA, but only for an 18-month period that will be deemed to have commenced at the start of your severance. You will only be entitled to receive the Insurance Benefit if you timely and properly elect continuation coverage under COBRA. If Biogen determines in its sole discretion that it cannot provide the Insurance Benefit without the possibility of violating applicable law (including, without limitation, the Patient Protection and Affordable Care Act) or it or you incurring additional taxes, including but not limited to under Section 105(h) of the Internal Revenue Code, Biogen will in lieu thereof provide to you a taxable monthly payment in an amount equal to the monthly COBRA premium that Biogen Idec would have otherwise paid under this arrangement in respect of the Insurance Benefit (which amount will be based on the premium for the first month of COBRA coverage) for the Insurance Benefit Period in equal installments in accordance with Biogen's normal payroll practices.

General

Biogen shall administer and shall have the discretionary authority to adopt rules for the management and operation of this arrangement, to interpret the provisions of the arrangement and to construe the terms of the severance arrangement in its sole discretion. The decision of Biogen, or the duly authorized delegate, is final and conclusive for all purposes.

The severance arrangement may be amended, modified, suspended or terminated by Biogen at any time; provided that the severance arrangement may not be amended or terminated without your written consent for a period of two years following a Corporate Transaction or a Change in Control.

This arrangement is unfunded. This arrangement will benefit and bind Biogen and its successors and permitted assigns and you and your heirs, executors and legal representatives. You do not have any right to transfer or assign your benefits under this arrangement.

This arrangement shall be construed, administered and enforced according to the laws of the State of Delaware, except to the extent that such laws are preempted by the federal laws of the United States of America.

Additional Summary Plan Description Information

Description	This document describes 3 Plan which is subject to the Employee Retirement Income Security Act of 1974 (ERISA). This document constitutes the Summary Plan Description (SPD) and Plan Document. Benefit determinations are controlled exclusively by this SPD and Plan Document.
Name of Plan	Severance Plan for U. S. Executive Vice Presidents
Name and Address of Employer	Biogen Inc. 225 Binney Street, Cambridge Massachusetts 02142
Plan Identification Number	Employer IRS Identification #: 04-3002117 Plan #: 523
Type of Welfare Plan	Severance
ERISA Plan Year Ends	December 31
Type of Administration	The Plan is administered by the Plan Administrator
Plan Administrator, Name, Address, and Telephone Number	Biogen Inc. is the Plan Administrator and named fiduciary of the Plan, with authority to delegate its duties. Biogen Inc. 225 Binney Street Cambridge, Massachusetts 02142 (617) 679-3400
Agent for Service of Legal Process on the Plan	Biogen Inc. 225 Binney Street Cambridge, Massachusetts 02142
Funding	This Plan is unfunded

Appeal Procedures	You have 180 days from your effective date of termination to file an appeal. Requests for appeals should be sent to the address specified in the claim denial. A decision on review will be made not later than 45 days following receipt of the written request for review. If the Plan Administrator determines that special circumstances require an extension of time for a decision on review, the review period may be extended by an additional 45 days (90 days in total). The Plan Administrator will notify you in writing if an additional 45 day extension is needed. If an extension is necessary due to your failure to submit the information necessary to decide the appeal, the notice of extension will specifically describe the required information, and you will be afforded at least 45 days to provide the specified information. If you deliver the requested information within the time specified, the 45 day extension of the appeal period will begin after you have provided that information. If you fail to deliver the requested information within the time specified, the Plan Administrator may decide your appeal without that information. You will have the opportunity to submit written comments, documents, or other information in support of your appeal. You will have access to all relevant documents as defined by applicable U.S. Department of Labor regulations. The review of the adverse benefit determination will take into account all new information, whether or not presented or available at the initial determination. No deference will be afforded to the initial determination. The review will be conducted by the Plan Administrator and will be made by a person different from the person who made the initial determination and such person will not be the original decision maker's subordinate. A notice that your request on appeal is denied will contain the following information: • The specific reason(s) for the determination; • A reference to the specific Plan provision(s) on which the determination is based; • A statement disclosing any internal rule, guidelines, protocol or similar criterion relied on in making the adverse determination (or a statement that such information will be provided free of charge upon request); • A statement describing your right to bring a lawsuit under Section 502(a) of ERISA if you disagree with the decision; • The statement that you are entitled to receive upon request, and without charge, reasonable access to or copies of all documents, records or other information relevant to the determination; and • The statement that "You or your plan may have other voluntary alternative dispute resolution options, such as mediation. One way to find out what may be available is to contact your local U.S. Department of Labor Office and your State insurance regulatory agency". Notice of the determination may be provided in written or electronic form. Electronic notices will be provided in a form that complies with any applicable legal requirements. Unless there are special circumstances, this administrative appeal process must be completed before you begin any legal action regarding your claim.

Your Rights Under ERISA	As a participant in this Plan, you are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA provides that all Plan participants shall be entitled to: • Receive Information About Your Plan and Benefits o Examine, without charge, at the Plan Administrator's office and at other specified locations, all documents governing the Plan, including a copy of the latest annual report (Form 5500 Series), if any, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration. o Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan, including copies of the latest annual report (Form 5500 Series), if any, and updated Summary Plan Description. o The Plan Administrator may make a reasonable charge for the copies. o Receive a summary of the Plan's annual financial report, if any. The Plan Administrator is required by law to furnish each participant with a copy of this summary annual report. • Prudent Actions by Plan Fiduciaries o In addition to creating rights for Plan participants, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate your Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Plan participants and beneficiaries. No one, including your Employer or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a benefit or exercising your rights under ERISA.

