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 June 30, 2021

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 o

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

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

Large accelerated filer	x	Accelerated filer	☐
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. o

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 July 21, 2021, was 149,033,443 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended June 30, 2021

TABLE OF CONTENTS

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the Act) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the Act. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” "goal," “intend,” “may,” “plan,” “potential,” “possible,” “will,” “would” 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 revenue; 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 expense; 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 new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- 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 discovery, research and development programs and business development opportunities as well as the potential benefits and results of, and the anticipated completion of, certain business development transactions;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals, of our products, drug candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators’ pipeline products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- 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 the COVID-19 pandemic on our business and operations, including sales, expense, supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, 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 begin manufacturing products or product candidates and for the gene therapy manufacturing facility in Research Triangle Park, North Carolina to be operational;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries and our collection of accounts receivable in such countries;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations; and
- the impact of new laws (including tax), regulatory requirements, judicial decisions and accounting standards.

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

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

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

NOTE REGARDING TRADEMARKS

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

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

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

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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product, net	$ 2,236.0	$ 2,795.7	$ 4,447.7	$ 5,700.3
Revenue from anti-CD20 therapeutic programs	440.0	478.3	829.0	998.7
Other	99.0	407.6	192.3	516.9
Total revenue	2,775.0	3,681.6	5,469.0	7,215.9
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	459.7	411.1	937.8	865.5
Research and development	585.1	647.6	1,099.3	1,123.9
Selling, general and administrative	637.3	555.1	1,232.3	1,125.2
Amortization and impairment of acquired intangible assets	604.1	61.5	702.2	133.0
Collaboration profit sharing	(15.2)	21.8	53.3	93.5
(Gain) loss on fair value remeasurement of contingent consideration	0.3	10.0	(33.5)	5.5
Acquired in-process research and development	18.0	—	18.0	75.0
Total cost and expense	2,289.3	1,707.1	4,009.4	3,421.6
Income from operations	485.7	1,974.5	1,459.6	3,794.3
Other income (expense), net	96.4	63.0	(410.5)	(57.5)
Income before income tax expense and equity in loss of investee, net of tax	582.1	2,037.5	1,049.1	3,736.8
Income tax (benefit) expense	(409.1)	446.1	(364.9)	738.2
Equity in (income) loss of investee, net of tax	(34.3)	(15.1)	(16.1)	(0.4)
Net income	1,025.5	1,606.5	1,430.1	2,999.0
Net income (loss) attributable to noncontrolling interests, net of tax	577.0	64.4	571.4	57.8
Net income attributable to Biogen Inc.	$ 448.5	$ 1,542.1	$ 858.7	$ 2,941.2
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 3.00	$ 9.60	$ 5.70	$ 17.65
Diluted earnings per share attributable to Biogen Inc.	$ 2.99	$ 9.59	$ 5.68	$ 17.61
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	149.7	160.6	150.8	166.7
Diluted earnings per share attributable to Biogen Inc.	150.1	160.9	151.2	167.0

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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Net income attributable to Biogen Inc.	$ 448.5	$ 1,542.1	$ 858.7	$ 2,941.2
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	(0.5)	8.7	(1.3)	0.9
Unrealized gains (losses) on cash flow hedges, net of tax	(11.0)	(51.2)	138.6	(17.4)
Gains (losses) on net investment hedges	(2.3)	(6.2)	20.1	16.8
Unrealized gains (losses) on pension benefit obligation, net of tax	0.4	0.1	2.4	0.9
Currency translation adjustment	15.9	16.9	(32.6)	(47.0)
Total other comprehensive income (loss), net of tax	2.5	(31.7)	127.2	(45.8)
Comprehensive income attributable to Biogen Inc.	451.0	1,510.4	985.9	2,895.4
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	576.9	65.5	572.0	59.6
Comprehensive income	$ 1,027.9	$ 1,575.9	$ 1,557.9	$ 2,955.0

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 June 30, 2021	As of December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,742.0	$ 1,331.2
Marketable securities	1,308.8	1,278.9
Accounts receivable, net	1,688.0	1,913.8
Due from anti-CD20 therapeutic programs	422.2	413.5
Inventory	1,254.8	1,068.6
Other current assets	767.9	881.1
Total current assets	7,183.7	6,887.1
Marketable securities	915.1	772.1
Property, plant and equipment, net	3,442.2	3,411.5
Operating lease assets	402.5	433.3
Intangible assets, net	2,385.0	3,084.3
Goodwill	5,763.9	5,762.1
Deferred tax asset	1,849.9	1,369.5
Investments and other assets	2,528.1	2,899.0
Total assets	$ 24,470.4	$ 24,618.9
LIABILITIES AND EQUITY		
Current liabilities:		
Taxes payable	$ 230.9	$ 142.0
Accounts payable	375.3	454.9
Accrued expense and other	2,741.0	3,145.3
Total current liabilities	3,347.2	3,742.2
Notes payable	7,269.2	7,426.2
Deferred tax liability	918.9	1,032.8
Long-term operating lease liabilities	363.9	402.0
Other long-term liabilities	1,356.4	1,329.6
Total liabilities	13,255.6	13,932.8
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	(171.8)	(299.0)
Retained earnings	13,900.7	13,976.3
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	10,751.9	10,700.3
Noncontrolling interests	462.9	(14.2)
Total equity	11,214.8	10,686.1
Total liabilities and equity	$ 24,470.4	$ 24,618.9

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	For the Six Months Ended June 30,	
	2021	2020
Cash flow from operating activities:		
Net income	$ 1,430.1	$ 2,999.0
Adjustments to reconcile net income to net cash flow from operating activities:		
Depreciation and amortization	219.8	232.8
Impairment of intangible assets	585.9	—
Acquired in-process research and development	18.0	75.0
Share-based compensation	124.1	115.8
Gain on interest rate swap	—	(3.3)
Contingent consideration	(33.5)	5.5
Deferred income taxes	(622.8)	180.2
(Gain) loss on strategic investments	283.6	(39.7)
Loss on equity method investment	(16.1)	1.6
Other	112.4	83.7
Changes in operating assets and liabilities, net:		
Accounts receivable	211.5	(268.8)
Due from anti-CD20 therapeutic programs	(8.7)	149.1
Inventory	(193.8)	(188.2)
Accrued expense and other current liabilities	(188.4)	(441.4)
Income tax assets and liabilities	171.5	504.6
Other changes in operating assets and liabilities, net	(97.3)	9.9
Net cash flow provided by operating activities	1,996.3	3,415.8
Cash flow from investing activities:		
Proceeds from sales and maturities of marketable securities	1,452.7	3,879.9
Purchases of marketable securities	(1,626.9)	(3,753.9)
Purchase of Sangamo Therapeutics, Inc. stock	—	(141.8)
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	28.1	—
Purchases of property, plant and equipment	(164.5)	(254.7)
Acquired in-process research and development	—	(75.0)
Acquisitions of intangible assets	—	(37.0)
Proceeds from sales of strategic investments	91.2	0.5
Other	2.0	(7.8)
Net cash flow used in investing activities	(217.4)	(389.8)
Cash flow from financing activities:		
Purchases of treasury stock	(1,050.0)	(5,029.1)
Payments related to issuance of stock for share-based compensation arrangements, net	(14.2)	(19.2)
Repayment of borrowings and premiums paid on debt exchange	(170.0)	—
Proceeds from borrowings	—	2,967.3
Repayment of borrowings	—	(1,500.0)
Cash proceeds from settlement of swap	—	3.3
Net distribution to noncontrolling interest	(94.8)	—
Other	(20.5)	19.0
Net cash flow used in financing activities	(1,349.5)	(3,558.7)
Net increase (decrease) in cash and cash equivalents	429.4	(532.7)
Effect of exchange rate changes on cash and cash equivalents	(18.6)	3.9
Cash and cash equivalents, beginning of the period	1,331.2	2,913.7
Cash and cash equivalents, end of the period	$ 1,742.0	$ 2,384.9

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, March 31, 2021	—	$ —	174.4	$ 0.1	$ —	$ (174.3)	$ 13,833.5	(23.8)	$ (2,977.1)	$ 10,682.2	$ (19.0)	$ 10,663.2
Net income	—	—	—	—	—	—	448.5	—	—	448.5	577.0	1,025.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	2.5	—	—	—	2.5	(0.1)	2.4
Capital contribution by noncontrolling interest	—	—	—	—	—	—	—	—	—	—	5.0	5.0
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(100.0)	(100.0)
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(1.6)	(450.0)	(450.0)	—	(450.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(1.6)	—	(69.5)	—	(380.5)	1.6	450.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	13.7	—	—	—	—	13.7	—	13.7
Issuance of common stock under stock award plan	—	—	—	—	—	—	(0.8)	—	—	(0.8)	—	(0.8)
Compensation related to share-based payments	—	—	—	—	55.8	—	—	—	—	55.8	—	55.8
Other	—	—	—	—	—	—	—	—	—	—	—	—
Balance, June 30, 2021	—	$ —	172.9	$ 0.1	$ —	$ (171.8)	$ 13,900.7	(23.8)	$ (2,977.1)	$ 10,751.9	$ 462.9	$ 11,214.8

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, 2020	—	$ —	176.2	$ 0.1	$ —	$ (299.0)	$ 13,976.3	(23.8)	$ (2,977.1)	$ 10,700.3	$ (14.2)	$ 10,686.1
Net income	—	—	—	—	—	—	858.7	—	—	858.7	571.4	1,430.1
Other comprehensive income (loss), net of tax	—	—	—	—	—	127.2	—	—	—	127.2	0.6	127.8
Capital contribution by noncontrolling interest	—	—	—	—	—	—	—	—	—	—	5.1	5.1
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(100.0)	(100.0)
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(3.8)	(1,050.0)	(1,050.0)	—	(1,050.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(3.8)	—	(163.3)	—	(886.7)	3.8	1,050.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	33.4	—	—	—	—	33.4	—	33.4
Issuance of common stock under stock award plan	—	—	0.3	—	—	—	(47.6)	—	—	(47.6)	—	(47.6)
Compensation related to share-based payments	—	—	—	—	128.4	—	—	—	—	128.4	—	128.4
Other	—	—	—	—	1.5	—	—	—	—	1.5	—	1.5
Balance, June 30, 2021	—	$ —	172.9	$ 0.1	$ —	$ (171.8)	$ 13,900.7	(23.8)	$ (2,977.1)	$ 10,751.9	$ 462.9	$ 11,214.8

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, March 31, 2020	—	$ —	191.1	$ 0.1	$ 0.1	$ (149.3)	$ 15,673.1	(23.8)	$ (2,977.1)	$ 12,546.9	$ (10.0)	$ 12,536.9
Net income	—	—	—	—	—	—	1,542.1	—	—	1,542.1	64.4	1,606.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	(31.7)	—	—	—	(31.7)	1.1	(30.6)
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(75.0)	(75.0)
Repurchase of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(9.0)	(2,808.9)	(2,808.9)	—	(2,808.9)
Retirement of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	(9.0)	—	(60.7)	—	(2,748.2)	9.0	2,808.9	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	—	—	11.1	—	—	—	—	11.1	—	11.1
Issuance of common stock under stock award plan	—	—	—	—	—	—	(0.3)	—	—	(0.3)	—	(0.3)
Compensation related to share-based payments	—	—	—	—	49.5	—	—	—	—	49.5	—	49.5
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

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	—	—	—	—	—	—	2,941.2	—	—	2,941.2	57.8	2,999.0
Other comprehensive income (loss), net of tax	—	—	—	—	—	(45.8)	—	—	—	(45.8)	1.8	(44.0)
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(75.0)	(75.0)
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	—	—	—	—	—	—	—	(12.2)	(3,750.0)	(3,750.0)	—	(3,750.0)
Retirement of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	(12.2)	—	(76.2)	—	(3,673.8)	12.2	3,750.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	29.1	—	—	—	—	29.1	—	29.1
Issuance of common stock under stock award plan	—	—	0.3	—	—	—	(48.0)	—	—	(48.0)	—	(48.0)
Compensation related to share-based payments	—	—	—	—	118.8	—	—	—	—	118.8	—	118.8
Other	—	—	—	—	(0.7)	—	—	—	—	(0.7)	—	(0.7)
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

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; ophthalmology; and neuropsychiatry. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; acute neurology; and neuropathic 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; ADUHELM for the treatment of Alzheimer's disease; and FUMADERM for the treatment of severe plaque psoriasis. We 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 audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 (2020 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 our agreements with 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. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, 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 2020 Form 10-K. Our accounting policies are described in the *Notes to Consolidated Financial Statements* in our 2020 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 six months ended June 30, 2021, 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 100.0% 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, revenue and expense and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and assumptions. 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 revenue and expense. 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, expense, 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 the COVID-19 pandemic 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.

Income Taxes

In December 2019 the FASB issued Accounting Standards Update No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard removes certain exceptions to the general principles in Topic 740 and simplifies certain other aspects of the accounting for income taxes. This standard became effective for us on January 1, 2021, 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 (CK1 inhibitor) for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). We are developing BIIB118 for the potential treatment of irregular sleep wake rhythm disorder in Parkinson's disease and plan to develop BIIB118 for the potential treatment of sundowning in Alzheimer'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.

3. Revenue

Product Revenue

Revenue by product is summarized as follows:

	For the Three Months Ended June 30,					
	2021			2020		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	$ 269.1	$ 309.4	$ 578.5	$ 921.7	$ 268.6	$ 1,190.3
Interferon**	257.4	143.0	400.4	345.6	135.8	481.4
TYSABRI	299.8	224.4	524.2	244.1	187.9	432.0
FAMPYRA	—	26.1	26.1	—	23.0	23.0
Subtotal: MS product revenue	826.3	702.9	1,529.2	1,511.4	615.3	2,126.7
Spinal Muscular Atrophy:						
SPINRAZA	149.3	350.4	499.7	210.3	284.3	494.6
Alzheimer's disease:						
ADUHELM***	1.6	—	1.6	—	—	—
Biosimilars:						
BENEPALI	—	121.5	121.5	—	106.2	106.2
IMRALDI	—	55.6	55.6	—	44.8	44.8
FLIXABI	—	25.3	25.3	—	20.6	20.6
Subtotal: Biosimilar product revenue	—	202.4	202.4	—	171.6	171.6
Other:						
FUMADERM	—	3.1	3.1	—	2.8	2.8
Total product revenue	$ 977.2	$ 1,258.8	$ 2,236.0	$ 1,721.7	$ 1,074.0	$ 2,795.7

*Fumarate includes TECFIDERA and VUMERITY.
**Interferon includes AVONEX and PLEGRIDY.
*** In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the United States (U.S.) during the second quarter of 2021. For additional information, please read *Note 16, Collaborative and Other Relationships - Eisai Co., Ltd. - ADUHELM Collaboration Agreement,* to these condensed consolidated financial statements.

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

	For the Six Months Ended June 30,					
	2021			2020		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	$ 505.1	$ 626.3	$ 1,131.4	$ 1,699.2	$ 591.9	$ 2,291.1
Interferon**	499.2	301.7	800.9	638.2	309.2	947.4
TYSABRI	573.1	454.4	1,027.5	521.8	432.6	954.4
FAMPYRA	—	52.7	52.7	—	51.3	51.3
Subtotal: MS product revenue	1,577.4	1,435.1	3,012.5	2,859.2	1,385.0	4,244.2
Spinal Muscular Atrophy:						
SPINRAZA	298.0	722.2	1,020.2	445.7	613.9	1,059.6
Alzheimer's disease:						
ADUHELM***	1.6	—	1.6	—	—	—
Biosimilars:						
BENEPALI	—	243.2	243.2	—	239.7	239.7
IMRALDI	—	113.5	113.5	—	106.4	106.4
FLIXABI	—	50.8	50.8	—	44.3	44.3
Subtotal: Biosimilar product revenue	—	407.5	407.5	—	390.4	390.4
Other:						
FUMADERM	—	5.9	5.9	—	6.1	6.1
Total product revenue	$ 1,877.0	$ 2,570.7	$ 4,447.7	$ 3,304.9	$ 2,395.4	$ 5,700.3

*Fumarate includes TECFIDERA and VUMERITY.
**Interferon includes AVONEX and PLEGRIDY.
*** In June 2021 the FDA granted accelerated approval of ADUHELM, which became commercially available in the U.S. during the second quarter of 2021. For additional information, please read *Note 16, Collaborative and Other Relationships - Eisai Co., Ltd. - ADUHELM Collaboration Agreement,* to these condensed consolidated financial statements.

We recognized revenue from two wholesalers accounting for 30.2% and 9.9% of gross product revenue for the three months ended June 30, 2021, and 30.1% and 9.6% of gross product revenue for the six months ended June 30, 2021.

We recognized revenue from two wholesalers accounting for 31.7% and 17.9% of gross product revenue for the three months ended June 30, 2020, and 30.8% and 16.2% of gross product revenue for the six months ended June 30, 2020.

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, 2020	$ 141.4	$ 1,093.0	$ 41.6	$ 1,276.0
Current provisions relating to sales in current year	375.6	1,577.0	7.4	1,960.0
Adjustments relating to prior years	1.1	(51.5)	1.6	(48.8)
Payments/credits relating to sales in current year	(275.5)	(906.9)	—	(1,182.4)
Payments/credits relating to sales in prior years	(119.2)	(676.4)	(6.9)	(802.5)
Balance, June 30, 2021	$ 123.4	$ 1,035.2	$ 43.7	$ 1,202.3

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

(In millions)	As of June 30, 2021	As of December 31, 2020
Reduction of accounts receivable	$ 160.2	$ 195.4
Component of accrued expense and other	1,042.1	1,080.6
Total revenue-related reserves	$ 1,202.3	$ 1,276.0

Revenue from Anti-CD20 Therapeutic Programs

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$ 178.8	$ 257.5	$ 352.9	$ 598.8
Other revenue from anti-CD20 therapeutic programs	261.2	220.8	476.1	399.9
Total revenue from anti-CD20 therapeutic programs	$ 440.0	$ 478.3	$ 829.0	$ 998.7

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 2020 Form 10-K.

Other Revenue

Other revenue is summarized as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Revenue from collaborative and other relationships:				
Revenue earned under our technical development agreement, manufacturing services agreements and royalty revenue on biosimilar products with Samsung Bioepis	$ 5.5	$ 4.5	$ 9.4	$ 8.2
Other revenue from collaborative and other relationships	—	0.5	—	0.7
Other royalty and corporate revenue:				
Royalty	6.4	7.1	12.6	18.5
Other corporate	87.1	395.5	170.3	489.5
Total other revenue	$ 99.0	$ 407.6	$ 192.3	$ 516.9

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

4. Inventory

The components of inventory are summarized as follows:

(In millions)	As of June 30, 2021	As of December 31, 2020
Raw materials	$ 328.0	$ 314.9
Work in process	723.0	544.5
Finished goods	203.8	209.2
Total inventory	$ 1,254.8	$ 1,068.6

5. Intangible Assets and Goodwill

Intangible Assets

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

		As of June 30, 2021			As of December 31, 2020		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,394.3	$ (5,252.7)	$ 2,141.6	$ 7,394.3	$ (5,136.5)	$ 2,257.8
In-process research and development	Indefinite until commercialization	179.4	—	179.4	762.5	—	762.5
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 7,637.7	$ (5,252.7)	$ 2,385.0	$ 8,220.8	$ (5,136.5)	$ 3,084.3

For the three and six months ended June 30, 2021, amortization and impairment of acquired intangible assets totaled $604.1 million and $702.2 million, respectively, compared to $61.5 million and $133.0 million, respectively, in the prior year comparative periods.

For the three and six months ended June 30, 2021, amortization and impairment of acquired intangible assets reflects a $350.0 million impairment charge related to BIIB111 (timrepigene emparvovec) for the potential treatment of choroideremia and a $191.6 million impairment charge related to BIIB112 (cotoretigene toliparvovec) for the potential treatment of X-linked retinitis pigmentosa.

For the six months ended June 30, 2021, amortization and impairment of acquired intangible assets also reflects a $44.3 million impairment charge related to vixotrigine (BIIB074) for the potential treatment of trigeminal neuralgia (TGN).

