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, 2022

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 19, 2022, was 145,113,047 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended June 30, 2022

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the anticipated amount, timing and accounting of 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 portfolio 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 and cost-reduction measures;
- 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, reserves and allowances, the supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;
- the current and potential impacts of the conflict in Ukraine, including impacts on our operations, sales and the possible disruptions or delays in our plans to conduct clinical trial activities in affected regions;
- 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 remaining portion of the Solothurn manufacturing facility to begin manufacturing products or product candidates and for the gene therapy manufacturing facility in Research Triangle Park (RTP), 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™, BYOOVIZ™, FLIXABI™, FUMADERM™ and IMRALDI™ are trademarks of Biogen.

CIMZIA®, 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,	
	2022	2021	2022	2021
Revenue:				
Product, net	$ 2,054.9	$ 2,236.0	$ 4,121.2	$ 4,447.7
Revenue from anti-CD20 therapeutic programs	436.3	440.0	835.7	829.0
Other	97.9	99.0	164.0	192.3
Total revenue	2,589.1	2,775.0	5,120.9	5,469.0
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	484.0	459.7	1,237.9	937.8
Research and development	528.6	585.1	1,080.3	1,099.3
Selling, general and administrative	572.6	637.3	1,207.5	1,232.3
Amortization and impairment of acquired intangible assets	67.5	604.1	134.4	702.2
Collaboration profit (loss) sharing	29.4	(15.2)	(87.9)	53.3
(Gain) loss on fair value remeasurement of contingent consideration	(4.5)	0.3	(11.6)	(33.5)
Acquired in-process research and development	—	18.0	—	18.0
Restructuring charges	70.6	—	108.7	—
Other (income) expense, net	(428.6)	(96.4)	(165.3)	410.5
Total cost and expense	1,319.6	2,192.9	3,504.0	4,419.9
Income before income tax expense and equity in loss of investee, net of tax	1,269.5	582.1	1,616.9	1,049.1
Income tax (benefit) expense	216.7	(409.1)	342.3	(364.9)
Equity in (income) loss of investee, net of tax	(5.9)	(34.3)	(2.6)	(16.1)
Net income	1,058.7	1,025.5	1,277.2	1,430.1
Net income (loss) attributable to noncontrolling interests, net of tax	0.7	577.0	(84.6)	571.4
Net income attributable to Biogen Inc.	$ 1,058.0	$ 448.5	$ 1,361.8	$ 858.7
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 7.25	$ 3.00	$ 9.30	$ 5.70
Diluted earnings per share attributable to Biogen Inc.	$ 7.24	$ 2.99	$ 9.27	$ 5.68
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	145.9	149.7	146.5	150.8
Diluted earnings per share attributable to Biogen Inc.	146.2	150.1	146.8	151.2

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,	
	2022	2021	2022	2021
Net income attributable to Biogen Inc.	$ 1,058.0	$ 448.5	$ 1,361.8	$ 858.7
Other comprehensive income:				
Unrealized gains (losses) on securities available for sale, net of tax	(8.3)	(0.5)	(18.0)	(1.3)
Unrealized gains (losses) on cash flow hedges, net of tax	57.2	(11.0)	73.1	138.6
Gains (losses) on net investment hedges, net of tax	(31.7)	(2.3)	(25.5)	20.1
Unrealized gains (losses) on pension benefit obligation, net of tax	1.8	0.4	2.7	2.4
Currency translation adjustment	(14.2)	15.9	(36.0)	(32.6)
Total other comprehensive income (loss), net of tax	4.8	2.5	(3.7)	127.2
Comprehensive income (loss) attributable to Biogen Inc.	1,062.8	451.0	1,358.1	985.9
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	0.7	576.9	(84.6)	572.0
Comprehensive income (loss)	$ 1,063.5	$ 1,027.9	$ 1,273.5	$ 1,557.9