	• Enforce Your Rights o If your claim for a benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules. o Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan and do not receive them within 30 days, you may file suit in a federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator. o If you have a claim for benefits that is denied or ignored, in whole or in part, you may file suit in a state or federal court. If it should happen that Plan fiduciaries misuse the Plan's money, or if you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, if, for example, it finds your claim is frivolous. • Assistance with Your Questions o If you have any questions about your Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.
Other Rights	The Plan Administrator, as fiduciary for the Plan, is entitled to legal and equitable relief to enforce its right to recover any overpayments to you under this Plan. This right of recovery is enforceable but will not exceed the benefits paid you. You agree that the Plan Administrator has a lien over such sources of income until any overpayments have been recovered in full.

Discretionary Acts	The Plan Administrator has discretionary authority to interpret the Plan and to make benefit determinations under the Plan. The Plan Administrator may act directly or through its employees and agents or further delegate their authority through contracts, letters or other documentation or procedures to other affiliates, persons or entities. Once you are deemed to have exhausted your appeal rights under the Plan, you have the right to seek court review under Section 502(a) of ERISA of any benefit determinations with which you disagree. The court will determine the standard of review it will apply in evaluating those decisions.

Exhibit 10.2

July 15, 2020

Dear Michael,

I am pleased to extend you this offer of employment to join Biogen with the job title of Executive Vice President and Chief Financial Officer. This position will report to Michel Vounatsos, Chief Executive Officer. Please note that neither this letter nor any other materials constitute a contract of employment with Biogen. Your employment at Biogen is employment at-will. This means that just as you are free to leave your employment at any time, with or without cause or notice, Biogen also has the same right to terminate your employment at any time, with or without cause or notice. The specific offer terms are listed below.

The position will be based at our Cambridge, MA facility.

Salary: This is a full-time, exempt position and your starting annual salary will be $850,000.00, and which will be paid biweekly in accordance with our standard payroll processes.

Sign-on Bonus: Upon employment, you will receive $1,000,000.00 as a one-time cash bonus. The bonus will be paid to you within two pay periods after your start date provided that you sign the enclosed Cash Sign-On Bonus Agreement, which describes the terms and conditions of the cash sign-on bonus.

Annual Bonus Plan: You will be eligible to participate in the Biogen Annual Bonus Plan, with a target bonus opportunity of 75% your annual base salary. Based upon your start date, your target bonus amount may be pro-rated. Eligibility details and other terms of the Plan are included in the current year's Plan document, which will be made available upon your employment with the Company.

Long Term Incentive Plan: You will be provided a one-time grant of Restricted Stock Units (RSUs) and Market Stock Units (MSUs) in connection with the commencement of your employment. The approximate grant date value of your RSU award will be $2,250,000.00 and the approximate grant date value of your MSU award will be $2,250,000.00. The number of shares granted to you will be calculated by dividing the grant date value by the closing price of Biogen stock (NASDAQ) on the grant date, with the resulting number of shares rounded to the nearest five shares. Your RSU and MSU awards will be granted on the first trading day of the month following your start date. Both your RSU award and MSU awards will vest in three equal installments of 33 1/3% beginning on the first anniversary of the grant date. Your grant amount has been determined based upon the start date listed in this offer letter. If your start date is delayed, the amount of the grant may decrease, the allocation of RSUs and MSUs may change, or other types of equity or non-equity benefits may be substituted for the above.

The actual terms of your RSU and MSU awards will be communicated to you following the grant date. Your grant will be awarded under the Biogen Inc. Omnibus Equity Plan in effect at that time. *Please see your LTI Award Agreements, which will be available following your grant date, for specific details on the terms and conditions of your awards.* Please read these documents for information about your Long-term Incentive grants.

Beginning in the year following your start date, we expect that you will be eligible to participate in the Biogen annual Long Term Incentive (LTI) program. Approved awards would be made under the Biogen Inc. Omnibus Equity Plan in effect at that time. The details of the LTI awards will be subject to the approval of, and made by, the Compensation and Management Development Committee of the Board of Directors of Biogen.

Relocation: Biogen will provide relocation benefits to facilitate your ability to establish a residence in the Boston, Massachusetts area. The relocation benefits and payments will be provided to you after you sign a U.S. Domestic Relocation Policy Acknowledgement and Relocation Repayment Agreement, which detail the terms and conditions of your relocation package and will be provided to you by our relocation service provider, Cartus Corporation. Payments and reimbursements will be made in accordance with Biogen's relocation policy. By signing below, you understand and agree that the position requires you to maintain a residence in the Cambridge, Massachusetts area as discussed and that relocation benefits provided to you

by Biogen must be utilized not later than one year from hire or as soon as practicable, subject to travel restrictions or other limitations resulting from the ongoing pandemic.

Employee Benefits: Biogen offers a robust and highly competitive employee benefits program. As an employee, you will be able to choose from a menu of options through our flexible benefits program. These benefits include a 401(k) savings plan; group health care, including medical, dental, prescription drug and vision coverage; life, dependent life and disability insurance; as well as flexible spending accounts for eligible medical and dependent care expenses.

You are also entitled to up to 20 vacation days (160 hours) per year (pro-rated if you work part-time). Additional benefit offerings include an Employee Stock Purchase Plan (ESPP) and work/life benefits such as a concierge service and access to subsidized back-up dependent care. Please visit Biogen's Benefits website using the below link and login information to familiarize yourself with Biogen's complete benefit plan offerings.

URL: [website]
Username: [username]
Password: [password]

Additional Executive Benefits

Supplemental Savings Plan: You will be entitled to participate in Biogen's Supplemental Savings Plan (SSP). This plan allows you to make pre-tax deferrals of up to 80% of your base salary and up to 100% of your Annual Bonus payment and certain other eligible incentive payments. Your contributions to this plan may be limited by your contributions towards other plans (e.g., 401(k), ESPP, medical, etc.). You will be provided with SSP enrollment information upon your employment with the Company.

Life Insurance: You will be provided life insurance coverage equal to three times your annual base salary, subject to meeting the medical standards stated in the group term life insurance policy for U.S. employees. Biogen pays the premium for this insurance. The IRS requires employers to impute the value of company-paid life insurance for coverage over $50,000. This imputed income will be displayed on your pay stub.