For the three and six months ended June 30, 2020, we had no impairment charges.

Completed Technology

Completed technology primarily relates to our acquisition of all remaining rights to TYSABRI as well as other amounts related to our other marketed products and programs acquired through business combinations.

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 June 30, 2021, relates to the various IPR&D programs we acquired in connection with our acquisitions of Nightstar Therapeutics plc (NST) and Convergence Pharmaceuticals Holdings Ltd. (Convergence). For additional information on our acquisition of NST, please read *Note 2, Acquisitions*, to our consolidated financial statements included in our 2020 Form 10-K.

Vixotrigine

In the periods since we acquired vixotrigine, there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN and for the potential treatment of diabetic painful neuropathy (DPN), another form of neuropathic pain. We have engaged with the FDA regarding the design of the Phase 3 studies of vixotrigine for the potential treatment of TGN and DPN and now plan to perform an additional clinical trial of vixotrigine before initiating a Phase 3 study of DPN.

The performance of this additional clinical trial has delayed the initiation of the Phase 3 studies of vixotrigine for the potential treatment of TGN, and, as a result, we recognized an impairment charge of $44.3 million related to vixotrigine for the potential treatment of TGN during the first quarter of 2021. As of June 30, 2021, the carrying value associated with our remaining vixotrigine IPR&D assets was $136.0 million, all of which is related to DPN.

BIIB111 and BIIB112

During the fourth quarter of 2020 we recognized an impairment charge of $115.0 million related to BIIB111 as a result of third-party manufacturing delays that impacted the timing and increased the costs associated with advancing BIIB111 through Phase 3 development.

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 did not meet its primary or key secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of $350.0 million during the second quarter of 2021, which resulted in a reduction of the IPR&D asset from $365.0 million to $15.0 million.

During the second quarter of 2021 we announced that our Phase 2/3 XIRIUS study of BIIB112 did not meet its primary endpoint; however, positive trends were observed across several clinically relevant prespecified secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of $191.6 million during the second quarter of 2021, which resulted in a reduction of the IPR&D asset from $220.0 million to $28.4 million.

We are evaluating the results of our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112, including evaluation of any future development activities we may perform. Our estimates of the current fair values of the BIIB111 and BIIB112 programs were derived by using a discounted, probability-weighted calculation of future estimated cash flows associated with the programs under multiple scenarios, including the possibility that we will cease further development of BIIB111 and/or BIIB112, which could result in further impairment of these assets. The key assumptions in our estimates are the amount and timing of revenue, probability of technical and regulatory success, discount rate and clinical data associated with the programs.

In addition, we have entered into third-party manufacturing agreements related to the BIIB111 and BIIB112 programs and we may incur a financial penalty if these agreements are terminated. Should we decide to terminate either or both of these programs and/or manufacturing agreements, we will likely incur impairment charges related to the remaining book value of the applicable program as well as charges up to, in the aggregate, approximately $30.0 million related to our inventory arrangements and other costs associated with discontinuing these programs.

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 June 30, 2021
2021 (remaining six months)	$ 110.0
2022	215.0
2023	215.0
2024	225.0
2025	220.0
2026	200.0

Goodwill

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

(In millions)	As of June 30, 2021
Goodwill, December 31, 2020	$ 5,762.1
Other	1.8
Goodwill, June 30, 2021	$ 5,763.9

As of June 30, 2021, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

6. Fair Value Measurements

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

	As of June 30, 2021			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 1,180.2	$ —	$ 1,180.2	$ —
Marketable debt securities:				
Corporate debt securities	1,382.5	—	1,382.5	—
Government securities	688.6	—	688.6	—
Mortgage and other asset backed securities	152.8	—	152.8	—
Marketable equity securities	1,593.5	273.3	1,320.2	—
Derivative contracts	20.8	—	20.8	—
Plan assets for deferred compensation	33.7	—	33.7	—
Total	$ 5,052.1	$ 273.3	$ 4,778.8	$ —
Liabilities:				
Derivative contracts	$ 72.4	$ —	$ 72.4	$ —
Contingent consideration obligations	226.3	—	—	226.3
Total	$ 298.7	$ —	$ 72.4	$ 226.3

	As of December 31, 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	$ 626.9	$ —	$ 626.9	$ —
Marketable debt securities:				
Corporate debt securities	1,301.5	—	1,301.5	—
Government securities	627.1	—	627.1	—
Mortgage and other asset backed securities	122.4	—	122.4	—
Marketable equity securities	1,974.3	271.1	1,703.2	—
Derivative contracts	20.5	—	20.5	—
Plan assets for deferred compensation	28.2	—	28.2	—
Total	$ 4,700.9	$ 271.1	$ 4,429.8	$ —
Liabilities:				
Derivative contracts	$ 217.2	$ —	$ 217.2	$ —
Contingent consideration obligations	259.8	—	—	259.8
Total	$ 477.0	$ —	$ 217.2	$ 259.8

There have been no material impairments of our assets measured and carried at fair value during the three and six months ended June 30, 2021. In addition, there have been no changes in valuation techniques during the three and six months ended June 30, 2021. 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 the common stock of Sangamo Therapeutics, Inc. (Sangamo), Denali Therapeutics Inc. (Denali) and Sage Therapeutics, Inc. (Sage) and are valued using an option pricing valuation model as the investments are each subject to certain holding period restrictions. The holding period restrictions for a portion of our Sangamo investment expired during the second quarter of 2021.

The fair value of this portion of our Sangamo investment was a Level 1 measurement as of June 30, 2021. For additional information on our investments in Sangamo, Denali and Sage common stock, please read *Note 7, Financial Instruments,* to these condensed consolidated financial statements.

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 2020 Form 10-K.

The following tables summarize the significant unobservable inputs in the fair value measurement of our contingent consideration obligations as of June 30, 2021 and December 31, 2020:

	As of June 30, 2021				
(In millions)	**Fair Value**	**Valuation Technique**	**Unobservable Input(s)**	**Range**	**Weighted Average**
Liabilities:					
Contingent consideration obligation	$ 226.3	Discounted cash flow	Discount rate	0.68%	0.68%
			Expected timing of achievement of development milestones	2022 to 2027	—

	As of December 31, 2020				
(In millions)	**Fair Value**	**Valuation Technique**	**Unobservable Input(s)**	**Range**	**Weighted Average**
Liabilities:					
Contingent consideration obligation	$ 259.8	Discounted cash flow	Discount rate	0.60%	0.60%
			Expected timing of achievement of development milestones	2021 to 2025	—

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 21.7% to certain probability, to the valuation models to estimate the fair values of our contingent consideration obligations.

Nonrecurring Fair Value Measurements

In addition to assets and liabilities that are recorded at fair value on a recurring basis, we record assets and liabilities at fair value on a nonrecurring basis as required by U.S. GAAP. Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges.

The gains or losses on assets measured at fair value on a nonrecurring basis, are summarized as follows:

	As of June 30, 2021		
(In millions)	**Beginning Book Value**	**Impairment**	**Ending Book Value**
BIIB111 intangible asset	$ 365.0	$ (350.0)	$ 15.0
BIIB112 intangible asset	220.0	(191.6)	28.4

For the three and six months ended June 30, 2021, we recorded a partial impairment charge of $350.0 million related to BIIB111 and $191.6 million related to BIIB112. For additional information, please read *Note 5, Intangible Assets and Goodwill*, to these condensed consolidated financial statements.

Debt Instruments

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

	As of June 30, 2021		As of December 31, 2020	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
3.625% Senior Notes due September 15, 2022	$ 1,037.8	$ 998.5	$ 1,054.1	$ 997.9
4.050% Senior Notes due September 15, 2025	1,945.3	1,742.0	2,003.1	1,741.2
2.250% Senior Notes due May 1, 2030	1,503.3	1,491.6	1,557.2	1,491.1
5.200% Senior Notes due September 15, 2045 [1]	1,483.1	1,099.7	2,365.1	1,723.4
3.150% Senior Notes due May 1, 2050	1,471.1	1,472.9	1,536.4	1,472.6
3.250% Senior Notes due February 15, 2051 [1]	700.1	464.5	—	—
Total	$ 8,140.7	$ 7,269.2	$ 8,515.9	$ 7,426.2

[1] In February 2021 we completed a private offer to exchange (Exchange Offer) our tendered 5.200% Senior Notes due September 15, 2045 (2045 Senior Notes), whereby approximately $624.6 million of our 2045 Senior Notes were exchanged for approximately $700.7 million of a new series of 3.250% Senior Notes due February 15, 2051 (2051 Senior Notes). For additional information on our Exchange Offer, please read *Note 10, 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 April 30, 2020 and September 15, 2015, please read *Note 12, Indebtedness,* to our consolidated financial statements included in our 2020 Form 10-K.

Contingent Consideration Obligations

In connection with our acquisitions of Convergence and Biogen International Neuroscience GmbH, 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 June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Fair value, beginning of period	$ 226.0	$ 341.6	$ 259.8	$ 346.1
Changes in fair value	0.3	10.0	(33.5)	5.5
Fair value, end of period	$ 226.3	$ 351.6	$ 226.3	$ 351.6

As of June 30, 2021 and December 31, 2020, approximately $226.3 million and $110.3 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 expense and other.

For the three and six months ended June 30, 2021, changes in the fair value of our contingent consideration obligations were primarily due to delays in the expected timing of the achievement of certain remaining developmental milestones related to our vixotrigine programs.

For the three and six months ended June 30, 2020, changes in the fair value of our contingent consideration obligations were primarily due to changes in the interest rates used to revalue our contingent consideration liabilities, changes in the probability and the expected timing of the achievement of certain remaining developmental milestones and the passage of time.

7. Financial Instruments

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

(In millions)	As of June 30, 2021	As of December 31, 2020
Commercial paper	$ 130.0	$ 61.1
Overnight reverse repurchase agreements	297.8	37.4
Money market funds	725.9	505.1
Short-term debt securities	26.5	23.3
Total	$ 1,180.2	$ 626.9

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, classified as available for sale:

	As of June 30, 2021			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 1,072.2	$ 0.3	$ (0.4)	$ 1,072.1
Non-current	309.9	0.6	(0.1)	310.4
Government securities:				
Current	236.5	0.1	—	236.6
Non-current	452.1	0.2	(0.3)	452.0
Mortgage and other asset backed securities:				
Current	0.2	—	—	0.2
Non-current	152.7	0.2	(0.3)	152.6
Total marketable debt securities	$ 2,223.6	$ 1.4	$ (1.1)	$ 2,223.9
Marketable equity securities				
Marketable equity securities, non-current	$ 1,168.9	$ 607.6	$ (183.0)	$ 1,593.5
Total marketable equity securities	$ 1,168.9	$ 607.6	$ (183.0)	$ 1,593.5

(In millions)	As of December 31, 2020 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 897.8	$ 0.4	$ (0.2)	$ 898.0
Non-current	402.5	1.1	(0.1)	403.5
Government securities:				
Current	380.6	0.1	—	380.7
Non-current	245.9	0.5	—	246.4
Mortgage and other asset backed securities:				
Current	0.2	—	—	0.2
Non-current	122.1	0.2	(0.1)	122.2
Total marketable debt securities	$ 2,049.1	$ 2.3	$ (0.4)	$ 2,051.0
Marketable equity securities				
Marketable equity securities, current	$ 70.6	$ 15.9	$ —	$ 86.5
Marketable equity securities, non-current	1,168.9	733.8	(14.9)	1,887.8
Total marketable equity securities	$ 1,239.5	$ 749.7	$ (14.9)	$ 1,974.3

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:

(In millions)	As of June 30, 2021 Estimated Fair Value	Amortized Cost	As of December 31, 2020 Estimated Fair Value	Amortized Cost
Due in one year or less	$ 1,308.8	$ 1,308.9	$ 1,278.9	$ 1,278.6
Due after one year through five years	870.9	870.5	722.6	721.3
Due after five years	44.2	44.2	49.5	49.2
Total marketable debt securities	$ 2,223.9	$ 2,223.6	$ 2,051.0	$ 2,049.1

The average maturity of our marketable debt securities available-for-sale as of June 30, 2021 and December 31, 2020, was approximately 13 months and 11 months, respectively.

Proceeds from Marketable Debt Securities

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

(In millions)	For the Three Months Ended June 30, 2021	2020	For the Six Months Ended June 30, 2021	2020
Proceeds from maturities and sales	$ 633.5	$ 1,490.6	$ 1,452.7	$ 3,879.9
Realized gains	0.1	6.1	0.3	11.8
Realized losses	(0.5)	(5.2)	(1.2)	(24.3)

Strategic Investments

As of June 30, 2021 and December 31, 2020, our strategic investment portfolio was comprised of investments totaling $1,647.8 million and $2,024.6 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 6, 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 months ended June 30, 2021, was primarily due to an increase in the fair value of our investment in Denali, partially offset by decreases in the fair values of our investments in Ionis Pharmaceuticals, Inc. (Ionis), Sage and Sangamo common stock. The decrease in our strategic investment portfolio for the six months ended June 30, 2021, was primarily due to decreases in the fair values of our investments in Ionis, Sage, Denali and Sangamo common stock.

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage. In connection with the closing of this transaction in December 2020 we purchased $650.0 million of Sage common stock, or approximately 6.2 million shares at approximately $104.14 per share, which are subject to transfer restrictions. 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 Sage common stock and a dividend yield of zero based upon the fact that Sage and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration arrangement with Sage, please read *Note 16, Collaborative and Other Relationships*, to these condensed consolidated financial statements.

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali. 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. 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 arrangement with Denali, please read *Note 16, 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 $225.0 million of Sangamo common stock, or approximately 24 million shares at approximately $9.21 per share, of which approximately 12 million shares remain subject to transfer restrictions as of June 30, 2021. 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 arrangement with Sangamo, please read *Note 16, Collaborative and Other Relationships,* to these condensed consolidated financial statements.

8. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

Due to the global nature of our operations, portions of our revenue and operating expense are recorded in currencies other than the U.S. dollar. The value of revenue and operating expense 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 revenue and operating expense.

Foreign currency forward contracts in effect as of June 30, 2021 and December 31, 2020, had durations of 1 to 18 months and 1 to 24 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 revenue when the sale of product in the currency being hedged is recognized and in operating expense 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 revenue and operating expense is summarized as follows:

	Notional Amount	
(In millions)	**As of June 30, 2021**	**As of December 31, 2020**
Euro	$ 2,269.2	$ 2,979.1
British pound	128.6	250.6
Swiss franc	109.9	—
Japanese yen	62.5	—
Canadian dollar	53.3	—
Total foreign currency forward contracts	$ 2,623.5	$ 3,229.7

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 as of June 30, 2021, reflected aggregate net unrealized losses of $53.7 million, composed of gross unrealized losses of approximately $67.0 million and gross unrealized gains of approximately $13.3 million, compared to aggregate net unrealized losses of $212.5 million as of December 31, 2020. We expect the net unrealized losses of $53.7 million to be settled over the next 18 months, of which $58.2 million of unrealized 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 revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of June 30, 2021 and December 31, 2020, 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 June 30,					
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)			Net Gains/(Losses) Recognized in Operating Income (in millions)		
Location	**2021**	**2020**	**Location**	**2021**	**2020**
Revenue	$ (30.7)	$ 23.7	Revenue	$ (0.8)	$ (1.6)
Operating expense	0.4	—	Operating expense	(0.3)	(0.2)

For the Six Months Ended June 30,						
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)				Net Gains/(Losses) Recognized in Operating Income (in millions)		
Location	2021		2020	Location	2021	2020
Revenue	$	(53.8)	$ 50.7	Revenue	$ (3.8)	$ 7.7
Operating expense		—	(0.1)	Operating expense	(0.4)	(1.1)

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. 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, which was recorded as a component of interest expense in our condensed consolidated statements of income during the second quarter of 2020.

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 June 30, 2021, had a remaining duration of four months. These contracts have been designated as net investment hedges. We recognize changes in the spot exchange rate in accumulated other comprehensive income (loss). The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net gains of $0.1 million and net losses of $21.2 million as of June 30, 2021 and December 31, 2020, 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 $0.1 million and $0.2 million as of June 30, 2021 and December 31, 2020, respectively.

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

For the Three Months Ended June 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	2021		2020	Location	2021	2020	Location	2021	2020
Gains (losses) on net investment hedge	$	(2.5)	$ (8.8)	Gains (losses) on net investment hedge	$ 0.3	$ 3.5	Other income (expense)	$ —	$ 0.8

	For the Six Months Ended June 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	2021	2020		Location	2021	2020	Location	2021	2020
Gains (losses) on net investment hedge	$ 21.3	$ 15.4		Gains (losses) on net investment hedge	$ (1.1)	$ 3.2	Other income (expense)	$ 0.1	$ 1.7

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, 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 $1,205.1 million and $1,158.0 million as of June 30, 2021 and December 31, 2020, respectively. Net gains of $4.8 million and net losses of $12.6 million related to these contracts were recorded as a component of other income (expense), net for the three and six months ended June 30, 2021, respectively, compared to net gains of $8.3 million and $5.9 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 June 30, 2021	As of December 31, 2020
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 9.7	$ —
	Investments and other assets	7.4	—
Liability derivative instruments	Accrued expense and other	55.2	157.1
	Other long-term liabilities	—	35.7
Net Investment Hedging Instruments:			
Asset derivative instruments	Other current assets	0.4	—
Liability derivative instruments	Accrued expense and other	—	19.7
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	3.3	20.5
Liability derivative instruments	Accrued expense and other	17.2	4.7

9. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was $1,880.3 million and $1,782.3 million as of June 30, 2021 and December 31, 2020, respectively. For the three and six months ended June 30, 2021, depreciation expense totaled $54.7 million and $103.5 million, respectively, compared to $51.3 million and $99.7 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. 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 June 30, 2021 and December 31, 2020, we had approximately $618.4 million and $1.8 billion, respectively, capitalized as construction in progress related to this facility. In the second quarter of 2021, a portion of the facility received a Good Manufacturing Practice multi-product license from the Swiss Agency for Therapeutic Products, resulting in approximately $1.3 billion of fixed assets being placed in service during the second quarter of 2021.

10. Indebtedness

Exchange Offer

In February 2021 we completed our Exchange Offer of our tendered 2045 Senior Notes for our 2051 Senior Notes and cash, and an offer to purchase our tendered 2045 Senior Notes for cash.

An aggregate principal amount of approximately $624.6 million of our 2045 Senior Notes was exchanged for an aggregate principal amount of approximately $700.7 million of our 2051 Senior Notes and aggregate cash payments of approximately $151.8 million. Our Exchange Offer has been accounted for as a debt modification; as such, the cash component has been reflected as additional debt discount and is amortized as an adjustment to interest expense over the term of our 2051 Senior Notes.

In addition, we redeemed an aggregate principal amount of approximately $8.9 million of our 2045 Senior Notes for aggregate cash payments of approximately $12.1 million, excluding accrued and unpaid interest. The redemption has been accounted for as a debt extinguishment; as such, we recognized a pre-tax charge of $3.2 million upon the extinguishment of such 2045 Senior Notes. This charge, which was recognized in interest expense in other income (expense), net in our condensed consolidated statements of income for the six months ended June 30, 2021, reflects the payment of an early call premium and the write-off of the remaining unamortized original debt issuance costs and discount balances associated with such 2045 Senior Notes.

Upon settlement, we also made aggregate cash payments of approximately $13.8 million to settle all accrued and unpaid interest from the last interest payment date on our 2045 Senior Notes that were exchanged or redeemed. We incurred approximately $6.1 million of costs associated with our Exchange Offer, which was recognized in interest expense in other income (expense), net in our condensed consolidated statements of income for the six months ended June 30, 2021.

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

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. For additional information on our 2020 Senior Notes, please read *Note 12, Indebtedness*, to our consolidated financial statements included in our 2020 Form 10-K.