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, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,646.6	$ 2,261.4
Marketable securities	2,151.3	1,541.1
Accounts receivable, net	1,567.6	1,549.4
Due from anti-CD20 therapeutic programs	435.9	412.3
Inventory	1,294.2	1,351.5
Other current assets	1,645.3	740.8
Total current assets	9,740.9	7,856.5
Marketable securities	1,102.9	892.0
Property, plant and equipment, net	3,355.1	3,416.4
Operating lease assets	321.1	375.4
Intangible assets, net	2,075.3	2,221.3
Goodwill	5,749.6	5,761.1
Deferred tax asset	1,235.7	1,415.1
Investments and other assets	1,500.8	1,939.5
Total assets	$ 25,081.4	$ 23,877.3
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$ 999.8	$ 999.1
Taxes payable	284.9	174.7
Accounts payable	434.8	589.2
Accrued expense and other	3,298.5	2,535.2
Total current liabilities	5,018.0	4,298.2
Notes payable	6,277.4	6,274.0
Deferred tax liability	480.6	694.5
Long-term operating lease liabilities	274.2	330.4
Other long-term liabilities	1,167.8	1,320.5
Total liabilities	13,218.0	12,917.6
Commitments, contingencies and guarantees		
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	—	68.2
Accumulated other comprehensive income (loss)	(110.4)	(106.7)
Retained earnings	14,959.9	13,911.7
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	11,872.5	10,896.2
Noncontrolling interests	(9.1)	63.5
Total equity	11,863.4	10,959.7
Total liabilities and equity	$ 25,081.4	$ 23,877.3

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,	
	2022	2021
Cash flow from operating activities:		
Net income	$ 1,277.2	$ 1,430.1
Adjustments to reconcile net income to net cash flow from operating activities:		
Depreciation and amortization	277.9	219.8
Impairment of intangible assets	—	585.9
Excess and obsolescence charges related to inventory	305.6	8.3
Acquired in-process research and development	—	18.0
Share-based compensation	123.3	124.1
Contingent consideration	(11.6)	(33.5)
Deferred income taxes	(47.5)	(622.8)
(Gain) loss on strategic investments	269.3	283.6
(Gain) loss on equity method investments	(2.6)	(16.1)
Gain on sale of equity interest in Samsung Bioepis	(1,505.4)	—
Other	112.2	104.1
Changes in operating assets and liabilities, net:		
Accounts receivable	(67.3)	211.5
Due from anti-CD20 therapeutic programs	(23.6)	(8.7)
Inventory	(243.3)	(193.8)
Accrued expense and other current liabilities	634.0	(188.4)
Income tax assets and liabilities	(65.9)	171.5
Other changes in operating assets and liabilities, net	(134.0)	(97.3)
Net cash flow provided by (used in) operating activities	898.3	1,996.3
Cash flow from investing activities:		
Purchases of property, plant and equipment	(94.8)	(164.5)
Proceeds from sales and maturities of marketable securities	1,461.5	1,452.7
Purchases of marketable securities	(2,311.6)	(1,626.9)
Proceeds from sale of equity in Samsung Bioepis	990.3	—
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	—	28.1
Acquisitions of intangible assets	(1.9)	—
Proceeds from the sales of strategic investments	—	91.2
Other	2.0	2.0
Net cash flow provided by (used in) investing activities	45.5	(217.4)
Cash flow from financing activities:		
Purchases of treasury stock	(500.0)	(1,050.0)
Payments related to issuance of stock for share-based compensation arrangements, net	(11.5)	(14.2)
Repayment of borrowings and premiums paid on debt exchange	—	(170.0)
Net (distribution) contribution to noncontrolling interest	12.1	(94.8)
Other	11.4	(20.5)
Net cash flow provided by (used in) financing activities	(488.0)	(1,349.5)
Net increase (decrease) in cash and cash equivalents	455.8	429.4
Effect of exchange rate changes on cash and cash equivalents	(70.6)	(18.6)
Cash and cash equivalents, beginning of the period	2,261.4	1,331.2
Cash and cash equivalents, end of the period	$ 2,646.6	$ 1,742.0

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, 2022	—	$ —	171.3	$ 0.1	$ 119.0	$ (115.2)	$ 14,215.5	(23.8)	$ (2,977.1)	$ 11,242.3	$ (21.6)	$ 11,220.7
Net income	—	—	—	—	—	—	1,058.0	—	—	1,058.0	0.7	1,058.7
Other comprehensive income (loss), net of tax	—	—	—	—	—	4.8	—	—	—	4.8	—	4.8
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	11.8	11.8
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(2.4)	(500.0)	(500.0)	—	(500.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(2.4)	—	(186.4)	—	(313.6)	2.4	500.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	10.0	—	—	—	—	10.0	—	10.0
Issuance of common stock under stock award plan	—	—	—	—	(0.7)	—	—	—	—	(0.7)	—	(0.7)
Compensation related to share-based payments	—	—	—	—	58.0	—	—	—	—	58.0	—	58.0
Other	—	—	—	—	0.1	—	—	—	—	0.1	—	0.1
Balance, June 30, 2022	—	$ —	169.0	$ 0.1	$ —	$ (110.4)	$ 14,959.9	(23.8)	$ (2,977.1)	$ 11,872.5	$ (9.1)	$ 11,863.4