Severance: You will be entitled to severance benefits in accordance with the attached Severance Plan for U.S. Executive Vice Presidents, as it may be amended in the future from time to time, and should refer to such document for details regarding terms, conditions, eligibility and potential tax implications.

Tax & Financial Planning and Executive Physicals: You are eligible for annual reimbursement of expenses for qualified services such as federal and state income tax planning and/or preparation, financial and estate planning services, and the purchase of tax and/or financial planning tools. Additionally, the Company will reimburse you for the expenses of an annual comprehensive physical exam when coordinated by the Executive Health Services team at Mass. General Hospital (MGH). The combined annual reimbursement you are eligible to receive is $7,500 per calendar year (January 1 – December 31), subject to the guidelines of the Tax & Financial Planning and Executive Physical Reimbursement Program. The details of these benefits are available upon your employment with the Company.

Stock Trading Plan: Upon employment with the Company, you will become subject to Biogen's Global Insider Trading Policy, a copy of which will be provided to you. The Biogen Global Insider Trading Policy sets forth guidelines designed to promote compliance with applicable federal and state securities laws that prohibit persons who are aware of material nonpublic information about the company from trading in securities of the company or providing material nonpublic information to other persons who may trade on the basis of that information. Upon your employment, you will be assigned, based on your job, to a specific trading group that will determine your obligations and restrictions under the policy, and you will be required to complete training on the policy.

Share Ownership Requirement: A key objective of our long-term incentive plans is to ensure strong alignment between the interests of our senior executives and those of our stockholders. It is expected that through our annual long-term incentive grants, you will accumulate and retain Biogen shares in an amount equivalent to 3x salary through the first 5 years of employment.

You are required to satisfy the following contingencies prior to employment at Biogen.

- **Pre-employment screening:** Employment at Biogen is contingent upon your successful completion and passing of both a background check and drug screen. Biogen's background check includes verification of employment history, educational and professional licenses, degrees and/or credentials, a criminal records check, a Social Security Number search and verification of any other professional qualifications that your position responsibilities at Biogen may warrant. Completion of your online Application for Employment authorizes Biogen to conduct these background checks. If you have any questions about the background check, please contact HRConnect@biogen.com.

- **Authorization to Work in the United States:** Please note that Biogen is an E-Verify employer. The Federal government requires you to provide proper identification verifying your eligibility to work in the United States. Please complete Section 1 of the Employment Eligibility Verification Form I-9, electronically as specified in your emails from Guardian. **On your first day of employment**, please bring original and unexpired documents and a scanned copy of your documents to complete the I-9 process. A list of acceptable documents can be found on the last page of the Form I-9 packet.

Signed Employee Proprietary Information and Inventions and Non-Compete Agreement: Prior to and as a condition of employment with Biogen you will be required to sign Biogen's Proprietary Information and Inventions and Non-Compete Agreement. This is required to, among other things, protect Biogen's substantial investment in creating and maintaining its confidential and proprietary information, and to maintain goodwill with our customers, vendors and other business partners. You will receive an email shortly that contains a link to this agreement for your review and electronic signature.

Michael, we are excited at the prospect of your joining Biogen. To confirm your acceptance of this offer of employment, please electronically sign this letter by July 17, 2020. You will be provided with a signed copy electronically for your personal records. We would anticipate your first day of employment to be October 19, 2020. If you have any questions, please feel free to contact me.

Best Regards,

Eileen Rivera

Cc: Michel Vounatsos

I accept this offer of employment and acknowledge the contingencies of employment described above, including the at-will nature of my employment.

ACCEPTED:

/s/ Michael McDonnell

BIOGEN CASH SIGN-ON BONUS AGREEMENT

I have accepted a position of employment with Biogen that provides for payment to me of a cash sign-on bonus of $1,000,000.00 following commencement of employment. I understand that the full benefit of this cash sign-on bonus is conditioned upon my remaining an employee of Biogen for at least 36 months.

I hereby accept Biogen's offer of a cash sign-on bonus according to the following terms:

The payment of the cash sign-on bonus by Biogen is taxable income to me and will be taxed at the time of payment.

I acknowledge and agree that if, within 36 months of my start date, I voluntarily terminate my employment or Biogen terminates my employment For Cause, as defined in the Biogen 2017 Inc. Omnibus Equity Plan, or for misconduct or poor performance, as determined in good faith by the Company, I will not have earned the cash sign-on bonus provided to me under this Agreement and I will repay such bonus according to the following schedule: (i) if my employment terminates on or before 12 months from my start date, the full amount of the cash sign-on bonus, net of the applicable proportion of tax withholdings; (ii) if my employment terminates after 12 months and on or before 24 months from my start date, 70% of the amount of the cash sign-on bonus, net of the applicable proportion of tax withholdings; or (iii) if my employment terminates after 24 months and on or before 36 months from my start date, 35% of the amount of the cash sign-on bonus, net of the applicable proportion of tax withholdings.

I shall pay to Biogen all such repayable amounts within thirty (30) days of the effective date of my employment termination or by the end of the year in which my employment terminates, whichever comes first. I voluntarily authorize Biogen to deduct, withhold and/or retain all or any portion of the amount which I may be required to refund or repay to Biogen hereunder from any wages, salary, vacation pay, severance pay or other pay which may be due and owing to me upon termination of employment, to the extent permitted under applicable law. I shall remain liable to Biogen for any amounts in excess of the sums so deducted, withheld and/or retained by Biogen.

Except as stated above, I shall have no liability or responsibility to refund or repay to Biogen any amounts paid by Biogen to me in connection with this sign-on bonus.

Nothing in this Agreement shall alter the at-will employment relationship between Biogen and me (e.g., Biogen and I can end the employment relationship at any time with or without cause). Therefore, I understand that nothing in this Agreement guarantees that the Company will employ me for any specific period of time.