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. In connection with our 2.90% Senior Notes, we 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 during the second quarter of 2020. This charge, which was recognized in interest expense in other income (expense), net in our condensed consolidated statements of income and 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 8, Derivative Instruments,* to these condensed consolidated financial statements.

11. 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. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million and 3.8 million shares of our common stock at a cost of approximately $450.0 million and $1.1 billion during the three and six months ended June 30, 2021, respectively. Approximately $3.6 billion remained available under our 2020 Share Repurchase Program as of June 30, 2021.

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), which 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 9.0 million and 12.2 million shares of our common stock at a cost of approximately $2.8 billion and $3.7 billion during the three and six months ended June 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), which 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 six months ended June 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, Net of Tax	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2020	$ 1.4	$ (179.0)	$ (8.5)	$ (66.3)	$ (46.6)	$ (299.0)
Other comprehensive income (loss) before reclassifications	(2.0)	90.2	20.2	2.4	(32.6)	78.2
Amounts reclassified from accumulated other comprehensive income (loss)	0.7	48.4	(0.1)	—	—	49.0
Net current period other comprehensive income (loss)	(1.3)	138.6	20.1	2.4	(32.6)	127.2
Balance, June 30, 2021	$ 0.1	$ (40.4)	$ 11.6	$ (63.9)	$ (79.2)	$ (171.8)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedge, Net of Tax	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	(9.0)	33.2	18.6	0.9	(47.0)	(3.3)
Amounts reclassified from accumulated other comprehensive income (loss)	9.9	(50.6)	(1.8)	—	—	(42.5)
Net current period other comprehensive income (loss)	0.9	(17.4)	16.8	0.9	(47.0)	(45.8)
Balance, June 30, 2020	$ 5.1	$ (9.6)	$ 41.9	$ (31.9)	$ (186.5)	$ (181.0)

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

		Amounts Reclassified from Accumulated Other Comprehensive Income (Loss)			
		For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	Income Statement Location	2021	2020	2021	2020
Gains (losses) on securities available for sale	Other income (expense)	$ (0.4)	$ 3.9	$ (0.9)	$ (12.5)
	Income tax benefit (expense)	0.1	(0.8)	0.2	2.6
Gains (losses) on cash flow hedges	Revenue	(30.7)	23.7	(53.8)	50.7
	Operating expense	0.4	—	—	(0.1)
	Other income (expense)	(0.1)	0.1	0.1	0.2
	Income tax benefit (expense)	3.0	(0.1)	5.3	(0.2)
Gains (losses) on net investment hedge	Other income (expense)	0.1	0.9	0.1	1.8
Total reclassifications, net of tax		$ (27.6)	$ 27.7	$ (49.0)	$ 42.5

12. Earnings per Share

Basic and diluted shares outstanding used in our earnings per share calculation are calculated as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Numerator:				
Net income attributable to Biogen Inc.	$ 448.5	$ 1,542.1	$ 858.7	$ 2,941.2
Denominator:				
Weighted average number of common shares outstanding	149.7	160.6	150.8	166.7
Effect of dilutive securities:				
Time-vested restricted stock units	0.2	0.1	0.2	0.1
Market stock units	0.1	0.1	0.1	0.1
Performance stock units settled in stock	0.1	0.1	0.1	0.1
Dilutive potential common shares	0.4	0.3	0.4	0.3
Shares used in calculating diluted earnings per share	150.1	160.9	151.2	167.0

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

13. Share-based Payments

Share-based Compensation Expense

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2021**	**2020**	**2021**	**2020**
Research and development	$ 19.1	$ 15.2	$ 52.7	$ 48.5
Selling, general and administrative	40.3	30.3	85.2	73.4
Subtotal	59.4	45.5	137.9	121.9
Capitalized share-based compensation costs	(1.7)	(1.5)	(4.3)	(3.0)
Share-based compensation expense included in total cost and expense	57.7	44.0	133.6	118.9
Income tax effect	(10.9)	(7.0)	(24.9)	(20.3)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 46.8	$ 37.0	$ 108.7	$ 98.6

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2021**	**2020**	**2021**	**2020**
Market stock units	$ 9.3	$ 7.4	$ 25.8	$ 26.5
Time-vested restricted stock units	40.4	34.5	83.2	72.0
Cash settled performance units	—	(0.1)	—	(1.7)
Performance units	—	—	—	(0.1)
Performance stock units settled in stock	3.0	2.1	9.3	12.4
Performance stock units settled in cash	3.4	(4.0)	9.4	4.9
Employee stock purchase plan	3.3	5.6	10.2	7.9
Subtotal	59.4	45.5	137.9	121.9
Capitalized share-based compensation costs	(1.7)	(1.5)	(4.3)	(3.0)
Share-based compensation expense included in total cost and expense	$ 57.7	$ 44.0	$ 133.6	$ 118.9

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

14. Income Taxes

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 18, Litigation,* to these condensed consolidated financial statements.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition.

As of December 31, 2020, we 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 $1.7 billion and reduced the value of deferred tax liabilities associated with global intangible low-taxed income (GILTI) and tax credits by approximately $1.6 billion. We continue to assess the realizability of these deferred tax assets and have recorded an increase in these deferred tax assets by approximately $92.6 million and an increase in these deferred tax liabilities by approximately $88.7 million for the three and six months ended June 30, 2021.

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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Statutory rate	21.0 %	21.0 %	21.0 %	21.0 %
State taxes	1.3	0.4	1.1	0.5
Taxes on foreign earnings	(7.7)	(3.4)	(9.1)	(3.7)
Tax credits	(2.9)	(1.0)	(3.3)	(1.0)
Purchased intangible assets	(0.8)	0.2	(0.1)	0.2
TECFIDERA impairment	—	2.7	—	1.5
GILTI	1.5	1.5	1.3	1.1
Neurimmune tax impacts	(83.1)	(0.2)	(46.3)	(0.2)
Other	0.4	0.7	0.6	0.4
Effective tax rate	(70.3)%	21.9 %	(34.8)%	19.8 %

Changes in Tax Rate

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in our effective tax rate were primarily due to a current year deferred tax benefit in Switzerland resulting from the accelerated approval of ADUHELM by the FDA in the U.S. We recorded a net deferred tax asset of approximately $500.0 million. The net deferred tax asset is comprised of approximately $875.0 million of gross deferred tax asset, reduced by approximately $375.0 million of unrecognized tax benefit discussed below. The deferred tax benefit relates to Neurimmune SubOne AG's (Neurimmune) tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc. For additional information on our collaboration arrangement with Neurimmune, please read *Note 17, Investments in Variable Interest Entities*, to these condensed consolidated financial statements.

In addition, the decreases in our effective tax rate, excluding the impact of the Neurimmune deferred tax asset discussed above, were primarily due to the change in the territorial mix of our profitability, which included the effect of generic competition for TECFIDERA in the U.S. market. Our 2020 effective tax rate reflected an 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 six months ended June 30, 2021, our 2021 effective tax rate reflects a decrease related to the non-cash tax effects of changes in the value of our equity investments, where we recorded a reduction of value in 2021. The tax effects of this change in value of our equity investments were recorded discretely, as the changes in value of equity investments cannot be forecasted.

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 2017 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.

As of June 30, 2021, we increased our gross unrecognized tax benefits by approximately $375.0 million, related to a deferred tax asset for Swiss tax purposes for Neurimmune's tax basis in ADUHELM, as discussed above. This unrecognized tax benefit was recorded as a reduction to the gross deferred tax asset, resulting in the net deferred tax asset discussed above, and not as a separate liability on our condensed consolidated balance sheet.

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 $20.0 million in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations.

15. Other Consolidated Financial Statement Detail

Other Income (Expense), Net

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2021**	**2020**	**2021**	**2020**
Interest income	$ 2.7	$ 7.6	$ 5.6	$ 32.0
Interest expense	(56.4)	(66.0)	(121.1)	(110.3)
Gain (loss) on investments, net	153.9	106.8	(282.7)	29.5
Foreign exchange gains (losses), net	(0.8)	10.4	(9.4)	(8.5)
Other, net	(3.0)	4.2	(2.9)	(0.2)
Total other income (expense), net	$ 96.4	$ 63.0	$ (410.5)	$ (57.5)

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 June 30, 2021, net unrealized gains and realized gains on our holdings in equity securities were approximately $153.9 million and $0.4 million, respectively, compared to net unrealized gains and realized gains (losses) of $102.9 million and zero, respectively, in the prior year comparative period. The net unrealized gains recognized during the three months ended June 30, 2021, primarily reflect an increase in the fair value of Denali common stock of approximately $263.0 million, partially offset by decreases in the fair value of Ionis, Sangamo and Sage common stock of approximately $105.8 million.

For the six months ended June 30, 2021, net unrealized losses and realized gains on our holdings in equity securities were approximately $288.4 million and $6.6 million, respectively, compared to net unrealized gains and realized gains (losses) of $42.0 million and zero, respectively, in the prior year comparative period. The net unrealized losses recognized during the six months ended June 30, 2021, primarily reflect decreases in the fair value of Ionis, Sangamo, Denali and Sage common stock of approximately $284.8 million.

The following table summarizes our gain (loss) on investments, net that relates to our equity securities held as of June 30, 2021 and 2020:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2021**	**2020**	**2021**	**2020**
Net gains (losses) recognized during the period on equity securities	$ 154.3	$ 102.9	$ (281.8)	$ 42.0
Less: Net gains (losses) realized during the period on equity securities	0.4	—	6.6	—
Unrealized gains (losses) recognized during the period on equity securities	$ 153.9	$ 102.9	$ (288.4)	$ 42.0

Accrued Expense and Other

Accrued expense and other consists of the following:

(In millions)	As of June 30, 2021	As of December 31, 2020
Revenue-related reserves for discounts and allowances	$ 1,042.1	$ 1,080.6
Collaboration expense	383.4	389.9
Employee compensation and benefits	242.5	333.8
Royalties and licensing fees	240.3	218.5
Derivative liabilities	72.4	181.5
Current portion of contingent consideration obligations	—	149.6
Other	760.3	791.4
Total accrued expense and other	$ 2,741.0	$ 3,145.3

Other Long-term Liabilities

Other long-term liabilities were $1,356.4 million and $1,329.6 million as of June 30, 2021 and December 31, 2020, respectively, and included accrued income taxes totaling $652.7 million and $709.9 million, respectively.

16. Collaborative and Other Relationships

Eisai Co., Ltd.

Lecanemab Collaboration

We have a collaboration agreement with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize lecanemab (BAN2401), an anti-amyloid antibody, and elenbecestat, the oral BACE (base amyloid cleaving enzyme) inhibitor, two Eisai product candidates for the potential treatment of Alzheimer's disease (the Lecanemab 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 lecanemab and all costs, including research, development, sales and marketing expense, are shared equally between us and Eisai. If lecanemab receives marketing approval, we and Eisai will co-promote lecanemab and share profits equally. In addition, the Lecanemab Collaboration provides both parties with certain rights and obligations in the event of a change in control of either party.

The Lecanemab Collaboration also provided Eisai with an option to jointly develop and commercialize ADUHELM (aducanumab) (ADUHELM 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 ADUHELM Option and we entered into a new collaboration agreement for the joint development and commercialization of ADUHELM (aducanumab) (the ADUHELM Collaboration Agreement).

Eisai may exercise the Anti-Tau Option after completion of the Phase 1 clinical trial of such anti-tau monoclonal antibody. If Eisai exercises its Anti-Tau Option, we will receive an upfront payment from Eisai and will be entitled to additional development and commercial milestone payments. Eisai has not yet exercised its Anti-Tau Option.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Total development expense incurred by the collaboration related to the advancement of lecanemab and elenbecestat	$ 62.2	$ 33.9	$ 117.7	$ 77.5
Biogen's share of lecanemab and elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	31.1	17.0	58.8	38.7
Total sales and marketing expense incurred by the Lecanemab Collaboration	4.3	1.4	10.0	6.3
Biogen's share of lecanemab and elenbecestat sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	2.1	0.7	5.0	3.2

For additional information on our Lecanemab Collaboration, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2020 Form 10-K.

ADUHELM Collaboration Agreement

Under the ADUHELM Collaboration Agreement, we lead the ongoing development of ADUHELM, and we and Eisai will co-promote ADUHELM with a region-based profit split. Beginning January 1, 2019, Eisai is reimbursing us for 45.0% of development costs incurred by the collaboration for the advancement of ADUHELM (ADUHELM 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 ADUHELM in patients with early Alzheimer's disease. 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 and subsequently paid approximately $45.0 million related to the termination of various clinical trials and research and development contracts net of the expected 45.0% Eisai reimbursement of development costs incurred under the ADUHELM Collaboration Agreement.

In October 2019 we and Eisai announced that we planned to pursue regulatory approval for ADUHELM in the U.S. A new analysis of a larger dataset from these trials, conducted in scientific collaboration with the FDA, showed that the Phase 3 EMERGE trial met its pre-specified primary and secondary endpoints. In July 2020 we completed the submission of a Biologics License Application (BLA) for the approval of ADUHELM to the FDA and made a $75.0 million milestone payment to Neurimmune. We recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone payment.

In June 2021 ADUHELM was granted accelerated approval by the FDA for the treatment of Alzheimer's disease and had its first commercial sale. As a result of the launch of ADUHELM in the U.S., we made a $100.0 million milestone payment to Neurimmune. For the three and six months ended June 30, 2021, we recognized net profit-sharing income of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment.

Sales and marketing expense are shared in proportion to the same region-based profit split that is utilized to co-promote ADUHELM. A summary of development expense, sales and marketing expense and milestone payments related to the ADUHELM Collaboration Agreement is as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2021**	**2020**	**2021**	**2020**
Total ADUHELM development expense	$ 42.1	$ 35.9	$ 89.1	$ 55.0
Biogen's share of ADUHELM development expense reflected in research and development expense in our condensed consolidated statements of income	23.2	19.7	49.0	30.3
Total ADUHELM sales and marketing expense incurred by the ADUHELM Collaboration Agreement	125.6	45.2	237.4	67.9
Biogen's share of ADUHELM sales and marketing expense reflected in selling, general and administrative expense and collaboration profit sharing in our condensed consolidated statements of income	67.6	25.2	127.9	37.5
Total ADUHELM collaboration third party milestones	100.0	75.0	100.0	75.0
Biogen's share of reimbursement from Eisai of ADUHELM milestone payments reflected in collaboration profit sharing in our condensed consolidated statements of income	45.0	33.8	45.0	33.8

Co-promotion Profits and Losses

In the U.S. we recognize revenue on sales to third parties as a component of product revenue, net in our condensed consolidated statements of income. We also record the related cost of revenue and sales and marketing expense in our condensed consolidated statements of income as these costs are incurred. Payments made to and received from Eisai for its 45.0% share of the co-promotion profits or losses in the U.S. are recognized in collaboration profit sharing in our condensed consolidated statements of income. For the three and six months ended June 30, 2021, we recognized net profit-sharing income of $40.1 million to reflect Eisai's 45.0% sharing of the net collaboration losses in the U.S.

For additional information on the ADUHELM Collaboration Agreement, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2020 Form 10-K.

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

We have a collaboration agreement with 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 expense, 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 June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Total UCB collaboration development expense	$ 16.1	$ 6.5	$ 33.0	$ 25.5
Biogen's share of UCB development expense reflected in research and development expense in our condensed consolidated statements of income	8.1	3.2	16.5	12.7

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage to jointly develop and commercialize BIIB125 (zuranolone) for the potential treatment of major depressive disorder and postpartum depression and BIIB124 (SAGE-324) for the potential treatment of essential tremor with potential in other neurological conditions such as epilepsy.

In connection with the closing of this transaction in December 2020 we purchased $650.0 million of Sage common stock, or approximately 6.2 million shares at approximately $104.14 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 Sage common stock acquired and a charge of approximately $209.0 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Sage common stock. We also made an upfront payment of $875.0 million that was recorded as research and development expense.

We may also pay Sage development and commercial milestone payments that could total up to approximately $1.6 billion if all the specified milestones set forth in this collaboration are achieved. Both companies will share equal responsibility and costs for development as well as profits and losses for commercialization in the U.S. Outside of the U.S., we are responsible for development and commercialization, excluding Japan, Taiwan and South Korea, with respect to zuranolone and may pay Sage potential tiered royalties in the high teens to low twenties.

A summary of development and sales and marketing expense related to this collaboration is as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Total Sage collaboration development expense	$ 54.0	$ —	$ 93.8	$ —
Biogen's share of Sage development expense reflected in research and development expense in our condensed consolidated statements of income	27.0	—	46.9	—
Total Sage sales and marketing expense incurred by the collaboration	10.5	—	15.8	—
Biogen's share of Sage sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	5.2	—	7.9	—

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 have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle (ATV): ATV enabled anti-amyloid beta program and a second program utilizing its Transport Vehicle technology. Further, we have the right of first negotiation on two additional Transport Vehicle-enabled therapeutics, 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 Denali development and commercial milestone payments that could total up to approximately $1.1 billion if the milestones related to the LRRK2 program are achieved. Under this collaboration, both companies share responsibility and costs for global development based on specified percentages and we are responsible for commercialization and may pay Denali potential tiered royalties.

A summary of development expense related to this collaboration is as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2021	2020	2021	2020
Total Denali collaboration development expense	$ 10.4	$ —	$ 18.7	$ —
Biogen's share of Denali development expense reflected in research and development expense in our condensed consolidated statements of income	6.2	—	11.2	—

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 adeno-associated virus 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, of which approximately 12 million shares remain subject to transfer restrictions as of June 30, 2021. 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 Sangamo 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 collaboration and all the specified milestones set forth in this collaboration 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 Sangamo 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.

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.

Other

For the three and six months ended June 30, 2021, we recorded $77.2 million as research and development expense in our condensed consolidated statements of income related to other research and discovery related arrangements, compared to $9.6 million in the prior year comparative periods.

Samsung Bioepis Co., Ltd.

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 June 30, 2021, 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 $675.0 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.

Certain officers and affiliates of our joint venture partner, Samsung BioLogics, are currently subject to ongoing criminal proceedings that we continue to monitor. While these proceedings 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 six months ended June 30, 2021, we recognized net income on our investment of $34.3 million and $16.1 million, respectively, reflecting our share of Samsung Bioepis' operating results and amortization of basis differences, net of tax, compared to net income on our investment of $15.1 million and $0.4 million, respectively, in the prior year comparative periods.

Net income on our investment for the three and six months ended June 30, 2021, reflects a $31.2 million benefit related to the release of a valuation allowance on deferred tax assets associated with Samsung Bioepis. The valuation allowance was released in the current period based on a consideration of the positive and negative evidence, including the historic earnings of Samsung Bioepis.

As of June 30, 2021 and December 31, 2020, the carrying value of our investment in Samsung Bioepis totaled 691.6 billion South Korean won ($612.8 million) and 673.8 billion South Korean won ($620.2 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets.

2019 Development and Commercialization Agreement

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar 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 condensed 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 an option to acquire exclusive rights to commercialize these products in China.

2013 Commercial Agreement

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

We share 50.0% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit sharing in our condensed consolidated statements of income. For the three and six months ended June 30, 2021, we recognized net profit-sharing expense of $69.9 million and $138.4 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits, compared to a net profit-sharing expense of $55.4 million and $127.2 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. Revenue related to these services are reflected in revenue from collaborative and other relationships as a component of other revenue in our condensed consolidated statements of income.

Amounts payable to Samsung Bioepis related to the agreements discussed above were $158.7 million and $99.0 million as of June 30, 2021 and December 31, 2020, respectively.

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 2020 Form 10-K.

17. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

We have a collaboration and license agreement with Neurimmune for the development and commercialization of antibodies for the potential treatment of Alzheimer's disease, including ADUHELM (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 100.0% 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 15.0% reduction in the previously negotiated royalty rates payable on products

developed under the Neurimmune Agreement, including royalties payable on commercial sales of ADUHELM. 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 commercial sales of ADUHELM, by an additional 5.0%. Our royalty rates payable on products developed under the Neurimmune Agreement, including royalty rates payable on commercial sales of ADUHELM, 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.