My signature below acknowledges that I have read and understand this Agreement and agree to be bound by its terms.

/s/ Michael McDonnell	Michael McDonnell	July 16, 2020	
Employee Signature		Employee Name (Please Print)	Date

Exhibit 10.3

BY ELECTRONIC DELIVERY ([email address])

July 16, 2020
Revised August 5, 2020

Jeff Capello [Address]

Re: Separation Agreement

Dear Jeff:

The purpose of this Separation Agreement (the "Agreement") is to confirm the terms of your separation from Biogen Inc. or one of its subsidiaries ("Biogen" or the "Company"). The specific severance pay and benefits being offered to you, and the terms on which they are being offered, are described below. This consideration is conditioned on you timely signing and not revoking this Agreement and complying with all of its provisions.

1. Transition Period and Separation. Your employment with the Company will end on September 15, 2020 (the "Separation Date") provided that you satisfactorily perform your job duties and otherwise comply with Company rules and policies (as determined by the Company reasonably and good faith) from the date you received this Agreement through your Separation Date ("Transition Employment Period").

You agree to continue performing your job duties to the Company's reasonable satisfaction through your last day of work, August 15, 2020. Throughout the Transition Employment Period, you will continue receiving your regular pay and benefits, and will be available to Biogen to assist with the transition of your successor and will respond to any inquiries necessary for an orderly transition. Upon your Separation Date, Biogen will pay you all unpaid wages due through that date, including all accrued but unused vacation (which the parties agree is a total of 21 days). Unless otherwise provided for in this Agreement, benefits which have vested under any other employee benefit plan of the Company on or before the Separation Date will be managed in accordance with and subject to the terms and conditions of such plans.

2. Severance Pay and Benefits. In exchange for the mutual promises set forth in this Agreement, including the release of claims, and pursuant to the Severance Plan for U.S. Executive Vice Presidents, Biogen agrees to provide you with the following severance pay and benefits (the "Severance Pay and Benefits"), provided you accept this Agreement as described below, and do not revoke your acceptance pursuant to Section 7 below:

a. The Company will provide you with a lump sum payment in the amount of $1,892,625, less lawful deductions. This amount represents sixteen (16) months of pay at your base salary and target bonus.

b. Your coverage under the Company's group health benefits will end on the last day of the month in which your employment terminates. Thereafter, the Company will subsidize your current level of participation in Biogen's group medical, vision and dental insurance plans through December 31, 2021 ("COBRA Subsidy Period"), provided that you complete and timely submit your COBRA election form. In particular, during the COBRA Subsidy Period, you will be required timely to pay the employee portion of the premiums and the Company will pay the employer portion of the premiums at the same rate as paid on behalf of current employees, as long as you do not become eligible to participate in another medical, vision and/or dental insurance plan. After the COBRA Subsidy Period, you may continue your group health benefits through COBRA for the period permitted by law, by timely paying the full premiums at your sole expense. A notice regarding your COBRA rights and benefits will be mailed separately by ADP, Biogen's COBRA administrator. The benefit period under COBRA will commence on the Separation Date. You agree to promptly notify the Company if you become eligible to participate in another medical, vision and/or dental insurance plan during the COBRA Subsidy Period.

c. The Company will forgive your obligation to repay Biogen the portion (35%) of your new hire sign-on bonus which would otherwise be due to Biogen based on the repayment terms of your Cash Sign-On Agreement, executed on November 18, 2017. You are responsible for any taxes that might result from the Company forgiving your repayment obligation.

d. The Company will provide you with up to twelve (12) months of executive outplacement services from a recognized provider of such services selected by the Company.

Supplemental Severance Pay: At the conclusion of the Transition Employment Period and after the Separation Date, if you accept and do not revoke your acceptance of the Reaffirmation of Release of Claims attached to this Agreement as **Exhibit A** ("Reaffirmation Agreement"), you will receive from Biogen supplemental severance pay ("Supplemental Severance Pay"). Payment of the Supplemental Severance Pay is expressly conditioned upon: (a) your signing and not revoking the Reaffirmation Agreement by the later of the 14-day period after your Separation Date or 21 days from your receipt of this Agreement; and (b) the termination of your employment. The Supplemental Severance Pay will be a lump sum payment to you in the amount of $2,600,000, less lawful deductions. This amount is in appreciation for your years of service to the Company and in recognition of your unvested equity. The Supplemental Severance Pay is discretionary and not intended to exactly replicate any benefits you may have been eligible to receive, if you had remained employed, pursuant to the Company's equity, incentive or bonus programs.

The Severance Pay and Benefits and Supplemental Severance Pay will be paid within fifteen (15) business days of the effective date of the Reaffirmation Agreement, except for (i) the outplacement benefits described in Section 2(d) which may begin at your initiation after execution of this Agreement but within six months of your Separation Date, and for the COBRA subsidy benefits described in Section 2(b) which will commence after you elect COBRA within the time periods required by applicable law (which will be retroactive to the Separation date if such benefits are timely elected).

3. Employee Affirmations. Biogen will pay you all unpaid wages due through your Separation Date, including all accrued but unused vacation. You affirm and agree that, with the payments and benefits set forth in this Agreement, you will have received all leave (paid or unpaid), compensation, wages, bonuses, commissions, and/or benefits to which you may be entitled and that no other leave (paid or unpaid), compensation, wages, bonuses, commissions and/or benefits are due to you. You furthermore affirm that you have no known workplace injuries or occupational diseases and have been provided and/or have not been denied any leave requested under the Family and Medical Leave Act. You also affirm that you have not been retaliated against for reporting any allegations of wrongdoing by the Company or its officers, including without limitation, any allegations of corporate fraud. In addition, you affirm that all decisions regarding your pay and benefits through the date of your execution of this letter agreement and general release were not discriminatory based on age, disability, race, color, sex religion, national origin or any other classification protected by law.