Under the terms of the Neurimmune Agreement, we were required to pay Neurimmune a milestone payment of $75.0 million upon the regulatory filing with the FDA for the approval of ADUHELM. During the second quarter of 2020 we paid Neurimmune $75.0 million upon the completed submission of the BLA for the approval of ADUHELM to the FDA, which was recognized as a charge to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income. In addition, during the second quarter of 2020 we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone payment, which was recognized in collaboration profit sharing in our condensed consolidated statements of income.

In June 2021 ADUHELM was granted accelerated approval by the FDA. Under the terms of the Neurimmune Agreement, we were required to pay Neurimmune a milestone payment of $100.0 million related to the launch of ADUHELM in the U.S. During the second quarter of 2021 we made this $100.0 million payment, which was recognized as a charge to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income. In addition, during the second quarter of 2021 we recognized net profit-sharing income of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment, which was recognized in collaboration profit sharing in our condensed consolidated statements of income.

Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay up to $100.0 million in additional milestones to Neurimmune, which includes $50.0 million if launched in three or more countries in the European Union (E.U.) and $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the ADUHELM Collaboration Agreement with Eisai.

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 six months ended June 30, 2021 and 2020, amounts reimbursed were immaterial.

During the three and six months ended June 30, 2021, we recorded a net deferred tax asset of approximately $500.0 million. The net deferred tax asset is comprised of approximately $875.0 million of gross deferred tax asset, reduced by approximately $375.0 million of unrecognized tax benefit. The deferred tax benefit relates to Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

Excluding the impact of the Neurimmune deferred tax asset, 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 ADUHELM 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 commercial sales of ADUHELM to be shared with Eisai.

For additional information on our collaboration arrangements with Eisai, please read *Note 16, 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 June 30, 2021 and December 31, 2020, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $15.2 million and $12.8 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 2020 Form 10-K.

18. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read *Note 1, Summary of Significant Accounting Policies,* to our consolidated financial statements included in our 2020 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

ADUHELM Securities Litigation

We and certain current and former officers are named as defendants in an action filed by a shareholder on November 13, 2020, in the U.S. District Court for the Central District of California and transferred to the U.S. District Court for the District of Massachusetts in March 2021. The action alleges violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seeks a declaration of the action as a class action and an award of damages, interest and attorneys' fees. An estimate of the possible loss or range of loss cannot be made at this time. No trial date has been set. We have filed a motion to dismiss the action, which is pending.

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. The request for preliminary injunction was denied in June 2019 and the decision was affirmed on appeal in February 2021. In July 2020 the Danish Patent Board of Appeal revoked the Danish Utility Models that were the subject of Fresenius Kabi's October 2018 request for a preliminary injunction and Fresenius Kabi has appealed those revocations to Denmark's Maritime and Commercial High Court. No hearing has been scheduled in that appeal.

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 was held in May and June 2021.

In November 2018 Fresenius Kabi commenced infringement proceedings for damages and injunctive relief against Biogen GmbH in the Düsseldorf Regional Court relating to the German counterpart of the ‘510 Patent. The case has been stayed pending proceedings at the European Patent Office (EPO).

In July 2019 Gedeon Richter PLC commenced proceedings against Biogen GmbH in the Düsseldorf Regional Court alleging infringement of the German counterpart of European Patent No. 3 212 667, which was issued in September 2018 and expires in October 2035, and seeking damages and injunctive relief. A hearing has been set for November 2021.

An estimate of the possible loss or range of loss in the 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.

Samsung BioLogics Arbitration

In December 2020 we requested arbitration in the International Chamber of Commerce Court of International Arbitration against Samsung BioLogics seeking interpretation of certain provisions in the Joint Venture Agreement executed on December 6, 2011, as amended, by and between Biogen and Samsung BioLogics (the Joint Venture Agreement). Samsung BioLogics has asserted counterclaims, including breach of the Joint Venture Agreement, and seeks declaratory relief and unspecified damages. An estimate of the possible loss or range of loss cannot be made at this time. We expect a hearing in the fourth quarter of 2021.

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.

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

In 2017 to 2020, 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, Cipla Limited, 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., Shilpa Medicare Limited, Slayback Pharma LLC, Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., Sun Pharma Global FZE, Torrent Pharmaceuticals Ltd., TWi Pharmaceuticals, Inc., Windlas Healthcare Pvt. Ltd. and Zydus Pharmaceuticals (USA) Inc. (collectively, 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).

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.

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 judgments and the appeal is pending.

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

In March 2021 Biogen and Alkermes Pharma Ireland Limited filed patent infringement proceedings relating to VUMERITY Orange-Book listed patents (U.S. Patent Nos. 8,699,281, 9,090,558 and 10,080,733) pursuant to the Hatch-Waxman Act in the Delaware Court against Teva Pharmaceuticals Development, Inc. A trial date has not yet been set.

European Patent Office Oppositions

In 2016 the 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 date has been set for January 2022.

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 September 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. The Polish Patent Office dismissed the action in February 2021. In August 2020 a related entity, Polpharma Biologics S.A., also brought an action seeking to revoke the Polish ‘263 Patent in the Polish Patent Office. The action was suspended by the Polish Patent Office in April 2021.

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. A hearing in the Italian action will be held in June 2022.

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

Pharmaceutical Works Polpharma SA (Polpharma) and Mylan Ireland Ltd. (Mylan Ireland) each filed applications in the General Court of the European Union (Polpharma in October 2018 and Mylan Ireland in November 2020) seeking to annul decisions of the European Medicines Agency (EMA) refusing to validate Polpharma’s and Mylan Ireland’s respective applications to market a generic version of TECFIDERA. The EMA's refusals were on the grounds that TECFIDERA benefits from regulatory data protection. Biogen and the European Commission were granted leave to intervene in support of the EMA in the case brought by Polpharma. On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to a generic application related to TECFIDERA in the E.U. This generic application is now before the EMA, which is reassessing TECFIDERA's regulatory data protection by performing a scientific assessment pursuant to the European General Court's decision. The result of the scientific assessment of the EMA is expected in the fourth quarter of 2021. We have appealed the European General Court's decision to the European Court of Justice and the appeal is pending. The case brought by Mylan Ireland has been stayed.

Product Liability and Other Legal Proceedings

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

19. Subsequent Events

In July 2021 we entered into a license and collaboration agreement with InnoCare Pharma Limited (InnoCare) for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor for the potential treatment of MS. Orelabrutinib is currently being studied in a multi-country, placebo-controlled Phase 2 trial in relapsing-remitting MS.

Under the terms of the proposed collaboration, we will have exclusive rights to orelabrutinib in the field of MS worldwide and certain autoimmune diseases outside of China (including Hong Kong, Macau and Taiwan), while InnoCare will retain exclusive worldwide rights to orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan).

InnoCare will receive a $125.0 million upfront payment and is eligible to receive up to approximately $812.5 million in potential development milestones and potential commercial payments should the collaboration achieve certain development, commercial milestones and sales thresholds. InnoCare is also eligible to receive tiered royalties in the low to high teens on potential future net sales of any product resulting from the collaboration.

Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

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, 2020 (2020 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; ophthalmology; and neuropsychiatry. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; acute neurology; and neuropathic 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; ADUHELM for the treatment of Alzheimer's disease; and FUMADERM for the treatment of severe plaque psoriasis. We 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 2020 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 our agreements with 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. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

We seek to ensure an uninterrupted supply of medicines to our 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. In the second quarter of 2021 a portion of the facility received a Good Manufacturing Practice (GMP) multi-product license from the Swiss Agency for Therapeutic Products (SWISSMEDIC). We believe that the Solothurn facility will support our anticipated near-term needs for the manufacturing of ADUHELM and other biologic assets. In addition, we believe that the Solothurn site may provide us with the ability to further expand if we need additional large scale manufacturing capacity to support future clinical and commercial manufacturing requirements.

Our revenue depends 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 revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue 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, revenue 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 our 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.

ADUHELM (aducanumab)

U.S.

In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which we are developing in collaboration with Eisai Co., Ltd. (Eisai), based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. As part of the accelerated approval, we will conduct a confirmatory trial to verify the clinical benefit of ADUHELM in patients with Alzheimer’s disease. The FDA may withdraw approval if, among other things, the confirmatory trial fails to verify clinical benefit, ADUHELM's benefit-risk is no longer positive or we fail to comply with the conditions of the accelerated approval.

The U.S. ADUHELM product label states that treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population which was studied in clinical trials. We expect patient uptake will be gradual and we do not expect all eligible patients will be treated with ADUHELM for a variety of reasons, including appropriate patient selection criteria, a complex diagnostic and care pathway, the lack of readiness of healthcare providers and institutions to initiate treatment, concern regarding the accelerated approval of ADUHELM and its data and the ability to obtain and maintain adequate reimbursement for ADUHELM.

Under our collaboration agreement with Eisai (ADUHELM Collaboration Agreement), we and Eisai will co-promote ADUHELM with a region-based profit split, with Eisai reimbursing us for 45.0% of development and commercialization costs incurred by the collaboration for the advancement of ADUHELM in the U.S. Shipments of ADUHELM commenced during the second quarter of 2021.

We have made, and will continue to make, commercial, medical and infrastructure investments in support of activities associated with the launch of ADUHELM in the U.S., including the adding of headcount and the manufacture of pre-launch inventory.

Rest of World

In October 2020 the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application for aducanumab and in December 2020 the Ministry of Health, Labor and Welfare accepted for review the Japanese New Drug Application for aducanumab.

If we do not receive regulatory approval or are unable to successfully commercialize aducanumab in other jurisdictions, our financial condition, business and operations may be adversely affected.

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.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition.

On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to a generic application related to TECFIDERA in the European Union (E.U.). This generic application is now before the EMA, which is reassessing TECFIDERA's regulatory data protection by performing a scientific assessment pursuant to the European General Court's decision. The result of the scientific assessment of the EMA is expected in the fourth quarter of 2021. We have appealed the European General Court's decision to the European Court of Justice and the appeal is pending.

We will face TECFIDERA generic competition in the E.U. if regulatory data protection is not upheld and we expect that this would have an adverse impact on our TECFIDERA sales and our results of operations.

For additional information, please read *Note 18, Litigation,* to our condensed consolidated financial statements included in this report and the discussion under *Results of Operations - Product Revenue - Multiple Sclerosis (MS) - Fumarate* below.

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, including sales, expense, 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 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 (LHI), 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 $2.99 for the three months ended June 30, 2021, representing a decrease of 68.8% compared to $9.59 in the same period in 2020.

As described below under *Results of Operations*, our net income and diluted earnings per share attributable to Biogen Inc. for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, reflects the following:

Revenue

- Total revenue was $2,775.0 million for the second quarter of 2021, representing a $906.6 million, or 24.6%, decrease compared to $3,681.6 million in the same period in 2020.
- Product revenue, net totaled $2,236.0 million for the second quarter of 2021, representing a $559.7 million, or 20.0%, decrease compared to $2,795.7 million in the same period in 2020. This decrease was primarily due to a $597.5 million, or 28.1%, decrease in MS product revenue, partially offset by a $5.1 million, or 1.0%, increase in SPINRAZA product revenue.
    - The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market.
    - We believe that, due to the COVID-19 pandemic, there was an acceleration in sales in the first quarter of 2020, primarily in the E.U., that increased product revenue by approximately $100.0 million. During the second quarter of 2020 we believe customers began to utilize the product purchased (approximately $75.0 million) in the first quarter of 2020, which adversely affected sales in the second quarter of 2020.
- Revenue from anti-CD20 therapeutic programs totaled $440.0 million for the second quarter of 2021, representing a $38.3 million, or 8.0%, decrease compared to $478.3 million in the same period in 2020. This decrease was primarily due to a $96.1 million, or 37.6%, decrease in RITUXAN revenue, partially offset by a $48.7 million, or 23.4%, increase in royalty revenue on sales of OCREVUS. We believe that sales of RITUXAN have been adversely affected by the onset of biosimilars competition.
- Other revenue totaled $99.0 million for the second quarter of 2021, representing a 75.7% decrease from $407.6 million in the same period in 2020.
    - In the second quarter of 2020 other revenue reflects $329.4 million in revenue related to the delivery of the license for certain of our manufacturing-related intellectual property to a contract manufacturing customer.

Expense

- Total cost and expense was $2,289.3 million for the second quarter of 2021, representing a $582.2 million, or 34.1%, increase compared to $1,707.1 million in the same period in 2020.
    - In June 2021 ADUHELM was granted accelerated approval by the FDA. Under the terms of our 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 ADUHELM (as amended, the Neurimmune Agreement), we were required to pay Neurimmune a milestone payment of $100.0 million related to the launch of ADUHELM in the U.S. During the second quarter of 2021 we recognized net profit-sharing income of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment, which was recognized in collaboration profit sharing in our condensed consolidated statements of income.
    - In the second quarter of 2021 we recorded a $350.0 million impairment charge related to BIIB111 (timrepigene emparvovec) for the potential treatment of choroideremia and a $191.6 million impairment charge related to BIIB112 (cotoretigene toliparvovec) for the potential treatment of X-linked retinitis pigmentosa.
- The increase in cost and expense for the second quarter of 2021 also reflects an increase in selling, general and administrative

expense in support of the launch of ADUHELM in the U.S.

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

- We generated $1,996.3 million of net cash flows from operations for the six months ended June 30, 2021.
- Cash, cash equivalents and marketable securities totaled approximately $3,965.9 million as of June 30, 2021.
- We repurchased and retired approximately 1.6 million shares of our common stock at a cost of approximately $450.0 million during the second quarter of 2021 under a program authorized by our Board of Directors in October 2020 to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Approximately $3.6 billion remained available under our 2020 Share Repurchase Program as of June 30, 2021.

Acquisitions and Collaborative and Other Relationships

InnoCare Pharma Limited

In July 2021 we entered into a license and collaboration agreement with InnoCare Pharma Limited (InnoCare) for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor for the potential treatment of MS. Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

For additional information on our proposed collaboration with InnoCare, please read *Note 19, Subsequent Events*, to our condensed consolidated financial statements included in this report.

Other Key Developments

Exchange Offer

In February 2021 we completed a private offer to exchange (Exchange Offer) our tendered 5.200% Senior Notes due September 15, 2045 (2045 Senior Notes) for a new series of 3.250% Senior Notes due February 15, 2051 (2051 Senior Notes) and cash, and an offer to purchase our tendered 2045 Senior Notes for cash.

For additional information on our Exchange Offer, please read *Note 10, Indebtedness*, to our condensed consolidated financial statements included in this report.

North Carolina Gene Therapy Manufacturing Facility

In March 2021 we announced our plans to build a new gene therapy manufacturing facility in Research Triangle Park, North Carolina to support our growing gene therapy pipeline across multiple therapeutic areas. The new facility will be 175,000 square feet and is expected to be operational by 2023, with an estimated total investment of approximately $200.0 million.

Solothurn, Switzerland Manufacturing Facility

In May 2021 we announced that a portion of our Solothurn manufacturing facility received a GMP multi-product license from SWISSMEDIC.

For additional information on our Solothurn manufacturing facility, please read *Note 9, Property, Plant and Equipment*, to our condensed consolidated financial statements included in this report.

BIIB125 (zuranolone)

In June 2021 we and Sage Therapeutics, Inc. (Sage) announced positive Phase 3 results for BIIB125 (zuranolone) for the potential treatment of major depressive disorder (MDD) and postpartum depression (PPD).

For additional information on our collaboration arrangement with Sage, please read *Note 16, Collaborative and Other Relationships*, to our condensed consolidated financial statements included in this report.

Lecanemab (BAN2401)

In June 2021 the FDA granted Breakthrough Therapy designation for lecanemab, an anti-amyloid antibody for the potential treatment of Alzheimer's disease, which we are developing in collaboration with Eisai.

Results of Operations

Revenue

Revenue is summarized as follows:

	For the Three Months Ended June 30,					
(In millions, except percentages)	**2021**		**2020**		**$ Change**	**% Change**
Product revenue, net:						
United States	$ 977.2	35.2 %	$ 1,721.7	46.8 %	$ (744.5)	(43.2)%
Rest of world	1,258.8	45.4	1,074.0	29.1	184.8	17.2
Total product revenue, net	2,236.0	80.6	2,795.7	75.9	(559.7)	(20.0)
Revenue from anti-CD20 therapeutic programs	440.0	15.9	478.3	13.0	(38.3)	(8.0)
Other revenue	99.0	3.5	407.6	11.1	(308.6)	(75.7)
Total revenue	$ 2,775.0	100.0 %	$ 3,681.6	100.0 %	$ (906.6)	(24.6)%

	For the Six Months Ended June 30,					
(In millions, except percentages)	**2021**		**2020**		**$ Change**	**% Change**
Product revenue, net:						
United States	$ 1,877.0	34.3 %	$ 3,304.9	45.8 %	$ (1,427.9)	(43.2)%
Rest of world	2,570.7	47.0	2,395.4	33.2	175.3	7.3
Total product revenue, net	4,447.7	81.3	5,700.3	79.0	(1,252.6)	(22.0)
Revenue from anti-CD20 therapeutic programs	829.0	15.2	998.7	13.8	(169.7)	(17.0)
Other revenue	192.3	3.5	516.9	7.2	(324.6)	(62.8)
Total revenue	$ 5,469.0	100.0 %	$ 7,215.9	100.0 %	$ (1,746.9)	(24.2)%

Product Revenue

Product revenue is summarized as follows:

	For the Three Months Ended June 30,					
(In millions, except percentages)	**2021**		**2020**		**$ Change**	**% Change**
Multiple Sclerosis:						
Fumarate*	$ 578.5	25.9 %	$ 1,190.3	42.6 %	$ (611.8)	(51.4)%
Interferon**	400.4	17.9	481.4	17.2	(81.0)	(16.8)
TYSABRI	524.2	23.4	432.0	15.5	92.2	21.3
FAMPYRA	26.1	1.2	23.0	0.8	3.1	13.5
Subtotal: MS product revenue	1,529.2	68.4	2,126.7	76.1	(597.5)	(28.1)
Spinal Muscular Atrophy:						
SPINRAZA	499.7	22.3	494.6	17.7	5.1	1.0
Alzheimer's disease:						
ADUHELM***	1.6	0.1	—	—	1.6	nm
Biosimilars:						
BENEPALI	121.5	5.4	106.2	3.8	15.3	14.4
IMRALDI	55.6	2.5	44.8	1.6	10.8	24.1
FLIXABI	25.3	1.2	20.6	0.7	4.7	22.8
Subtotal: Biosimilar product revenue	202.4	9.1	171.6	6.1	30.8	17.9
Other:						
FUMADERM	3.1	0.1	2.8	0.1	0.3	10.7
Total product revenue, net	$ 2,236.0	100.0 %	$ 2,795.7	100.0 %	$ (559.7)	(20.0)%

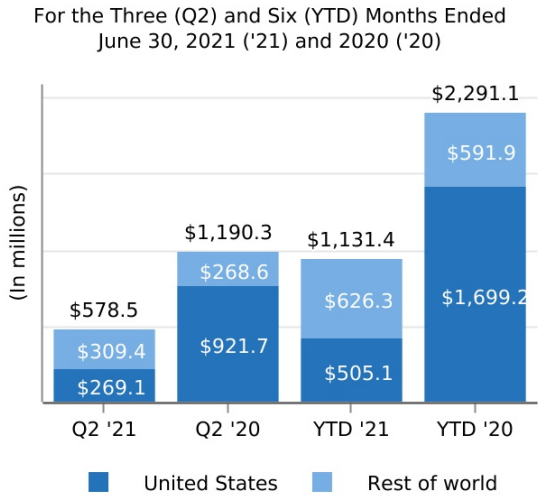
*Fumarate includes TECFIDERA and VUMERITY.
**Interferon includes AVONEX and PLEGRIDY.
***In June 2021 the FDA granted accelerated approval of ADUHELM, which became commercially available in the U.S. during the second quarter of 2021. For additional information, please read *Note 16, Collaborative and Other Relationships - Eisai Co., Ltd. - ADUHELM Collaboration Agreement*, to our condensed consolidated financial statements included in this report.
nm Not meaningful

(In millions, except percentages)	For the Six Months Ended June 30, 2021		2020		$ Change	% Change
Multiple Sclerosis:						
Fumarate*	$ 1,131.4	25.4 %	$ 2,291.1	40.2 %	$ (1,159.7)	(50.6)%
Interferon**	800.9	18.0	947.4	16.6	(146.5)	(15.5)
TYSABRI	1,027.5	23.1	954.4	16.7	73.1	7.7
FAMPYRA	52.7	1.2	51.3	1.0	1.4	2.7
Subtotal: MS product revenue	3,012.5	67.7	4,244.2	74.5	(1,231.7)	(29.0)
Spinal Muscular Atrophy:						
SPINRAZA	1,020.2	23.0	1,059.6	18.6	(39.4)	(3.7)
Alzheimer's disease:						
ADUHELM***	1.6	—	—	—	1.6	nm
Biosimilars:						
BENEPALI	243.2	5.5	239.7	4.2	3.5	1.5
IMRALDI	113.5	2.6	106.4	1.9	7.1	6.7
FLIXABI	50.8	1.1	44.3	0.7	6.5	14.7
Subtotal: Biosimilar product revenue	407.5	9.2	390.4	6.8	17.1	4.4
Other:						
FUMADERM	5.9	0.1	6.1	0.1	(0.2)	(3.3)
Total product revenue, net	$ 4,447.7	100.0 %	$ 5,700.3	100.0 %	$ (1,252.6)	(22.0)%

*Fumarate includes TECFIDERA and VUMERITY.
**Interferon includes AVONEX and PLEGRIDY.
***In June 2021 the FDA granted accelerated approval of ADUHELM, which became commercially available in the U.S. during the second quarter of 2021. For additional information, please read *Note 16, Collaborative and Other Relationships - Eisai Co., Ltd. - ADUHELM Collaboration Agreement*, to our condensed consolidated financial statements included in this report.
nm Not meaningful

Multiple Sclerosis (MS)

Fumarate



Fumarate revenue includes 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 six months ended June 30, 2021, compared to the same periods in 2020, the decreases of 70.8% and 70.3%, respectively, in U.S. Fumarate revenue were primarily due to a decrease in TECFIDERA demand as well as higher discounts and allowances as a result of multiple TECFIDERA generic entrants in the U.S. market. The decrease was partially offset by an increase in VUMERITY sales volume.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases of 15.2% and 5.8%, respectively, in rest of world Fumarate revenue were primarily due to increases in TECFIDERA sales volumes of 13.0% and 4.0%, respectively, and an increase in pricing.