You represent that, based on your current knowledge and understanding, you have complied with all laws, regulations, rules and policies pertaining to Medicare, Medicaid, or any other federal health care program while employed at Biogen. You further affirm that either (i) you are unaware of any non-compliant conduct by Biogen or its employees; or (ii) you have provided Biogen with any and all information you have, whether based on direct or indirect information, of any wrongdoing, irregularities, improprieties or illegalities regarding the ordering or delivery of any item or performance of any service by Biogen that is reimbursable by Medicare, Medicaid, or any other federal health care program.

You acknowledge and agree that, but for executing this Agreement, you would not be receiving the Severance Pay and Benefits, or Supplemental Severance Pay, described herein. If you apply for and accept a position at Biogen (in any capacity, including employee, supplemental staff, contractor, consultant, etc.) either before or within 16 months following your Separation Date, you agree to repay Biogen a prorated amount of the Severance Pay and Benefits you received.

4. Long-Term Incentive (LTI) Awards. You acknowledge and agree that, in accordance with the Company's Omnibus Equity Plan and award agreements, all of your LTI awards that are unvested as of the Separation Date will be forfeited and revert to Biogen on the Separation Date and you will have no further or future rights to any of those forfeited and reverted LTI Awards.

5. Release of Claims. In consideration for the promises and representations of Biogen as

described in this Agreement, you hereby agree to forever release and discharge Biogen and any of its divisions, affiliates, subsidiaries, related entities, and its and their current and former directors, officers, employees, attorneys, agents, insurers, successors and assigns, in their individual and official capacities, as well as their health, welfare and benefits plans and programs or the administrators or trustees of the plans and programs (collectively "Releasees"), from any and all claims, demands, actions, liabilities, obligations, accounts, expenses, attorneys' fees and causes of action, of every kind and nature, in law, equity or otherwise, whether known or unknown, asserted or unasserted, which you ever had, now have, or which may hereafter accrue in connection with any event, act or occurrence arising prior to the date that you execute this Agreement, including but not limited to all matters that arise in any way out of your employment or separation from employment with Biogen.

This release is to be interpreted broadly and is intended to include, without limitation, any and all claims you may have against Releasees under federal, state or local statutes, ordinances, regulations or rules, including without limitation the following:

(a) Any and all federal statutory or regulatory claims such as claims under the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans with Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., and the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., all as amended; all claims arising out of the Fair Credit Reporting Act, 15 U.S.C. §1681 et seq., the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §1001 et seq., the Sarbanes-Oxley Act of 2002, the Immigration Reform and Control Act, the Equal Pay Act, Sections 1981 thorough 1988 of Title 42 if the United States Code and the Genetic information Nondiscrimination Act.

(b) Any and all state statutory or regulatory claims such as claims under the Massachusetts Fair Employment Practices Law, M.G.L. ch. 151B; the Massachusetts Wage Payment Statute, G.L. c. 149, §§ 148, 148A, 148B, 149, 150,150A-150C, 151, 152, 152A, et seq.; and the Massachusetts Wage and Hour laws, G.L. c. 151§1A et seq.; the North Carolina Equal Employment Practices Act – N.C. Gen. Stat. §143-422.1 et seq.; the North Carolina Persons With Disabilities Protection Act – N.C. Gen. Stat. §168A-1 et seq.; the North Carolina Retaliatory Employment Discrimination Law – N.C. Gen. Stat. §95-240 et seq.; the North Carolina Wage and Hour Act, as amended, including N.C. Gen. Stat. §95-25.2 et seq., and §95-25.14 et seq.

(c) Any and all other claims under public policy, contract, tort or common law such as claims for breach of contract, detrimental reliance, breach of the covenant of good faith and fair dealing, wrongful discharge, employment discrimination, harassment, or

retaliation, infliction of emotional distress, negligence, defamation, fraud, and non- payment of wages or benefits.

(d) Any and all claims for recovery of costs, fees, or other expenses including attorneys' fees incurred in any matter.

Notwithstanding the foregoing, by signing this Agreement, you are not waiving any rights you may have to: (i) your own vested accrued employee benefits under the Company's health, welfare, or retirement benefit plans as of the Separation Date; (ii) benefits and/or the right to seek benefits under applicable workers' compensation and/or unemployment compensation statutes; (iii) pursue claims which by law cannot be waived by signing this Agreement; (iv) enforce this Agreement; (v) challenge the validity of this Agreement; and/or (vi) indemnification pursuant to the indemnification agreement between you and Biogen dated December 11, 2017 (the "Indemnification Agreement"), under the Company's by-laws and certificate of incorporation, and coverage, if any, under a Biogen directors and officers insurance policy.

Nothing in this release or elsewhere in this Agreement shall be deemed to prohibit you from filing a charge or complaint of employment related discrimination with the Equal Employment Opportunity Commission ("EEOC") or equivalent state agency, or from participating in any investigation or proceeding conducted by the EEOC or equivalent state agency. Notwithstanding your right to file a charge or complaint with and/or participate in any investigation or proceeding by the EEOC or equivalent state agency, to the fullest extent permitted by law, you expressly waive your right to recover any individual monetary relief or other individual remedies from Biogen or any other Releasees, in any administrative action or proceeding, whether state or federal, and whether brought by you or on your behalf by an administrative agency, related in any way to the matters released herein. Likewise, nothing in this release or elsewhere in this Agreement (including without limitation any confidentiality or non-disparagement obligations below) shall be construed to prevent you from responding truthfully and completely to any lawfully issued court order or subpoena or from communicating with a government agency.

6. Consideration Period. In signing this Agreement, you acknowledge that you understand its provisions, that your agreement is knowing and voluntary, that you are hereby afforded an opportunity to take at least twenty-one (21) days to consider its terms and consult with or seek advice from any person of your choosing, and that you are hereby advised by the Company to consult with an attorney prior to executing the Agreement. You acknowledge that, if you choose to sign this Agreement as by the dates set forth below, you have had a fully adequate opportunity to review the Agreement. You agree that any modifications, material or otherwise, do not restart, extend or affect in any manner the original consideration period.