We believe that, due to the COVID-19 pandemic, there was an acceleration in sales during the first quarter of 2020 that increased rest of world Fumarate revenue by approximately $28.0 million. During the second quarter of 2020 we believe customers began to utilize the product purchased (approximately $17.0 million in rest of world) in the first quarter of 2020, which adversely affected sales in the second quarter of 2020.

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.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition.

We anticipate an increase in TECFIDERA sales volume in rest of world in 2021, compared to 2020, notwithstanding the increasing competition from additional treatments for MS and potential disruptions due, directly or indirectly, to the COVID-19 pandemic.

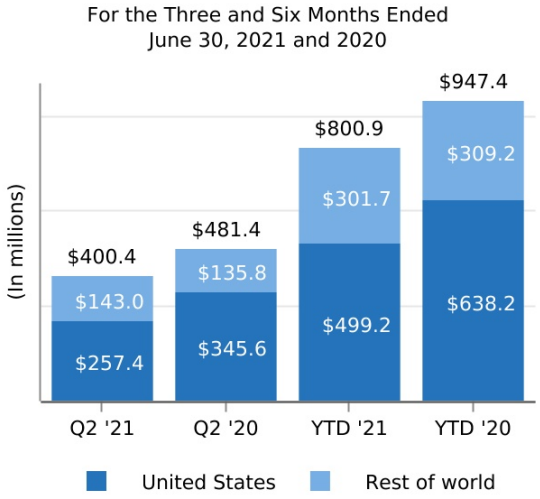
On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to a generic application related to TECFIDERA in the E.U. This generic application is now before the EMA, which is reassessing TECFIDERA's regulatory data protection by performing a scientific assessment pursuant to the European General Court's decision. The result of the scientific assessment of the EMA is expected in the fourth quarter of 2021. We have appealed the European General Court's decision to the European Court of Justice and the appeal is pending.

We will face TECFIDERA generic competition in the E.U. if regulatory data protection is not upheld and we expect that this would have an adverse impact on our TECFIDERA sales and our results of operations.

For additional information, please read *Note 18, Litigation,* to our condensed consolidated financial statements included in this report.

We expect an increase in VUMERITY sales volume driven by demand growth.

Interferon



For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases of 25.5% and 21.8%, respectively, in U.S. Interferon revenue were primarily due to decreases in Interferon sales volumes of 20.5% and 19.1%, 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.

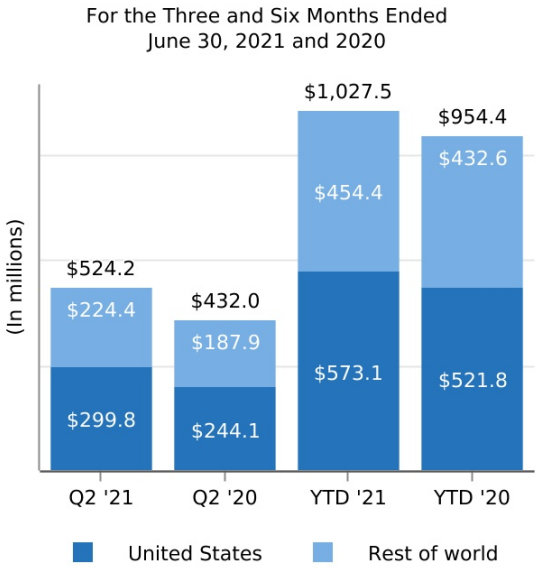
For the three months ended June 30, 2021, compared to the same period in 2020, the increase of 5.3% in rest of world Interferon revenue was primarily due to an increase in Interferon sales volumes of 6.2%.

For the six months ended June 30, 2021, compared to the same period in 2020, the decrease of 2.4% in rest of world Interferon revenue was primarily due to a decrease in pricing.

We believe that, due to the COVID-19 pandemic, there was an acceleration in sales during the first quarter of 2020 that increased rest of world Interferon revenue by approximately $25.0 million, primarily in the rest of world. During the second quarter of 2020 we believe customers began to utilize the product purchased (approximately $15.0 million in rest of world) in the first quarter of 2020, which adversely affected sales in the second quarter of 2020.

We expect that Interferon revenue will continue to decline in both the U.S. and rest of world markets in 2021, compared to 2020, as a result of increasing competition from our other MS products as well as other treatments for MS, including biosimilars, and pricing reductions in certain European markets.

TYSABRI



For the three months ended June 30, 2021, compared to the same period in 2020, the increase of 22.8% in U.S. TYSABRI revenue was primarily due to an increase in pricing and a favorable volume impact, resulting from favorable shipping dynamics.

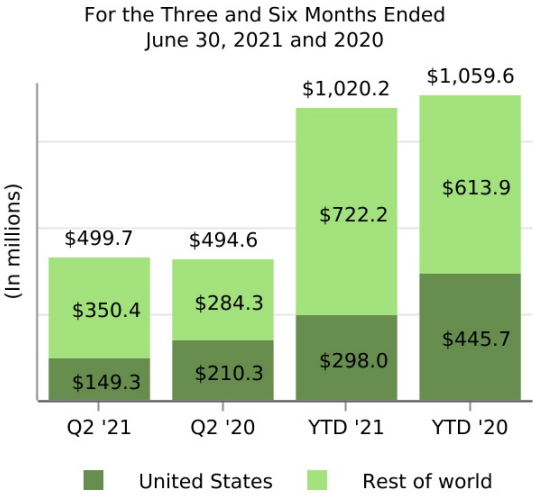
For the six months ended June 30, 2021, compared to the same period in 2020, the increase of 9.8% in U.S. TYSABRI revenue was primarily due to an increase in pricing.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases of 19.4% and 5.0%, respectively, in rest of world TYSABRI revenue were primarily due to favorable volume impacts, partially offset by decreases in pricing.

We anticipate TYSABRI sales volume to modestly increase on a global basis in 2021, compared to 2020, despite increasing competition from additional treatments for MS, including OCREVUS. We expect to continue to face price reductions in certain European markets.

Spinal Muscular Atrophy

SPINRAZA



For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases of 29.0% and 33.1%, respectively, in U.S. SPINRAZA revenue were primarily due to decreases in sales volumes resulting from increased competition.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases of 23.3% and 17.7%, respectively, in rest of world SPINRAZA revenue were primarily due to increases in sales volumes of 17.2% and 14.3%, respectively, due in part to timing of shipments in developing markets and increases in patients. The increases were also due to the favorable impact of foreign currency exchange of 6.7% and 4.9%, respectively.

In 2021 we expect that SPINRAZA revenue will be subject to increased competition resulting in higher discontinuations and a lower rate of new patient starts combined with the impact of loading dose dynamics as patients transition to dosing once every four months and lower prices in certain rest of world countries.

We face competition from a gene therapy product and an oral product. We expect that we will experience competition from both products in additional jurisdictions in the future, which may adversely affect our sales of SPINRAZA.

For additional 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 2020 Form 10-K.

Alzheimer's Disease

ADUHELM

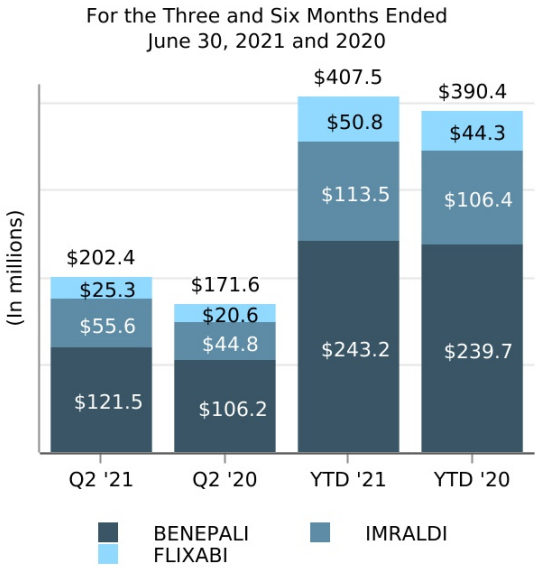
In June 2021 the FDA granted accelerated approval of ADUHELM, which became commercially available in the U.S. during the second quarter of 2021. For the three and six months ended June 30, 2021, U.S. ADUHELM revenue was approximately $1.6 million.

In 2021 we expect modest sales of ADUHELM in the U.S.

For additional information on our collaboration arrangements with Eisai, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Biosimilars

BENEPALI, IMRALDI and FLIXABI



For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases of 17.9% and 4.4%, respectively, in biosimilar revenue were primarily due to the favorable impact of higher volumes and foreign currency exchange, partially offset by decreases in pricing.

We believe that, due to the COVID-19 pandemic, there was an acceleration in sales during the first quarter of 2020 that increased biosimilar revenue by approximately $15.0 million. During the second quarter of 2020 we believe customers began to utilize the product purchased (approximately $9.0 million) in the first quarter of 2020, which adversely affected sales in the second quarter of 2020.

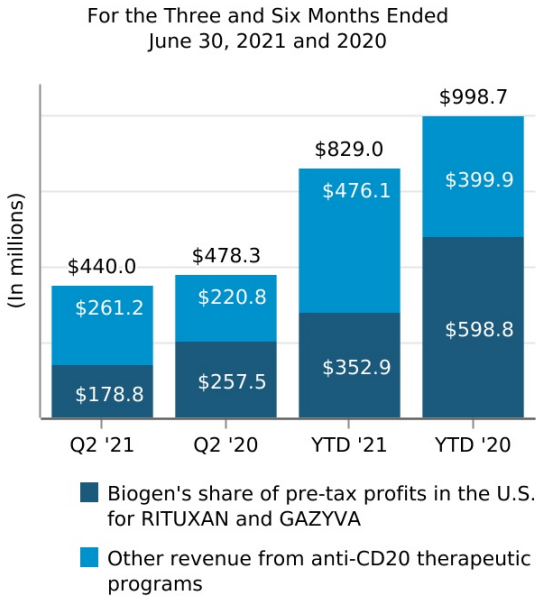
In 2021 we expect modest revenue growth for our biosimilars business. We expect to continue to face price reductions in certain European countries.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Revenue 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 revenue 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 June 30,	
(In millions)	**2021**	**2020**
Product revenue, net	$ 554.1	$ 807.9
Cost and expense	77.9	121.5
Pre-tax profits in the U.S.	476.2	686.4
Biogen's share of pre-tax profits	$ 178.8	$ 257.5

(In millions)	For the Six Months Ended June 30, 2021	2020
Product revenue, net	$ 1,105.5	$ 1,886.1
Cost and expense	152.1	268.9
Pre-tax profits in the U.S.	953.4	1,617.2
Biogen's share of pre-tax profits	$ 352.9	$ 598.8

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in U.S. product revenue, net were primarily due to decreases in sales volumes of RITUXAN in the U.S. of 29.8% and 40.0%, respectively, primarily due to the onset of competition from multiple biosimilar products.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, product revenue, net also reflected increases in GAZYVA sales volume of 28.9% and 13.5%, respectively.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in collaboration costs and expense were primarily due to lower cost of sales on RITUXAN.

We are aware of several other anti-CD20 molecules, including biosimilar products, that have recently been approved and are competing with RITUXAN and GAZYVA in the oncology and other markets. In November 2019, January 2020 and January 2021 biosimilar products referencing RITUXAN were launched in the U.S. and are being offered at lower prices. This competition has had a significant adverse impact on the pre-tax profits of our collaboration arrangements with Genentech, as the sales of RITUXAN have decreased substantially compared to prior periods. We expect that biosimilar competition will continue to increase as these products capture additional market share and that this will have a significant adverse impact on our co-promotion profits in the U.S. in future years.

Other Revenue from Anti-CD20 Therapeutic Programs

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

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases in other revenue from anti-CD20 therapeutic programs were primarily due to sales growth of OCREVUS. Royalty revenue recognized on sales of OCREVUS for the three and six months ended June 30, 2021, totaled $257.0 million and $466.3 million, respectively, compared to $208.2 million and $370.5 million, respectively, in the prior year comparative periods.

OCREVUS royalty revenue is 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 revenue 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 revenue from anti-CD20 therapeutic programs, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2020 Form 10-K.

Other Revenue

Other revenue is summarized as follows:

(In millions, except percentages)	For the Three Months Ended June 30, 2021		2020		% Change	$ Change
Revenue from collaborative and other relationships	$ 5.5	5.6 %	$ 5.0	1.2 %	10.0 %	$ 0.5
Other royalty and corporate revenue	93.5	94.4	402.6	98.8	(76.8)	(309.1)
Total other revenue	$ 99.0	100.0 %	$ 407.6	100.0 %	(75.7)%	$ (308.6)

(In millions, except percentages)	For the Six Months Ended June 30, 2021		2020		% Change	$ Change
Revenue from collaborative and other relationships	$ 9.4	4.9 %	$ 8.9	1.7 %	5.6 %	$ 0.5
Other royalty and corporate revenue	182.9	95.1	508.0	98.3	(64.0)	(325.1)
Total other revenue	$ 192.3	100.0 %	$ 516.9	100.0 %	(62.8)%	$ (324.6)

Revenue from Collaborative and Other Relationships

Revenue from collaborative and other relationships primarily includes royalty revenue on biosimilar products from Samsung Bioepis.

For additional information on our collaborative arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Other Royalty and Corporate Revenue

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

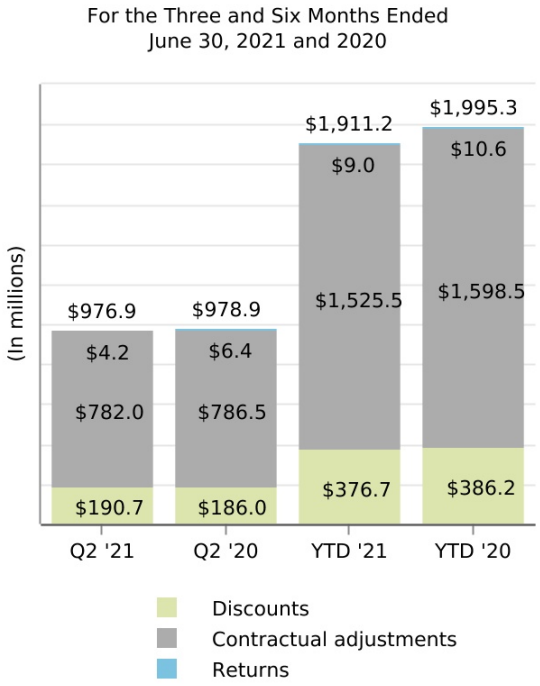
For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in other corporate revenue were primarily due to higher contract manufacturing revenue during the second quarter of 2020, resulting from $329.4 million in revenue related to the delivery of the license for certain of our manufacturing-related intellectual property to a contract manufacturing customer.

Reserves for Discounts and Allowances

Revenue from product sales is 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 revenue are summarized as follows:



For the three and six months ended June 30, 2021, reserves for discounts and allowances as a percentage of gross product revenue were 29.2% and 28.6%, respectively, compared to 26.0% and 25.8%, respectively, in the prior year comparative periods.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three months ended June 30, 2021, compared to the same period in 2020, the increase in discounts was primarily driven by higher discount rates, partially offset by a decrease in gross sales.

For the six months ended June 30, 2021, compared to the same period in 2020, the decrease in discounts was primarily driven by a decrease in gross sales.

Contractual Adjustments

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

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in contractual adjustments were primarily caused by lower TECFIDERA sales in the U.S., resulting in lower Medicaid and managed care rebates, partially offset by pharmacy rebates.

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 revenue is recognized, resulting in a reduction to product sales.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, return reserves were relatively consistent.

For additional information on our revenue reserves, please read *Note 3, Revenue,* to our condensed consolidated financial statements included in this report.