7. Revocation Period. You further understand that for a period of seven (7) days following your execution of this Agreement, you may revoke the Agreement, and this Agreement shall not become effective or enforceable until this seven (7) day revocation period has expired, therefore

making the effective date the eighth (8th) day after this Agreement is signed by you, provided that you do not revoke this Agreement during the seven (7) day revocation period (the "Effective Date"). Any revocation within the seven (7) day revocation period must be personally delivered or mailed by Federal Express or Express Mail to Ginger Gregory at Biogen, 225 Binney Street, Cambridge, MA 02142, within seven (7) days of your execution of this Agreement. This Agreement shall not become effective or enforceable until the revocation period has expired. If the last day of the revocation period is a Saturday, Sunday, or legal holiday in Massachusetts or the state in which you reside, then the revocation period shall not expire until the next following day which is not a Saturday, Sunday, or legal holiday.

8. No Pending Suits. You acknowledge and agree that you have no pending lawsuit or complaint against Biogen or any of the other Releasees in any court of law. You further waive the right to seek or receive any money damages based upon any claim that might be asserted arising out of your employment against Biogen or any of the other Releasees.

9. Return of Property. You agree to return (and not destroy) all property and documents of Biogen in your custody and possession on or before your Separation Date. This includes, without limitation, all Biogen-related documents, both in paper and electronic form, all Biogen equipment and other property such as laptop or other portable computers, lab notebooks, proprietary and/or confidential company information, parking passes, your office and building keys and/or security cards, and your identification badge. Biogen will make arrangements for your return of any property by providing you with suitable mailing materials. Excepted from this provision is your Company-issued iPhone, which Biogen will permit you to retain provided that:
(a) your device will be wiped by the Company on August 15, 2020; and (b) you transfer your device to your own personal data plan by September 15, 2020.

10. Non-Compete/Non-Solicitation and Confidentiality of Company Information. You agree to abide by all common law and statutory obligations relating to the protection and non- disclosure of Biogen's trade secrets and confidential and proprietary documents and information. In addition, by accepting this Agreement, you hereby confirm that you have previously executed on or around November 18, 2017 Biogen's Proprietary Information and Inventions and Non- Compete Agreement ("PII Agreement"), which is incorporated herein by this reference and attached hereto as **Exhibit B**, and you hereby reaffirm and/or agree to all obligations under the PII Agreement that survive the termination of your employment, including but not limited to the Non-Solicitation and Non-Compete restrictions therein (paras. 17-22).

11. Confidentiality of This Agreement. Except as required by law, you agree not to disclose the existence or content of this Agreement to any person, firm or entity, except to your accountant(s), financial planner(s), attorney(s), and members of your immediate family, and to them only if they agree to keep this Agreement confidential.

12. Breach. In the event of your material breach of Paragraphs 9, 10, 11, 13, or 14 of this Agreement or of any provision of the PII Agreement: (a) all of Biogen's obligations under this Agreement shall cease; (b) you agree to repay Biogen (i) all compensation paid to you under this Agreement other than wages and accrued vacation earned through your Separation Date, and (ii) the value of all benefits you received under this Agreement; and (c) the general release set forth in paragraph 5 remains in full force and effect. This provision shall in no way affect Biogen's ability to recover other damages, or obtain any other form of relief, otherwise available as a result of your breach of the PII Agreement.

13. Cooperation. You agree that you will make yourself available to Biogen, upon reasonable notice, either by telephone or in person to assist Biogen in any matter relating to the services performed by you during your employment with Biogen. You also agree that you will cooperate fully with Biogen in the defense or prosecution of any claims or actions now in existence or which may be brought in the future or on behalf of Biogen or its agents. Your full cooperation in connection with such claims or actions shall include, but not be limited to, your being available to meet with Biogen's counsel to prepare for trial or discovery or an administrative hearing and to act as a witness when requested by Biogen at reasonable times designated by Biogen. To the extent that the Company requests your cooperation, the Company will seek to accommodate your schedule and will reimburse you for reasonable out-of-pocket and travel expenses consistent with the Company's travel and expense reimbursement policy then in effect, provided such expenses are approved by Biogen in advance and are substantiated with receipts or other appropriate documentation required by Biogen. Nothing in this section is intended or should be construed as requiring anything other than your cooperation in providing truthful and accurate information.

14. Non-Disparagement. You agree not to make any statements that are, or could reasonably be interpreted to be, disparaging about, or adverse to the business interests of Biogen, its directors, officers, and employees, including but not limited to, any statements that disparage any product, service, finances, capability or any other aspect of the business of Biogen. Breach of this provision shall constitute a material breach of this Agreement and cause substantial, irreparable harm to Biogen, for which you acknowledge there would be no adequate remedy at law. Biogen agrees that it will instruct the following Biogen employees not to make any statements that are, or could reasonably be interpreted to be, disparaging about you, or adverse to your business interests: Michel Vounatsos, Susan Alexander and Ginger Gregory. It shall not be a breach of this section 14 for any Biogen employee, contractor, officer, director or other personnel to make a truthful statement about your accomplishments at Biogen; and you may state that your employment with Biogen ended based on a mutual parting of ways.

15. Miscellaneous. Except as expressly provided for herein, this Agreement supersedes any and all prior oral or written agreements and sets forth the entire agreement between Biogen and you with respect to your separation from Biogen, including without limitation, any severance plan or policy. Notwithstanding anything in the foregoing sentence to the contrary, the Indemnification Agreement and your obligations under the PII shall continue in

full force and effect. No variations or modifications may be effective unless reduced to writing and signed by both parties.