Cost and Expense

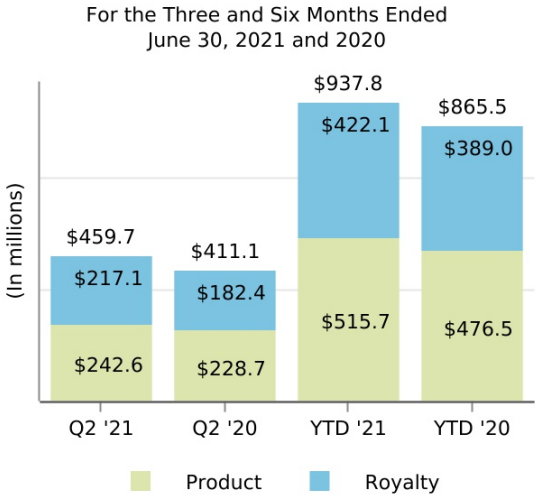
A summary of total cost and expense is as follows:

	For the Three Months Ended June 30,			
(In millions, except percentages)	**2021**	**2020**	**% Change**	**$ Change**
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 459.7	$ 411.1	11.8 %	$ 48.6
Research and development	585.1	647.6	(9.7)	(62.5)
Selling, general and administrative	637.3	555.1	14.8	82.2
Amortization and impairment of acquired intangible assets	604.1	61.5	882.3	542.6
Collaboration profit sharing	(15.2)	21.8	(169.7)	(37.0)
(Gain) loss on fair value remeasurement of contingent consideration	0.3	10.0	(97.0)	(9.7)
Acquired in-process research and development	18.0	—	nm	18.0
Total cost and expense	$ 2,289.3	$ 1,707.1	34.1 %	$ 582.2

	For the Six Months Ended June 30,			
(In millions, except percentages)	**2021**	**2020**	**% Change**	**$ Change**
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 937.8	$ 865.5	8.4 %	$ 72.3
Research and development	1,099.3	1,123.9	(2.2)	(24.6)
Selling, general and administrative	1,232.3	1,125.2	9.5	107.1
Amortization and impairment of acquired intangible assets	702.2	133.0	428.0	569.2
Collaboration profit sharing	53.3	93.5	(43.0)	(40.2)
(Gain) loss on fair value remeasurement of contingent consideration	(33.5)	5.5	(709.1)	(39.0)
Acquired in-process research and development	18.0	75.0	(76.0)	(57.0)
Total cost and expense	$ 4,009.4	$ 3,421.6	17.2 %	$ 587.8

[nm] Not meaningful

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



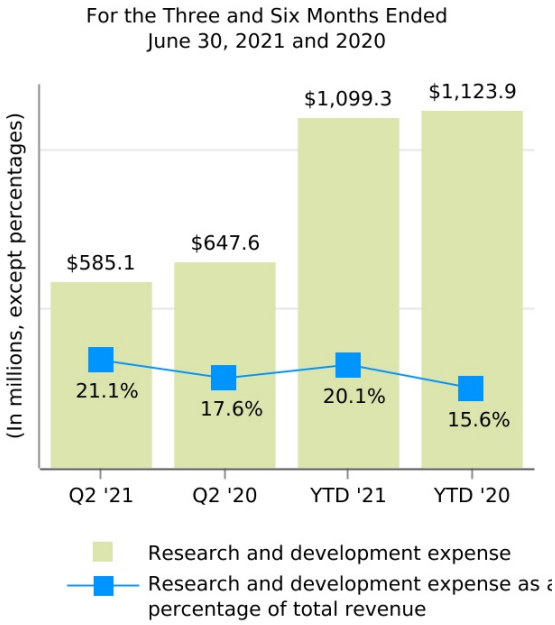
Product Cost of Sales

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases in product cost of sales were primarily due to product mix and higher cost of sales associated with contract manufacturing agreements.

Royalty Cost of Sales

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases in royalty cost of sales were 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 consists 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 and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in research and development expense were primarily due to $208.0 million in charges recognized upon the closing of our collaboration with Sangamo Therapeutics, Inc. (Sangamo) in the second quarter of 2020, partially offset by an increase in spending related to the EMBARK redosing study for aducanumab, the development of zuranolone for the potential treatment of MDD and PPD, the development of BIIB124 (SAGE-324) for the potential treatment of essential tremor, which we are developing in collaboration with Sage, and the impact of business development license transactions.

Early Stage Programs

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in spending related to our early stage programs were primarily due to decreases in costs associated with:

- the discontinuation of opicinumab (anti-LINGO) in MS;
- the discontinuation of BIIB054 (cinpanemab) in Parkinson's disease;
- the advancement of dapirolizumab pego, an anti-CD40L pegylated Fab that we are developing in collaboration with UCB, for the potential treatment of systemic lupus erytheatosus (SLE) into late stage; and
- the advancement of BIIB059 (anti-BDCA2) for the potential treatment of SLE into late stage.

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

- an increase in spending in the development of BIIB124 for the potential treatment of essential tremor;
- an increase in spending in the development of BIIB122 (DNL151) for the potential treatment of Parkinson's disease, which we are developing in collaboration with Denali Therapeutics Inc. (Denali); and
- the close out costs related to the discontinuation of gosuranemab (BIIB092) in Alzheimer's disease.

Late Stage Programs

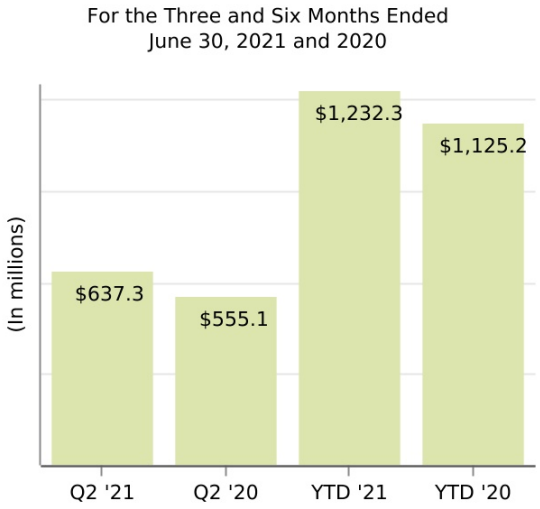
For the three and six months ended June 30, 2021, compared to the same periods in 2020, the increases in spending associated with our late stage programs were primarily due to:

- an increase in spending in the development of zuranolone for the potential treatment of MDD and PPD;
- the advancement of dapirolizumab pego for the potential treatment of SLE into late stage;
- the advancement of BIIB059 for the potential treatment of SLE into late stage; and
- an increase in spending related to lecanemab.

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

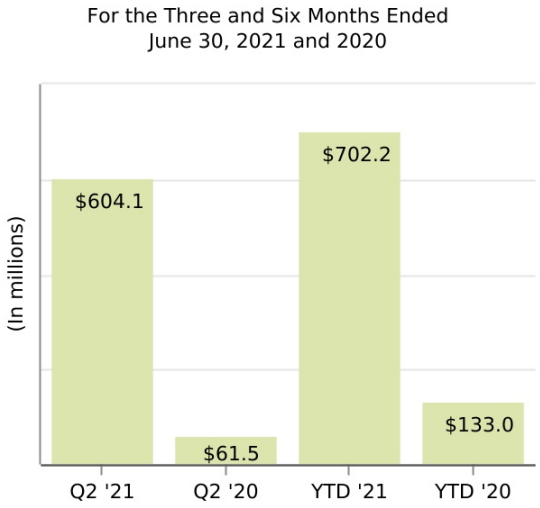
For additional information on our collaboration arrangements with Eisai, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Selling, General and Administrative



For the three and six months ended June 30, 2021, compared to the same periods in 2020, selling, general and administrative expense increased 14.8% and 9.5%, respectively, primarily due to increases in personnel in support of the launch of ADUHELM in the U.S.

Amortization and Impairment of Acquired Intangible Assets



Our amortization expense is based on the economic consumption and impairment of intangible assets. Our most significant amortizable 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 six months ended June 30, 2021, amortization and impairment of acquired intangible assets reflects a $350.0 million

impairment charge related to BIIB111 for the potential treatment of choroideremia and a $191.6 million impairment charge related to BIIB112 for the potential treatment of X-linked retinitis pigmentosa.

For the six months ended June 30, 2021, amortization and impairment of acquired intangible assets also reflects a $44.3 million impairment charge related to vixotrigine (BIIB074) for the potential treatment of trigeminal neuralgia (TGN).

For the three and six months ended June 30, 2020, we had no impairment charges.

We monitor events and expectations regarding product performance. If new information indicates that the assumptions underlying our most recent analysis are substantially different than those utilized in our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenue 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

In-process research and development (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 revenue 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 may result in a significant change to our valuation of our IPR&D assets.

Vixotrigine

In the periods since we acquired vixotrigine, there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN and for the potential treatment of diabetic painful neuropathy (DPN), another form of neuropathic pain. We have engaged with the FDA regarding the design of the Phase 3 studies of vixotrigine for the potential treatment of TGN and DPN and now plan to perform an additional clinical trial of vixotrigine before initiating a Phase 3 study of DPN.

The performance of this additional clinical trial has delayed the initiation of the Phase 3 studies of vixotrigine for the potential treatment of TGN, and, as a result, we recognized an impairment charge of $44.3 million related to vixotrigine for the potential treatment of TGN during the first quarter of 2021. As of June 30, 2021, the carrying value associated with our remaining vixotrigine IPR&D assets was $136.0 million, all of which is related to DPN.

BIIB111 and BIIB112

During the fourth quarter of 2020 we recognized an impairment charge of $115.0 million related to BIIB111 as a result of third-party manufacturing delays that impacted the timing and increased the costs associated with advancing BIIB111 through Phase 3 development.

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 did not meet its primary or key secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of $350.0 million during the second quarter of 2021, which resulted in a reduction of the IPR&D asset from $365.0 million to $15.0 million.

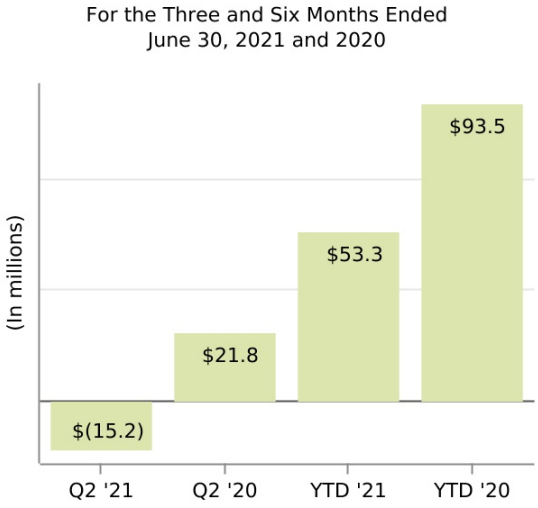
During the second quarter of 2021 we announced that our Phase 2/3 XIRIUS study of BIIB112 did not meet its primary endpoint; however, positive trends were observed across several clinically relevant prespecified secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of $191.6 million during the second quarter of 2021, which resulted in a reduction of the IPR&D asset from $220.0 million to $28.4 million.

We are evaluating the results of our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112, including evaluation of any future development activities we may perform. Our estimates of the current fair values of the BIIB111 and BIIB112 programs were derived by using a discounted, probability-weighted calculation of future estimated

cash flows associated with the programs under multiple scenarios, including the possibility that we will cease further development of BIIB111 and/or BIIB112, which could result in further impairment of these assets. The key assumptions in our estimates are the amount and timing of revenue, probability of technical and regulatory success, discount rate and clinical data associated with the programs.

In addition, we have entered into third-party manufacturing agreements related to the BIIB111 and BIIB112 programs and we may incur a financial penalty if these agreements are terminated. Should we decide to terminate either or both of these programs and/or manufacturing agreements, we will likely incur impairment charges related to the remaining book value of the applicable program as well as charges up to, in the aggregate, approximately $30.0 million related to our inventory arrangements and other costs associated with discontinuing these programs.

Collaboration Profit Sharing



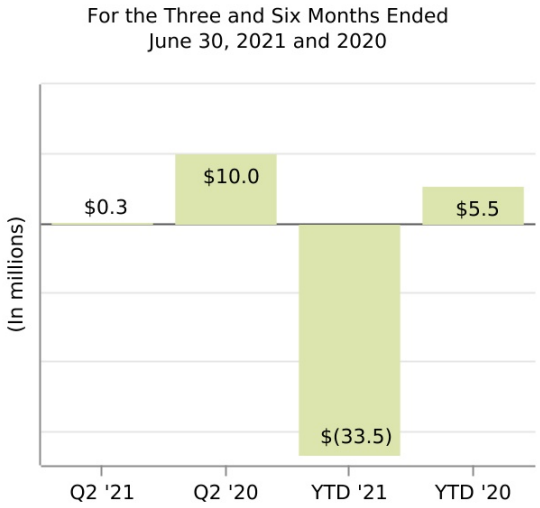
Collaboration profit sharing primarily includes Samsung Bioepis' 50.0% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis and, beginning in the second quarter of 2021, Eisai's 45.0% share of income and expenses in the U.S. related to the ADUHELM Collaboration Agreement.

For the three and six months ended June 30, 2021, we recognized net profit-sharing expense of $69.9 million and $138.4 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits compared to a net profit sharing expense of $55.4 million and $127.2 million, respectively, in the prior year comparative periods. For the three and six months ended June 30, 2021, we also recognized net profit-sharing income of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment made to Neurimmune related to the launch of ADUHELM in the U.S., and net profit-sharing income of $40.1 million to reflect Eisai's 45.0% share of loss related to the ADUHELM Collaboration Agreement.

For the three and six months ended June 30, 2020, we also recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone payment made to Neurimmune related to the submission of the Biologics License Application (BLA) for the approval of ADUHELM to the FDA.

For additional information on our collaboration arrangements with Samsung Bioepis and Eisai, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

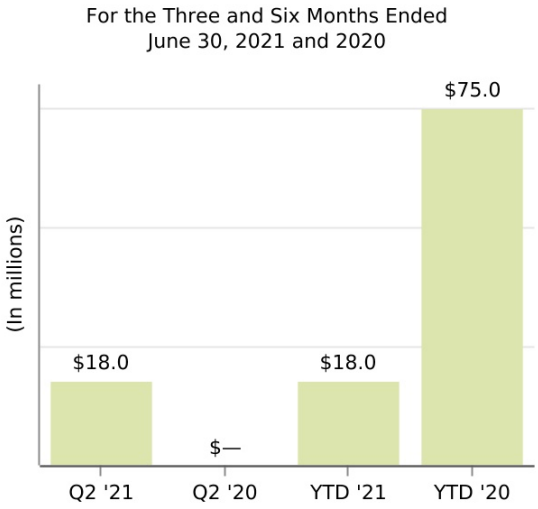
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration



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 six months ended June 30, 2021, compared to the same periods in 2020, changes in the fair value of our contingent consideration obligations were primarily due to delays in the expected timing of the achievement of certain remaining developmental milestones related to our vixotrigine programs.

Acquired In-Process Research and Development

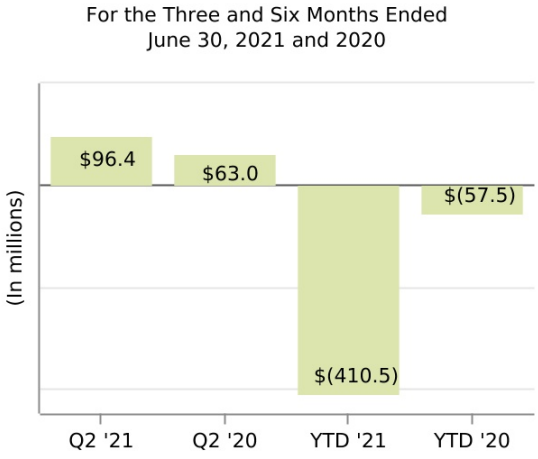


BIIB118 Acquisition

In March 2020 we acquired BIIB118 (CK1 inhibitor) for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). 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 June 30, 2021, compared to the same period in 2020, the change in other income (expense), net primarily reflects net unrealized gains on our holdings in equity securities.

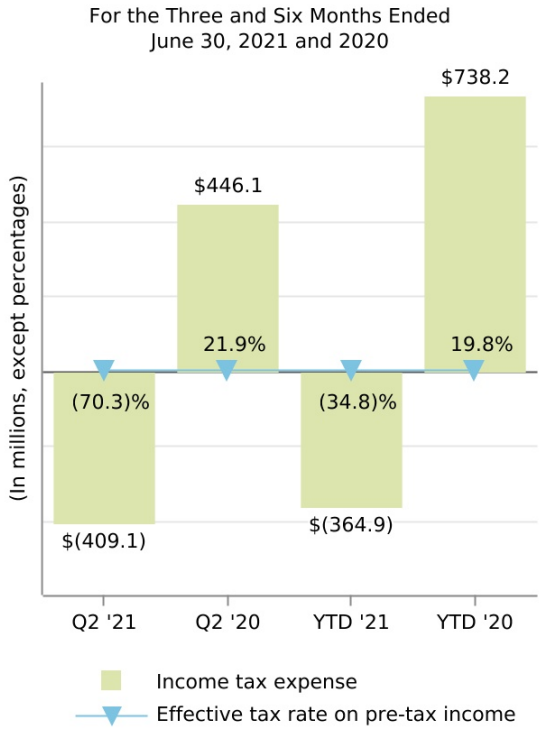
For the six months ended June 30, 2021, compared to the same period in 2020, the change in other income (expense), net primarily reflects net unrealized losses on our holdings in equity securities.

For the three months ended June 30, 2021, net unrealized gains and realized gains on our holdings in equity securities were approximately $153.9 million and $0.4 million, respectively, compared to net unrealized gains and realized gains (losses) of $102.9 million and zero, respectively, in the prior year comparative period. The net unrealized gains recognized during the three months ended June 30, 2021, primarily reflect an increase in the fair value of Denali common stock of approximately $263.0 million, partially offset by decreases in the fair value of Ionis, Sangamo and Sage common stock of approximately $105.8 million.

For the six months ended June 30, 2021, net unrealized losses and realized gains on our holdings in equity securities were approximately $288.4 million and $6.6 million, respectively, compared to net unrealized gains and realized gains (losses) of $42.0 million and zero, respectively, in the prior year comparative period. The net unrealized losses recognized during the six months ended June 30, 2021, primarily reflect decreases in the fair value of Ionis, Sangamo, Denali and Sage common stock of approximately $284.8 million.

We expect a moderate increase in interest expense for 2021, compared to 2020, primarily due to lower interest being capitalized as a result of assets being placed into service during 2021.

Income Tax (Benefit) 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 expense, the levels of certain deductions and credits, acquisitions and licensing transactions.

For the three and six months ended June 30, 2021, compared to the same periods in 2020, the decreases in our effective tax rate were primarily due to a current year deferred tax benefit in Switzerland resulting from the accelerated approval of ADUHELM by the FDA in the U.S. We recorded a net deferred tax asset of approximately $500.0 million. The net deferred tax asset is comprised of approximately $875.0 million of gross deferred tax asset, reduced by approximately $375.0 million of unrecognized tax benefit discussed below. The deferred tax benefit relates to Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

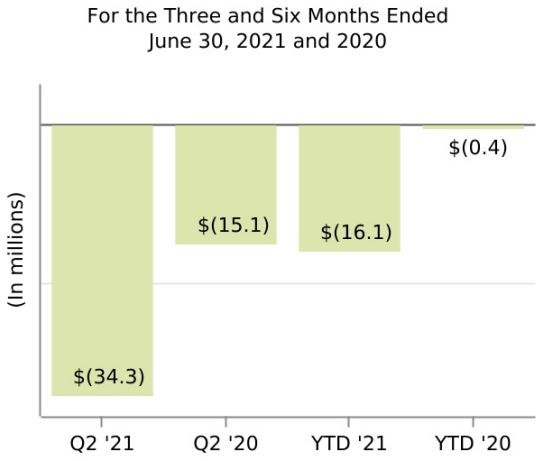
For additional information on our collaboration arrangement with Neurimmune, please read *Note 17, Investments in Variable Interest Entities*, to our condensed consolidated financial statements included in this report.

In addition, the decreases in our effective tax rate, excluding the impact of the Neurimmune deferred tax asset discussed above, were primarily due to the change in the territorial mix of our profitability, which included the effect of generic competition for TECFIDERA in the U.S. market. Our 2020 effective tax rate reflected an 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 the six months ended June 30, 2021, our 2021 effective tax rate reflects a decrease related to the non-cash tax effects of changes in the value of our equity investments, where we recorded a reduction of value in 2021. The tax effects of this change in value of our equity investments were recorded discretely, as the changes in value of equity investments cannot be forecasted.

For additional information on our income taxes please read *Note 14, 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. As of June 30, 2021, 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. We recognize amortization on certain basis differences resulting from our November 2018 investment.

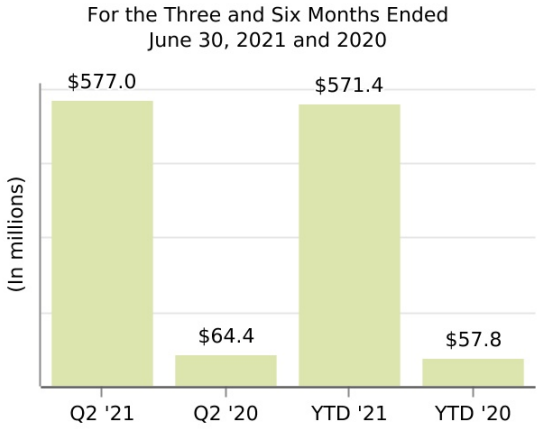
Certain officers and affiliates of our joint venture partner, Samsung BioLogics, are currently subject to ongoing criminal proceedings that we continue to monitor. While these proceedings could impact the operations of Samsung Bioepis and its business, we have assessed the value of our investment in 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 six months ended June 30, 2021, we recognized net income on our investment of $34.3 million and $16.1 million, respectively, reflecting our share of Samsung Bioepis' operating results and amortization of basis differences, net of tax, compared to net income on our investment of $15.1 million and $0.4 million, respectively, in the prior year comparative periods.

Net income on our investment for the three and six months ended June 30, 2021, reflects a $31.2 million benefit related to the release of a valuation allowance on deferred tax assets associated with Samsung Bioepis. The valuation allowance was released in the current period based on a consideration of the positive and negative evidence, including the historic earnings of Samsung Bioepis.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Noncontrolling Interests



For the three and six months ended June 30, 2021, compared to the same periods in 2020, we recorded a current year deferred tax benefit associated with the accelerated approval of ADUHELM by the FDA in the U.S. We recorded a net deferred tax asset of approximately $500.0 million related to Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

For the three and six months ended June 30, 2021, the changes in net income (loss) attributable to noncontrolling interests, net of tax was also due to the $100.0 million milestone payment to Neurimmune related to the launch of ADUHELM in the U.S. during the second quarter of 2021.

For the three and six months ended June 30, 2020, the changes in net income (loss) attributable to noncontrolling interests, net of tax were primarily due to the $75.0 million milestone payment to Neurimmune related to the submission of the BLA for the approval of ADUHELM to the FDA.

For additional information on our collaboration agreement with Neurimmune, please read *Note 17, Investments in Variable Interest Entities,* to our condensed consolidated financial statements included in this report.

For additional information on our income taxes please read *Note 14, Income Taxes,* 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 June 30, 2021	As of December 31, 2020	Change %
Financial assets:			
Cash and cash equivalents	$ 1,742.0	$ 1,331.2	30.9 %
Marketable securities — current	1,308.8	1,278.9	2.3
Marketable securities — non-current	915.1	772.1	18.5
Total cash, cash equivalents and marketable securities	$ 3,965.9	$ 3,382.2	17.3 %
Borrowings:			
Notes payable	$ 7,269.2	$ 7,426.2	(2.1)%
Total borrowings	$ 7,269.2	$ 7,426.2	(2.1)%
Working capital:			
Current assets	$ 7,183.7	$ 6,887.1	4.3 %
Current liabilities	(3,347.2)	(3,742.2)	(10.6)
Total working capital	$ 3,836.5	$ 3,144.9	22.0 %

For the six months ended June 30, 2021, certain significant cash flows were as follows:

- $1,996.3 million in net cash flow provided by operating activities;
- $1,050.0 million used for share repurchases;
- $170.0 million used in connection with our Exchange Offer;
- $164.5 million used for purchases of property, plant and equipment; and
- $100.0 million milestone payment to Neurimmune.

Overview

We have historically financed our operating and capital expenditures primarily through cash flow earned through our operations. 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 our cash flow earned from our operations as well as our existing cash resources. We believe generic competition for TECFIDERA in the U.S. will continue to reduce our cash flow from operations in 2021 and will have a significant adverse impact on our future cash flow 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.

As of June 30, 2021, we had cash, cash equivalents and marketable securities totaling approximately $4.0 billion compared to approximately $3.4 billion as of December 31, 2020. The change in cash, cash equivalents and marketable securities at June 30, 2021, from December 31, 2020, was primarily due to net cash flow provided by operating activities, partially offset by cash used for share repurchases and capital expenditures, cash payments

made in connection with our Exchange Offer and a milestone payment made to Neurimmune.

Investments and other assets in our condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020, include the carrying value of our investment in Samsung Bioepis of $612.8 million and $620.2 million, respectively. As Samsung Bioepis is a privately-held entity, our ability to liquidate our investment 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.

In connection with our collaboration with Sangamo, we purchased approximately 24 million shares of Sangamo common stock in April 2020. As of June 30, 2021 and December 31, 2020, the fair value of this investment was $271.6 million and $333.7 million, respectively.

In connection with our collaboration with Denali, we purchased approximately 13 million shares of Denali common stock in September 2020. As of June 30, 2021 and December 31, 2020, the fair value of this investment was $901.5 million and $935.7 million, respectively.

In connection with our collaboration with Sage, we purchased approximately 6.2 million shares of Sage common stock in December 2020. As of June 30, 2021 and December 31, 2020, the fair value of this investment was $293.3 million and $433.9 million, respectively.

Our investment in Ionis common stock had a fair value of $114.7 million and $249.1 million as of June 30, 2021 and December 31, 2020, respectively. The decrease was partially due to the sale of a portion of our investment in Ionis common stock during the first quarter of 2021.

For additional information on our collaboration arrangements with Samsung Bioepis, Sangamo, Denali and Sage, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

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 2020 Form 10-K.

Borrowings

In February 2021 we completed our Exchange Offer, consisting of the following:

- $624.6 million aggregate principal amount of our 2045 Senior Notes was exchanged for $700.7 million aggregate principal amount of our 2051 Senior Notes and approximately $151.8 million of aggregate cash payments; and
- $8.9 million aggregate principal amount of our 2045 Senior Notes was redeemed for approximately $12.1 million of aggregate cash payments, excluding accrued and unpaid interest.

In April 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 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 unsecured 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
- $1.12 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.

For a summary of the fair and carrying values of our outstanding borrowings as of June 30, 2021 and December 31, 2020, please read *Note 6, Fair Value Measurements,* to our condensed consolidated financial statements included in this report.

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. As of June 30, 2021, 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 June 30, 2021, from December 31, 2020, reflects an increase in total current assets of approximately $296.6 million and a decrease in total current liabilities of approximately $395.0 million.

The increase in total current assets was primarily driven by an increase in net cash, cash equivalents and marketable securities, due to $1,996.3 million of cash generated from operations, partially offset by cash used for share repurchases, capital expenditures and a Neurimmune milestone payment as well as cash payments made in conjunction with our Exchange Offer.

The net decrease in current liabilities was primarily due to a reduction in accounts payable as well as accrued expense and other, which was primarily related to decreases in the accrual of contingent payments, the accrual for employee compensation and benefits and the fair values of derivative liabilities.

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. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million and 3.8 million shares of our common stock at a cost of approximately $450.0 million and $1.1 billion during the three and six months ended June 30, 2021, respectively. Approximately $3.6 billion remained available under our 2020 Share Repurchase Program as of June 30, 2021.

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), which 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 9.0 million and 12.2 million shares of our common stock at a cost of approximately $2.8 billion and $3.7 billion during the three and six months ended June 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), which 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 six months ended June 30, 2020.

Cash Flow

The following table summarizes our cash flow activity:

	For the Six Months Ended June 30,		
(In millions, except percentages)	**2021**	**2020**	**% Change**
Net cash flow provided by operating activities	$ 1,996.3	$ 3,415.8	(41.6)%
Net cash flow used in investing activities	(217.4)	(389.8)	44.2
Net cash flow used in financing activities	(1,349.5)	(3,558.7)	62.1

Operating Activities

Cash flow from operating activities represents 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 six months ended June 30, 2021, compared to the same period in 2020, the decrease

in net cash flow provided by operating activities was primarily due to lower net income.

Investing Activities

For the six months ended June 30, 2021, compared to the same period in 2020, the decrease in net cash flow used in investing activities was primarily due to higher capital expenditures and acquisitions of IPR&D and other intangible assets in 2020 as well as the upfront payment made to Sangamo, partially offset by higher net proceeds received from the sale of marketable securities in 2020 as compared to the current year.

Financing Activities

For the six months ended June 30, 2021, compared to the same period in 2020, the decrease in net cash flow used in financing activities was primarily due to the greater number of shares repurchased in 2020 as compared to the comparative period in 2021, partially offset by cash used in connection with our Exchange Offer and a milestone payment to Neurimmune in 2021.

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, 2020.

Royalty Payments

TYSABRI

We are obligated to make contingent payments of 18.0% on annual worldwide net sales of TYSABRI up to $2.0 billion and 25.0% on annual worldwide net sales of TYSABRI that exceed $2.0 billion. Royalty payments are recognized as cost of sales in our condensed consolidated statements of income.

SPINRAZA

We make royalty payments 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.

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 condensed consolidated statements of income.

In October 2019 we entered into a new supply agreement and amended our license and collaboration agreement with Alkermes. We have elected to initiate a technology transfer and, following a transition period, to manufacture VUMERITY or have VUMERITY manufactured by a third party we have engaged in exchange for paying an increased royalty rate to Alkermes on any portion of future worldwide net commercial sales of VUMERITY that is manufactured by us or our designee. 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 2020 Form 10-K.

Contingent Consideration related to Business Combinations

In connection with our acquisition of Convergence Pharmaceuticals Holdings Ltd., we agreed to make additional payments based upon the achievement of certain milestone events.

We recognized the contingent consideration liabilities associated with this acquisition at its fair value on the acquisition date and revalue this obligation each reporting period. We may pay up to approximately $400.0 million in remaining milestones related to this acquisition.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of June 30, 2021, we could trigger potential future milestone payments to third parties of up to approximately $10.5 billion, including approximately $2.0 billion in development milestones, approximately $1.2 billion in regulatory milestones and approximately $7.3 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 June 30, 2021, 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.

If certain clinical and commercial milestones are met, we may pay up to $68.2 million in milestones in 2021 under our current agreements. In addition, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay up to $100.0 million in additional milestones to Neurimmune, which includes $50.0 million if launched in three or more countries in the E.U. and $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the ADUHELM Collaboration Agreement.

For additional information on our collaboration arrangements with Eisai, please read *Note 16, 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 17, Investments in Variable Interest Entities,* to our condensed consolidated financial statements included in this report.

Other Funding Commitments

As of June 30, 2021, 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 expense of approximately $43.7 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of June 30, 2021. We have approximately $646.8 million in cancellable future commitments based on existing CRO contracts as of June 30, 2021.

As part of the sale of our Hillerød, Denmark manufacturing operations to FUJIFILM Corporation (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. Based upon current estimates we do not expect to incur an adverse commitment obligation associated with such guarantees. We developed this estimate using a probability-weighted estimate of future manufacturing activity and may further 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.

For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to our consolidated financial statements included in our 2020 Form 10-K.

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 June 30, 2021, we have approximately $96.5 million of liabilities associated with uncertain tax positions.

As of June 30, 2021 and December 31, 2020, we have accrued income tax liabilities of approximately $633.0 million and $697.0 million, respectively, under a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). Of the amounts accrued as of June 30, 2021, approximately $72.7 million 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, revenue and expense and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and assumptions. 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 revenue and expense. 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 2020 Form 10-K. There have been no material changes to our critical accounting estimates since our 2020 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 flow 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. As a result, our consolidated financial position, results of operations and cash flow 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. revenue will decline when reported in U.S. dollars. The impact to net income as a result of a strengthening U.S. dollar will be partially mitigated by the value of non-U.S. expense, which will also decline when reported in U.S. dollars. As the U.S. dollar weakens versus other currencies, the value of the non-U.S. revenue and expense 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 flow 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 100.0%, 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 June 30, 2021, 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 revenue and operating expense. 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 18 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read *Note 8, Derivative Instruments,* to our condensed consolidated financial statements included in this report.

Our ability to mitigate the impact of foreign currency exchange rate changes on revenue 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 flow from these contracts are reported as operating activities in our condensed consolidated statements of cash flow.

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 flow from these contracts are reported as operating activities in our condensed consolidated statements of cash flow.

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 June 30,

2021 and December 31, 2020, a hypothetical adverse 10.0% 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 $386.4 million and $458.2 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 interest 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 four months. As of June 30, 2021 and December 31, 2020, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $54.9 million and $56.9 million, respectively. The estimated fair value was determined by measuring the impact of the hypothetical spot rate movement on outstanding forward contracts.

Interest Rate Risk

Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of June 30, 2021 and December 31, 2020, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $14.6 million and $13.2 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.

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. Our inability to obtain and maintain adequate prices in a particular country may not only limit the revenue from our products within that country but may also adversely affect our ability to 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 new originator therapies, generics, prodrugs and biosimilars of existing products and 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 revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for

TECFIDERA has significantly reduced our TECFIDERA revenue and is expected to have a substantial negative impact on our TECFIDERA revenue for as long as there is generic competition.

On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to a generic application related to TECFIDERA in the E.U. This generic application is now before the EMA, which is reassessing TECFIDERA's regulatory data protection by performing a scientific assessment pursuant to the European General Court's decision. The result of the scientific assessment of the EMA is expected in the fourth quarter of 2021. We have appealed the European General Court's decision to the European Court of Justice and the appeal is pending.

We will face TECFIDERA generic competition in the E.U. if regulatory data protection is not upheld and we expect that this would have an adverse impact on our TECFIDERA sales and our results of operations.

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 June 30, 2021 and December 31, 2020. 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 June 30, 2021. 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 June 30, 2021, 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 June 30, 2021, please read *Note 18, Litigation,* to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

Item 1A. Risk Factors

Risks Related to Our Business

We are substantially dependent on revenue from our products.

Our revenue depends upon continued sales of our products as well as the financial rights we have in our anti-CD20 therapeutic programs. A significant portion of our revenue is 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 revenue and results of operations or could cause a decline in our stock price:

- the introduction or greater acceptance of competing products, including new originator therapies, generics, prodrugs and biosimilars of existing products 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 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.

ADUHELM is in the early stages of commercial launch in the U.S. In addition to risks associated with new product launches and the other factors described in these Risk Factors, our ability to successfully commercialize ADUHELM may be adversely affected due to:

- the lack of readiness of healthcare providers to initiate treatment as well as our ability to successfully identify eligible patients based on the information included in ADUHELM’s label;
- concern regarding the accelerated approval of ADUHELM and its data;
- our ability to obtain and maintain adequate reimbursement for ADUHELM;
- the lack of market acceptance of ADUHELM;
- the effectiveness of our commercial strategy for marketing ADUHELM;
- delays in the manufacturing, distribution and supply of ADUHELM;
- the approval of other new products for the same or similar indications; and
- our ability to maintain a positive reputation among patients, healthcare providers and others in the Alzheimer’s disease community, which may be impacted by pricing and reimbursement decisions relating to ADUHELM.

As part of the accelerated approval, we will conduct a confirmatory trial to verify the clinical benefit of ADUHELM in patients with Alzheimer's disease. The FDA may withdraw approval if, among other things, the confirmatory trial fails to verify clinical benefit, ADUHELM's benefit-risk is no longer positive or we fail to comply with the conditions of the accelerated approval.

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

Our long-term success will depend upon the successful development of new products from our research and development activities or our licenses or acquisitions from third parties, including our commercialization agreements with Samsung Bioepis, as well as additional indications for our existing products.

Product development is very expensive and involves a high degree of uncertainty and risk and may not be successful. Only a small number of research and development programs result in the commercialization of a product. It is difficult to predict the success and the time and cost of product development of novel approaches for the treatment of diseases. 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 approval from regulatory authorities that have limited experience with the development of such therapies.

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, limit the scope of the approval or deny approval altogether. Furthermore, the approval of a product candidate by one regulatory agency does not mean that other regulatory agencies will also approve such product candidate.

Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects, result in unexpected adverse events or raise other concerns that may significantly reduce the likelihood of regulatory approval. This may result in terminated programs, significant restrictions on use and safety warnings in an approved label, adverse placement within the treatment paradigm or significant reduction in the commercial potential of the product candidate.

Even if we 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 we prefer to pursue other opportunities in our pipeline.

Sales of new products or products with additional indications may not meet investor expectations.

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.

Our products continue to face increasing competition from the introduction of new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Some of these products are likely to be sold at substantially lower prices than our branded products. The introduction of such products as well as other lower-priced competing products has reduced, and may in the future, 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 revenue. For instance, demand and price for TECFIDERA declined significantly as a result of multiple TECFIDERA generic entrants entering the U.S. market in 2020. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time.

Our ability to compete, maintain and grow our business may also be adversely affected due to a number of factors, including:

- the introduction of other products, including products that may be more efficacious, safer, less expensive or more convenient alternatives to our products, including our own products and products of our collaborators;
- the off-label use by physicians of therapies indicated for other conditions to treat patients;
- patient dynamics, including the size of the patient population and our ability to identify, attract and maintain new and current patients to our therapies;
- the reluctance of physicians to prescribe, and patients to use, our products without additional data on the efficacy and safety of such products;
- damage to physician and patient confidence in any of our products, generic or biosimilars of our 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, pricing and reimbursement decisions or adverse experiences or events that may occur with patients treated with our products or generic or biosimilars of our products;

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

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

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

While we believe we have a number of promising programs in our pipeline, failure 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 made, and may continue to make, significant operating and capital expenditures for potential new products 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.

We may fail to initiate or complete transactions for many reasons, including failure to obtain regulatory or other approvals as well as disputes or litigation. Furthermore, 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.

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, revenue and results of operations.

Sales of our products depend, to a significant extent, on adequate coverage, pricing and reimbursement from third-party payors. 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 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. Our inability to obtain and maintain adequate prices in a particular country may not only limit

the revenue from our products within that country but may also adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. 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 revenue.

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. For example, two committees of the U.S. House of Representatives are investigating the approval and price of ADUHELM. Competition from current and future competitors may negatively impact our ability to maintain pricing and our market share. New products marketed by our competitors could cause our revenue to decrease due to potential price reductions and lower sales volumes. Additionally, the introduction of generic or biosimilar versions of our products, follow-on products, prodrugs or products approved under abbreviated regulatory pathways may significantly reduce the price that we are able to charge for our products and the volume of products we sell.

Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including 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). 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. 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, revenue and results of operations.

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

- we may be unable to control the resources our collaborators, joint venture partners or third parties devote to our programs, products or product candidates;
- disputes may arise under an agreement, including with respect to the achievement and payment of milestones or ownership of rights to technology developed, and the underlying agreement 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 revenue, or may adopt tax strategies that could have an adverse effect on our business, results of operations or financial condition;
- third-party relationships 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 third parties to comply with applicable laws, including tax laws, regulatory requirements and/or applicable contractual obligations or to fulfill any responsibilities they may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenue 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 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.

Certain officers and affiliates of our joint venture partner, Samsung BioLogics, are currently subject to ongoing criminal proceedings that may impact its operations and business or divert the attention of the Samsung Bioepis management team from its ongoing operations. In addition, as Samsung Bioepis is a privately-held entity, our ability to liquidate our investment may be limited and we may realize significantly less than the value of such investment.

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, revenue from products could decline and/or we may not realize the anticipated benefits of these arrangements.

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

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

We may face uncertainties as a result of 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.

There is increasing public attention on the costs of prescription drugs and we expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. For example, two committees of the U.S. House of Representatives are investigating the approval and price of ADUHELM. In addition, there have been, and are expected to continue to be, legislative proposals to address prescription drug pricing. Some of these proposals could have significant effects on our business, including an executive order issued in September 2020 to test a “most favored nation” model for Part B and Part D drugs that tie reimbursement rates to international drug pricing metrics. 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, including as a result of the COVID-19 pandemic, 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 revenue and may continue to adversely affect our revenue and results of operations in the future.

Our success in commercializing biosimilars is subject to risks and uncertainties inherent in the development, manufacture and commercialization of biosimilars. If we are unsuccessful in such activities, our business may be adversely affected.

The development, manufacture and commercialization of biosimilar products require specialized expertise and are very costly and subject to complex regulation. Our success in commercializing biosimilars is subject to a number of risks, including:

- *Reliance on Third Parties.* We are dependent, in part, on the efforts of Samsung Bioepis, collaboration partners and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If these third parties fail to perform successfully, our biosimilar product development or commercialization of biosimilar products could be delayed, revenue from biosimilar products could decline and/or we may not realize the anticipated benefits of these arrangements;
- *Regulatory Compliance.* Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- *Intellectual Property and Regulatory Challenges.* Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years or result in imposition of monetary damages, penalties or other civil sanctions and damage our reputation;
- *Failure to Gain Market and Patient Acceptance.* Market success of biosimilar products will be adversely affected if patients, physicians and/or payors do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- *Ability to Provide Adequate Supply.* Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties we may be unable to meet higher than anticipated demand. We are dependent on a third-party for the manufacture of biosimilar products and such third-party may not perform its 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; and
- *Competitive Challenges.* Biosimilar products face significant competition, including from innovator products and biosimilar products offered by other companies. Local tendering processes may restrict biosimilar products from being marketed and sold in some 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.