This Agreement shall be deemed to have been made in Massachusetts and shall take effect as an instrument under seal within Massachusetts. The validity, interpretation and performance of this Agreement, shall be governed by, and construed in accordance with, the internal laws of Massachusetts, without giving effect to conflict of law principles. Any action, demand, claim or counterclaim arising under this Agreement shall be commenced in Massachusetts and both parties acknowledge that material witnesses and documents would be located within Massachusetts. **Both you and Biogen waive the right to a trial by jury with respect to any such action or proceeding.**

The provisions of this Agreement are severable, and if for any reason any part hereof shall be found to be unenforceable, the remaining provisions shall be enforced in full. This Agreement may be executed in counterparts, each of which shall be an original, but all of which together shall constitute one agreement. Execution of a facsimile copy of this Agreement shall have the same force and effect as execution of an original, and a facsimile or PDF signature shall be deemed an original and valid signature.

It is Biogen's desire and intent to make certain that you fully understand the provisions and effects of this Agreement. To that end, you are encouraged and given an opportunity to consult with legal counsel. By executing this Agreement, you are acknowledging that you have been afforded sufficient time to understand the provisions and effects of this Agreement and to consult with legal counsel, that your agreements and obligations under this Agreement are made voluntarily, knowingly and without duress and that neither Biogen nor its agents or representatives have made any representations inconsistent with this Agreement.

16. No Admissions. The parties agree that neither this Agreement nor the furnishing of the consideration for this Agreement and the release shall be deemed or construed at any time for any purpose as an admission by Releasees of any liability or wrongdoing.

Nothing in this Agreement shall be construed to prevent you from responding truthfully and completely to any lawfully issued court order or subpoena or from communicating with a government agency.

If the foregoing correctly sets forth our agreement, please electronically sign, date and return this Agreement to HR Operations by 5:00 p.m. ET on August 14, 2020. Please print a copy of the Agreement for your records.

Very truly yours,

/s/ Ginger Gregory Ginger

Gregory

EVP, Human Resources

The foregoing Separation Agreement is agreed to and accepted by me on August 6, 2020.

/s/ Jeff Capello Jeff Capello

Exhibit A REAFFIRMATION OF

RELEASE OF CLAIMS

1. This Reaffirmation of Release of Claims ("Reaffirmation Agreement") is being executed by me upon the ending of my employment with Biogen Inc. or one of its subsidiaries (*"Biogen"* or *"the Company"*), pursuant to the Separation Agreement previously signed by the parties ("Separation Agreement"). **I understand that this Reaffirmation Agreement may not be signed by me until after my last day of employment with Biogen and will be considered null and void if I sign it before such date. I also understand that this Reaffirmation Agreement must be signed before the later of (a) 14 days after my Separation Date; and (b) 21 days from receipt of this Reaffirmation Agreement, in order to be eligible for the Supplemental Severance Pay (as that term is defined in the Separation Agreement).**

2. In consideration for the Supplemental Severance Pay (as that term is defined in the Separation Agreement), I hereby reaffirm my agreement to all of the terms and conditions of that Separation Agreement, including my agreement to release any and all claims, known or unknown, against the Releasees, as that term is defined therein. Specifically, I hereby agree to forever release and discharge Biogen and any of its divisions, affiliates, subsidiaries, related entities, and its and their current and former directors, officers, employees, attorneys, agents, insurers, successors and assigns, in their individual and official capacities, as well as their health, welfare and benefits plans and programs or the administrators or trustees of the plans and programs (collectively "Releasees"), from any and all claims, demands, actions, liabilities, obligations, accounts, expenses, attorneys' fees and causes of action, of every kind and nature, in law, equity or otherwise, whether known or unknown, asserted or unasserted, which I ever had, now have, or which may hereafter accrue in connection with any event, act or occurrence arising prior to the date that I execute this Reaffirmation Agreement, including but not limited to all matters that arise in any way out of my employment or separation from employment with Biogen.

I agree that this release is to be interpreted broadly and is intended to include any claims I may have against Releasees including, without limitation, any and all claims under federal, state or local statutes, ordinances, regulations or rules, including without limitation the following:

a) Any and all federal statutory or regulatory claims such as claims under the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans with Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29
U.S.C. § 2101 et seq., and the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., all as amended; all claims arising out of the Fair Credit Reporting Act, 15 U.S.C. §1681 et seq., the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C.

§1001 et seq., the Sarbanes-Oxley Act of 2002, the Immigration Reform and Control Act, the Equal Pay Act, Sections 1981 thorough 1988 of Title 42 if the United States Code; and the Genetic information Nondiscrimination Act.

b) Any and all state statutory or regulatory claims such as claims under the Massachusetts Fair Employment Practices Law, M.G.L. ch. 151B; the Massachusetts Wage Payment Statute, G.L. c. 149, §§ 148, 148A, 148B, 149, 150,150A-150C, 151, 152, 152A, et seq.; and the Massachusetts Wage and Hour laws, G.L. c. 151§1A et seq.; the North Carolina Equal Employment Practices Act – N.C. Gen. Stat. §143-422.1 et seq.; the North Carolina Persons With Disabilities Protection Act – N.C. Gen. Stat. §168A-1 et seq.; the North Carolina Retaliatory Employment Discrimination Law – N.C. Gen. Stat. §95-240 et seq.; the North Carolina Wage and Hour Act, as amended, including N.C. Gen. Stat. §95-25.2 et seq., and §95-25.14 et seq.

c) Any and all other claims under public policy, contract, tort or common law such as claims for breach of contract, detrimental reliance, breach of the covenant of good faith and fair dealing, wrongful discharge, employment discrimination, harassment, or retaliation, infliction of emotional distress, negligence, defamation, fraud, and non- payment of wages or benefits.

d) Any and all claims for recovery of costs, fees, or other expenses including attorneys' fees incurred in any matter.