Risks Related to Intellectual Property

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, including certain regulatory forms of exclusivity, that are important to the commercialization of our products and product candidates. Patent protection and/or regulatory exclusivity in the U.S. and 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 obtain or preserve patent and other intellectual property rights, including certain regulatory forms of exclusivity, 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, which could result in financial, business or reputational harm to us or could cause a decline or volatility in our stock price. In addition, settlements of such proceedings often result in reducing the period of patent and other protections, resulting in a reduction in revenue from affected products.

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 do 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 revenue may be reduced in a short period of time. In addition, manufacturers of generics and biosimilars may choose to launch or attempt to launch their products before the expiration of our patent or other intellectual property protections.

Furthermore, our products may be determined to infringe patents or other intellectual property rights held by third parties. Legal proceedings, administrative challenges or other types of proceedings are and may in the future be necessary 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. Such proceedings are unpredictable and are often protracted and expensive. Negative outcomes of such proceedings could hinder or prevent us from manufacturing

and marketing 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. A failure to obtain necessary licenses for an infringed product or technology could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits 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.

Risks Related to Development, Clinical Testing and Regulation of Our Products and Product Candidates

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

Positive results in a 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. 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, including 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 expense, have an adverse effect on our business, financial condition and results of operations and/or cause our stock price to decline or experience periods of volatility.

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, including 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 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 denied.

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 and if such CRO does not adequately perform, many of our trials may be affected. We may need to replace our CROs, which may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates.

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

Adverse safety events involving our marketed products, generic or biosimilar versions of our marketed products or 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/or 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 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 to decline or our stock price to 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) in the label for certain of our products, may significantly reduce expected revenue for those products and require significant expense and management time.

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. 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 and 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 social media. We may also encounter criticism on social media regarding our company, management, product candidates or products. The immediacy of social media precludes us from having real-time control over postings made regarding us via social media, whether matters of fact or opinion. Our reputation could be damaged by negative publicity or if adverse information concerning us is posted on social media platforms or similar mediums, which we may not be able to reverse. 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.

Risks Related to Our Operations

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

We are increasingly dependent upon technology systems and data to operate our business. Further, 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 our cloud technologies, 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 our cloud technologies, continue to increase in multitude and complexity, making them potentially vulnerable to breakdown, malicious intrusion and random attack. Data privacy or security breaches also 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, operational or reputational harm to us, loss of competitive advantage or loss of consumer

confidence. 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.

Regulators 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 established regulations regarding the handling of personal data, and provides an enforcement authority and imposes large penalties for noncompliance. New U.S. data privacy and security laws, such as the California Consumer Privacy Act (CCPA), and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with the 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, policies, industry standards or legal obligations or any security incident resulting in the unauthorized access to, or acquisition, release or transfer of personal information may result in governmental enforcement actions, litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have a material adverse effect on our business and results of operations.

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.

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. New members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new opportunities or reduce or change emphasis on our existing programs.

Our success is dependent upon our ability to attract and retain qualified management and key personnel in a highly competitive environment. Qualified individuals are in high demand, and we may incur significant costs to attract them, particularly at the executive level. We may face difficulty in attracting and retaining key talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more late stage programs or recruitment by competitors. In addition, remote or hybrid working arrangements could impact employees' productivity and morale. We cannot ensure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any 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 in the U.S. and in foreign jurisdictions, and are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our business practices. The FDA and comparable foreign agencies 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, product risk management and our compliance with good practice quality guidelines and regulations. Our interactions 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 are facing heightened scrutiny of their relationships with health care providers and 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 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 or perspectives that may delay or prevent the approval of new products and result in lost market opportunity;
- government shutdowns or relocations may result in delays to the review and approval process, slowing the time necessary for new drug candidates to be reviewed and/or approved, which may adversely affect our business;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action, which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or otherwise adversely affect the market for our products.

Violations of governmental regulation may be punishable by criminal and civil sanctions, 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. We could also 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 submitted to the government. In addition, legal proceedings and investigations are inherently unpredictable, and large judgments or settlements sometimes occur. While we believe that we have appropriate compliance controls, policies and procedures in place to comply with the laws or regulations of the jurisdictions in which we operate, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers might violate such laws or regulations. Whether or not we have complied with the law, an investigation or litigation related to alleged unlawful conduct could increase our expense, 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, subjecting us to many risks that could adversely affect our business and revenue. 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. 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 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 the global economy and the delivery of healthcare treatments;
- less favorable intellectual property or other applicable laws;
- the inability to obtain necessary foreign regulatory 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 revenue, net income and value of certain of our investments;
- 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 United Kingdom (U.K.), including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- changes in tax laws; and
- the imposition of tariffs or embargoes and other trade restrictions.

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. In addition, while we believe that we have appropriate compliance controls, policies and procedures in place to comply with the FCPA, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers might violate the FCPA and we might be held responsible. If our employees, agents, distributors, collaborators or third-party providers are found to have engaged in such practices, we could suffer severe penalties and may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

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.

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 or this investment will be recouped. If we are unable to 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.

Although a portion of the Solothurn facility received a GMP multi-product license from SWISSMEDIC in May 2021, the manufacturing of a product or product candidate at the Solothurn facility must be approved by the applicable regulatory agencies, including the FDA. There can be no assurance that the regulatory authorities will approve the Solothurn facility for the manufacturing of a product or a product candidate. If we do not receive the necessary regulatory approvals of the Solothurn facility or if our future growth and drug development plans increase, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.

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

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 GMP (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 other regulatory authorities to confirm 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 operations or those of third parties to receive regulatory approval or 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 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 many other factors. In addition, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. If we do not receive the necessary regulatory approvals to manufacture products or product candidates at the Solothurn facility, 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 expense for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

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 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 or our current expectations due to many 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.

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. 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, which 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. Further, the new administration could introduce new tax laws or revise or issue new interpretations of the 2017 Tax Act.

The Swiss Federal Act on Tax Reform and AHV Financing (TRAF) resulted in significant changes to the Swiss cantonal income tax system. 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.

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.

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

Our business could be adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic. National, state and local governments have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns and other measures. These measures may disrupt normal business operations and may 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, including limiting travel and working from home. We have also suspended the vast majority of our in-person interactions by our customer-facing professionals in healthcare settings. This limits 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.

Remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. 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, which may be less secure and more susceptible to hacking attacks.

The COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. Furthermore, delays and disruptions experienced by our collaborators, joint venture partners or other 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.

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 LHI has been delayed as this study involves administration of BIIB093 in an acute hospital setting. 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 and 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. 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. 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.

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 and is aimed at providing emergency assistance and health care for individuals, families and businesses and generally supporting the U.S. economy. 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.

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 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.

Risks Related to Holding Our Common Stock

Our operating results are subject to significant fluctuations.

Our quarterly revenue, expense 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 or our equity investments;
- bad debt expense and increased bad debt reserves;
- outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters;
- payments in connection with acquisitions, divestitures and other business development activities and under license and collaboration agreements;
- failure to meet certain contractual commitments; 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 revenue and certain assets and liabilities are also subject to foreign currency exchange rate fluctuations due to the global nature of our operations. 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 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. 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 a 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 investment portfolio 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 as well as investments in equity securities of certain biotechnology companies. Changes in the value of our investment portfolio could adversely affect our earnings. The value of our investments may decline due to, among other things, increases in interest rates, downgrades of the bonds and other securities in our portfolio, instability in the global financial markets that reduces the liquidity of securities in our portfolio, declines in the value of collateral underlying the securities in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these

risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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

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

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

We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets 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 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, 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.

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.

General Risk Factors

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.

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 2020 Share Repurchase Program during the second quarter of 2021:

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)
April 2021	—	$ —	—	$ 4,000.0
May 2021	1,620,858	$ 277.63	1,620,858	$ 3,550.0
June 2021	—	$ —	—	$ 3,550.0
Total	1,620,858	$ 277.63		

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. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million and 3.8 million shares of our common stock at a cost of approximately $450.0 million and $1.1 billion during the three and six months ended June 30, 2021, respectively. Approximately $3.6 billion remained available under our 2020 Share Repurchase Program as of June 30, 2021.

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 9.0 million and 12.2 million shares of our common stock at a cost of approximately $2.8 billion and $3.7 billion during the three and six months ended June 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 six months ended June 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
3.1	Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
3.2	Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015.
3.3	Certificate of Amendment of Biogen Inc.'s Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on June 8, 2021.
10.1*+	Amended and Restated Biogen Inc. 2019 Performance-Based Management Incentive Plan, effective as of June 2, 2021.
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 June 30, 2021, 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 Flow, (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 June 30, 2021, formatted in Inline XBRL.

* Management contact 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
Chief Financial Officer
(principal financial officer)

July 22, 2021

BIOGEN INC.
PERFORMANCE-BASED MANAGEMENT INCENTIVE PLAN

1. Purpose

This Performance-Based Management Incentive Plan (this "Plan") is established by Biogen Inc. (the "Company") to attract and retain persons of outstanding abilities and to stimulate efforts to bring about strong operating performance and reward the individuals who contribute to this performance. This Plan supersedes and replaces any performance-based management incentive plan previously adopted by the Company or its predecessors and applies to awards granted on or after January 1, 2019.

2. Basic Concepts

Award programs under this Plan shall be developed under the following basic concepts:

A. There shall be an identification of performance periods, which may be a minimum of six (6) and a maximum of sixty (60) consecutive months in length. Because multiple awards may be granted to a Participant under this Plan, performance periods need not be sequential and may overlap or occur simultaneously.

B. With respect to each performance period, there shall be a determination of (i) eligible Participants, (ii) the amount of each participant's target incentive awards, (iii) the applicable performance goals, based on the Performance Criteria listed in Section 4.B below and/or such other Company and/or individual performance goals as may be approved by the Compensation and Management Development Committee of the Board of Directors of the Company (the "Committee"), and (iv) the extent to which performance relative to each such performance goal shall determine the amount of the award payable to a Participant.

3. Eligibility

A. Participation in this Plan shall be limited to executive officers of the Company and its subsidiaries and affiliates. Each employee participating in this Plan is referred to as a "Participant."

B. Unless otherwise authorized by the Committee, Participants shall be excluded from participation in any other cash bonus or incentive program of the Company or any of its subsidiaries and affiliates; provided, however, that Participants shall not be excluded from participation in any equity incentive plan adopted by the Company (whether or not such awards are settled in stock or in cash).

4. Determination of Awards

A. Except as provided otherwise in this Section 4, awards under this Plan shall be paid on account of the attainment of one or more performance goals which: (i) are established by the Committee; (ii) are based on one or more of the criteria listed below in Section 4.B and/or such other Company and/or individual performance goals as may be approved by the Committee, and (iii) state the method for computing the amount of

compensation payable to a Participant if the performance goal or goals are attained. Unless otherwise determined by the Committee, Performance Criteria or other performance goals shall be adopted with respect to each performance period by the Committee (A) for performance periods of one year or more, no later than ninety (90) days after the commencement of the performance period; and (B) for periods of less than one year, before twenty-five percent (25%) of the performance period has elapsed. The Committee may waive the achievement of one or more of the applicable performance goals in the case of the death or disability of the Participant or under such other circumstances as the Committee determines are appropriate. The Committee may provide that if certain specified goals are not met, no awards will be made for the performance period to which such goals relate.

B. Performance goals shall be based on specified Company or individual criteria, which may include objectively determinable measures of performance relating to any of, or to any combination of, the following (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, functional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Committee specifies ("Performance Criteria")): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization or other items, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition, expansion or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or achievement of clinical trial or research objectives. A Performance Criterion and any targets with respect thereto determined by the Committee need not be based upon an increase, a positive or improved result or avoidance of loss and may be based on GAAP, non-GAAP or other metrics as contemplated hereby. The Committee may provide that one or more of the Performance Criteria applicable to an award will be adjusted to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable Performance Criterion or Criteria. Performance goals may also consist of such other individual performance criteria and/or subjective Company performance criteria as determined by the Committee.

C. Except as provided in Section 8.B below, no incentive awards shall be paid to Participants under this Plan unless and until the Committee determines that the applicable Performance Criteria or other performance goals have been attained, and such determination will be final and conclusive.

D. A Participant may receive an incentive award under this Plan that is less than, equal to or greater than his or her target incentive award. The Committee may in its sole discretion adjust an incentive award otherwise payable to a Participant, including on the basis of Company and/or specific individual goals, which may be based on nonobjective factors related to the performance of the Company and/or the Participant, as the case may be.

5. Basis of Participation in Award Programs

A. Awards may, but are not required to, be denominated in (i.e., valued by reference to) the Common Stock of the Company or units of Common Stock of the Company; provided, however, that any awards denominated in cash will be paid in cash as provided in Section 8.A below. Awards denominated in cash may be expressed as a percentage of the annual base pay of the Participant or as a specified dollar amount.

B. In addition to any other terms and conditions set forth in this Plan, all or part of the grant, vesting and/or payment of an award may be made subject to future service and such other restrictions and conditions as may be established by the Committee, and as may be set forth in any award agreement.

6. Administration

A. The overall administration of this Plan shall be under the direction of the Committee. The Committee has discretionary authority, subject only to the express provisions of this Plan, to interpret this Plan; determine eligibility for and grant awards; determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary or desirable to carry out the purposes of this Plan. Determinations of the Committee made under this Plan will be conclusive and will bind all persons. The Committee may delegate: (i) to one or more of its members such of its duties, powers and responsibilities as it may determine and (ii) to such employees or other persons as it determines such ministerial tasks as it deems appropriate.

B. Responsibility for the ministerial administration of this Plan (for example, payment of awards approved by the Committee) shall be under the direction of the Company's Head of Human Resources.

7. Determination of Incentive Awards; Limitations on Awards

A. The maximum amount payable under this Plan to any Participant during any calendar year may not exceed $6,000,000 for the Chief Executive Officer and $3,000,000 for any other Participant.

B. The final determination of the extent to which the Performance Criteria and/or other performance goals were achieved for an award will be made by the Committee promptly following the availability of all necessary performance results.

C. For the avoidance of doubt, in no event will any payment of an award exceed 225% of the Participant's target incentive award.

8. Payments; Effect of Termination of Employment

A. All payments of awards hereunder shall be made in cash within the sooner of 90 days following the end of the applicable performance period or March 15 of the year following the calendar year in which the award was earned.

B. If a Participant's employment terminates during a performance period due to death or disability, a determination of the amount payable to the Participant or his or her

estate will be made as soon as practicable thereafter. Unless otherwise determined by the Committee, the amount to be paid under these circumstances shall be determined by multiplying the Participant's target incentive award by a fraction, the numerator of which is the number of days completed during the performance period before termination of employment, and the denominator of which is the original length of the performance period. Payment of awards under this Section 8.B will be made within the sooner of 90 days of the termination of employment or March 15 of the year following the calendar year in which employment terminated. If a Participant's employment terminates during a performance period for any reason other than death or disability, unless the Committee determines otherwise, payment will not be made in respect of any award.

C. Participants are required to maintain employment with the Company through the payout date to receive payment, unless this practice is in conflict with local law. If a Participant terminates employment for any reason other than death or disability after the end of the performance period but before the payout date, they will not be entitled to any award payments.

9. General Conditions

A. While it is the intent of the Company to continue this Plan indefinitely, the Company reserves the right to amend, modify or terminate this Plan, any incentive program under this Plan or any Participant's participation in this Plan at any time or on such conditions as the Committee shall deem appropriate; provided, however, that to the extent that stockholder approval is required pursuant to law or by reason of the rules of the applicable exchange on which shares of the Company's common stock is publicly traded, no such amendment or modification shall be effective until such time as such stockholder approval is obtained. Except as provided in 8.B above, no Participant shall have any right to any incentive award under this Plan until such award and the amount thereof has been finally approved by the Committee and communicated to such Participant after the end of the performance period for which the award is being made and the Participant remains employed with the Company through such date.

B. This Plan is not a contract between the Company and any Participant. Neither the establishment of this Plan, nor any action taken hereunder, shall be construed as giving any Participant any right to be retained in the employ of the Company.

C. The Committee may cancel, rescind, withhold or otherwise limit or restrict any unpaid award (or require the repayment of an award) at any time if the Participant is not in compliance with all applicable provisions of this Plan and award agreement, if any, or if the Participant engages in any "Detrimental Activity" or as otherwise provided under any applicable clawback or recoupment policy of the Company, as in effect from time to time.

1) In particular, but not in limitation of the foregoing, in the event that a Participant engages or has engaged in Detrimental Activity, any amounts payable to the Participant in the year in which termination of employment occurs under this Plan may be forfeited and the entire amount of any payments made during such year of termination of employment shall be repaid to the Company. Each Participant, by accepting or being deemed to have accepted an award under this Plan, agrees to cooperate fully with the Committee to effectuate any forfeiture required under this Plan. The Participant (and

neither the Committee nor the Company) will be solely responsible for any adverse tax or other consequences to a Participant that may arise in connection with this Section 9.C.

2) For purposes of this Plan, “Detrimental Activity” shall include any action or failure to act that, in the sole determination of the Committee: (i)(a) constitutes financial malfeasance that is materially injurious to the Company, (b) violates the Company’s Code of Conduct, (c) results in the Company’s restatement of its earnings, financial results or financial statements or (d) results in a violation or breach of law or contract that is materially injurious to the Company or (ii) violates any non-competition, non-disclosure or non-solicitation agreement with the Company, or in the event that the Participant has not entered into any such agreement with the Company, the Participant engages in any “Competitive Activity.”

3) For purposes of this Plan, “Competitive Activity” shall include: (i) the rendering of services for any organization or engaging directly or indirectly in any business which is or becomes competitive with the Company, or which organization or business, or the rendering of services to such organization or business, is or becomes otherwise prejudicial to or in conflict with the interests of the Company; (ii) the disclosure to anyone outside the Company, or the use in other than the Company’s business, without prior written authorization from the Company, of any confidential information or material relating to the business of the Company, acquired by the Participant either during or after employment with the Company or (iii) any attempt directly or indirectly to induce any employee of the Company to be employed or perform services elsewhere or any attempt directly or indirectly to solicit the trade or business of any current or prospective customer, supplier or partner of the Company.

D. A Participant’s right and interest under this Plan may not be assigned or transferred, and any attempted assignment or transfer shall be null and void and shall extinguish, in the Company’s sole discretion, the Company’s obligation under this Plan to pay incentive awards with respect to the Participant.

E. This Plan shall be unfunded. The Company shall not be required to establish any special or separate fund, or to make any other segregation of assets, to assure payment of awards.

F. The Company shall have the right to deduct from incentive awards paid any taxes or other amounts required by law to be withheld.

G. Awards under this Plan are intended either to be exempt from the rules of Section 409A of the Code or to satisfy those rules, and shall be construed accordingly. Notwithstanding anything to the contrary in this Plan, neither the Company, nor any affiliate, nor the Committee, nor any person acting on behalf of the Company, any affiliate, or the Committee, shall be liable to any Participant or to the estate or beneficiary of any Participant or to any other holder of an award by reason of any acceleration of income, or any additional tax, asserted by reason of the failure of an award to satisfy the requirements of Section 409A of the Code or by reason of Section 4999 of the Code.

H. The validity, construction, interpretation and effect of this Plan shall exclusively be governed by and determined in accordance with the laws of the State of Delaware, without giving effect to its conflict of laws provisions.

(Approved 02.12.2019, amended 06.02.21)

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: July 22, 2021

/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: July 22, 2021

/s/ Michael R. McDonnell
Michael R. McDonnell
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 June 30, 2021 (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: July 22, 2021

/s/ Michel Vounatsos
Michel Vounatsos
Chief Executive Officer
[principal executive officer]

Date: July 22, 2021

/s/ Michael R. McDonnell
Michael R. McDonnell
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.