By signing this Reaffirmation Agreement, I understand that I am not waiving any rights I may have to: (i) my own vested accrued employee benefits under the Company's health, welfare, or retirement benefit plans as of the Separation Date; (ii) benefits and/or the right to seek benefits under applicable workers' compensation and/or unemployment compensation statutes; (iii) pursue claims which by law cannot be waived by signing this Reaffirmation Agreement; (iv) enforce the Separation Agreement or this Reaffirmation Agreement; (v) challenge the validity of the Separation Agreement or this Reaffirmation Agreement; and/or (vi) indemnification under the Indemnification Agreement, under the Company's by-laws and certificate of incorporation, and coverage, if any, under a Biogen directors and officers insurance policy.

3.I further represent that, as of the date I sign this Reaffirmation Agreement, I have not filed any lawsuits, complaints, petitions, claims or other accusatory pleadings against the Company or any of the Releasees in any court of law. I further agree that, to the fullest extent of the law, I will not prosecute in any court, whether state or federal, any claim or demand of any type related to the matters released, it being the intention of the parties that with the execution of this Reaffirmation Agreement, the Releasees will be absolutely, unconditionally and forever discharged of and from all obligations to or on behalf of me related in any way to the matters discharged herein. Additionally, I expressly waive my right to recover any type of personal relief from the Company, including monetary damages or reinstatement, in any administrative

action or proceeding, whether state or federal, and whether brought by me or on my behalf by an administrative agency, related in any way to the matters released herein.

4. This Reaffirmation Agreement is also intended to release and discharge any claims I may have under the Age Discrimination in Employment Act ("ADEA") based on any transactions or occurrences between the Company and me after the execution date of the Separation Agreement and through the Effective Date of the Reaffirmation Agreement. To satisfy the requirements of the Older Workers' Benefit Protection Act, 29 U.S.C. § 626(f), the parties agree as follows:

a) I acknowledge that I have read and understand the terms of this Reaffirmation Agreement.

b) I understand that I am advised to consult with an attorney concerning this Reaffirmation Agreement and have received all legal advice I deem necessary concerning this Reaffirmation Agreement.

c) I have been given until the later of (a) a date that is 14 days after the Separation Date; and (b) 21 days from receipt of this Reaffirmation Agreement, to consider whether or not to enter into this Reaffirmation Agreement, and have taken as much of this time as necessary to consider whether to enter into this Reaffirmation Agreement, and have chosen to enter into this Reaffirmation Agreement freely, knowingly and voluntarily.

d) For a seven day period following the execution of this Reaffirmation Agreement, I understand that I may revoke this Reaffirmation Agreement, by personally delivering or mailing by Federal Express or Express Mail, a written revocation to Ginger Gregory at Biogen, 225 Binney Street, Cambridge, MA 02142, within seven (7) days of my execution of this Reaffirmation Agreement, on or before the seventh day in order to be effective. This Reaffirmation Agreement shall not become effective and enforceable until the revocation period has expired. I understand that the Supplemental Severance Pay called for in paragraph 2 of the Separation Agreement is expressly conditioned upon my signing this Reaffirmation Agreement and will not be paid before the eighth day after I sign and deliver this Reaffirmation Agreement to the Company ("the Effective Date of the Reaffirmation"). I further understand that any revocation of this Reaffirmation Agreement shall not act as a revocation of the Separation Agreement or otherwise impact the validity of the release of claims contained in the Separation Agreement.

e) I understand that this Reaffirmation Agreement shall not apply to any claims for age discrimination that arise after the Effective Date of this Reaffirmation Agreement.

5. With the sole exception of the Severance Pay and Benefits and the Supplemental Severance Pay, I acknowledge that I have received all compensation, wages, bonuses, commissions, payout for accrued paid time off, expense reimbursement and/or benefits of any kind to which I may be entitled and that no other compensation, wages, bonuses, commissions,

payout for accrued paid time off, expense reimbursement and/or benefits of any kind are owed to me by the Company.

6. Entire Agreement; Integration. I understand that this Reaffirmation Agreement and the Separation Agreement, including without limitation the provisions referenced in paragraph 10 of the Separation Agreement and expressly incorporated therein, represent the entire agreement between me and the Company with respect to the subject matter hereof, superseding all previous oral or written communications, representations, understandings or agreements relating to this subject.

I understand that nothing in this Reaffirmation Agreement shall be deemed to prohibit me from filing a charge or complaint of employment related discrimination with the Equal Employment Opportunity Commission ("EEOC") or equivalent state agency, or from participating in any investigation or proceeding conducted by the EEOC or equivalent state agency. Notwithstanding my right to file a charge or complaint with and/or participate in any investigation or proceeding by the EEOC or equivalent state agency, to the fullest extent permitted by law, I expressly waive my right to recover any individual monetary relief or other individual remedies from Biogen or any other Releasees in any administrative action or proceeding, whether state or federal, and whether brought by me or on my behalf by an administrative agency, related in any way to the matters released herein. Likewise, **nothing in this Reaffirmation Agreement shall be construed to prevent me from responding truthfully and completely to any lawfully issued court order or subpoena or from communicating with a government agency.**

BY SIGNING BELOW, I certify that I have read and understand all of this Reaffirmation Agreement, that I have received any advice or counsel I deem necessary regarding this Reaffirmation Agreement, and that I am is entering into this Reaffirmation Agreement freely and voluntarily, intending to be bound by its terms.

Dated: September 16, 2020 By: / s/ Jeff Capello

Jeff Capello

Exhibit 31.1

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 21, 2020

/s/ Michel Vounatsos

Michel Vounatsos

Chief Executive Officer

Exhibit 31.2

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

I, Michael R. McDonnell, 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 21, 2020

/s/ Michael R. McDonnell

Michael R. McDonnell
Executive Vice President and
Chief Financial Officer

Exhibit 32.1

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, 2020 (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.

Date: October 21, 2020

/s/ Michel Vounatsos

Michel Vounatsos
Chief Executive Officer
[principal executive officer]

Date: October 21, 2020

/s/ Michael R. McDonnell

Michael R. McDonnell
Executive Vice President and
Chief Financial 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.