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, 2021	—	$ —	170.8	$ 0.1	$ 68.2	$ (106.7)	$ 13,911.7	(23.8)	$ (2,977.1)	$ 10,896.2	$ 63.5	$ 10,959.7
Net income	—	—	—	—	—	—	1,361.8	—	—	1,361.8	(84.6)	1,277.2
Other comprehensive income (loss), net of tax	—	—	—	—	—	(3.7)	—	—	—	(3.7)	—	(3.7)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	12.0	12.0
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(2.4)	(500.0)	(500.0)	—	(500.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(2.4)	—	(186.4)	—	(313.6)	2.4	500.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	28.9	—	—	—	—	28.9	—	28.9
Issuance of common stock under stock award plan	—	—	0.4	—	(40.4)	—	—	—	—	(40.4)	—	(40.4)
Compensation related to share-based payments	—	—	—	—	128.4	—	—	—	—	128.4	—	128.4
Other	—	—	—	—	1.3	—	—	—	—	1.3	—	1.3
Balance, June 30, 2022	—	$ —	169.0	$ 0.1	$ —	$ (110.4)	$ 14,959.9	(23.8)	$ (2,977.1)	$ 11,872.5	$ (9.1)	$ 11,863.4

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, 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
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(100.0)	(100.0)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	5.0	5.0
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
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
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(100.0)	(100.0)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	5.1	5.1
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.

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. We have a leading portfolio of medicines to treat multiple sclerosis (MS), have introduced the first approved treatment for spinal muscular atrophy (SMA) and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. We also commercialize biosimilars of advanced biologics and focus on advancing our pipeline in neuroscience and specialized immunology. Lastly, we are focused on accelerating our efforts in digital health to support our commercial and pipeline programs while also creating opportunities for potential digital therapeutics. 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 (PPMS) and relapsing MS (RMS); and other potential anti-CD20 therapies, including mosunetuzumab, 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, 2021 (2021 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 collaboration with Samsung Bioepis Co., Ltd. (Samsung Bioepis) 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, as well as BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 17, Collaborative and Other Relationships,* to these unaudited condensed consolidated financial statements (condensed consolidated financial statements).

Basis of Presentation

In the opinion of management, our condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair statement of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The information included in this quarterly report on Form 10-Q should be read in conjunction with our audited consolidated financial statements and the accompanying notes included in our 2021 Form 10-K. Our accounting policies are described in the *Notes to Consolidated Financial Statements* in our 2021 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, 2022, 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, net of tax 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. 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, the supply chain, manufacturing, clinical trials, research and development costs and employee-related costs, 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. Additionally, the ongoing geopolitical tensions related to the conflict in Ukraine, and the related sanctions and other penalties imposed, are creating substantial uncertainty in the global economy. The extent and duration of the conflict, sanctions and resulting market disruptions are highly unpredictable. We have made estimates of the impact of the COVID-19 pandemic and the ongoing geopolitical conflict 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 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 had or may have a material impact on our condensed consolidated financial statements or disclosures.

Fair Value Measurements

In June 2022 the Financial Accounting Standards Board issued Accounting Standards Update No. 2022-03, *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. This standard clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This standard becomes effective for us on January 1, 2024, and is not expected to have a material impact on our condensed consolidated financial statements and related disclosures.

2. DISPOSITIONS

Sale of Joint Venture Equity Interest in Samsung Bioepis

In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics Co., Ltd (Samsung BioLogics). Under the terms of this transaction, we received approximately $1.0 billion in cash at closing and expect to receive approximately $1.3 billion in cash to be deferred over two payments of approximately $812.5 million due at the first anniversary and approximately $437.5 million due at the second anniversary of the closing of the transaction.

Prior to the sale, the carrying value of our investment in Samsung Bioepis totaled $581.6 million. For the three and six months ended June 30, 2022, we recognized a pre-tax gain of approximately $1.5 billion related to the transaction, which was recorded in other (income) expense, net in our condensed consolidated statements of income. This pre-tax gain included reclassifications from accumulated other comprehensive income (loss) to net income of approximately $58.9 million in cumulative translation losses, partially offset by approximately $57.0 million in gains resulting from the termination of our net investment hedge.

We have concluded that the divestment of Samsung Bioepis does not meet the criteria to be reported as discontinued operations in our condensed consolidated financial statements, as our decision to divest this business does not represent a strategic shift that will have a major effect on our operations and financial results.

We have elected the fair value option and measured the payments due to us from Samsung BioLogics at fair value based on risk-adjusted discount rates of 3.1% and 3.7% for the first and second payments due, respectively. As of June 30, 2022, the estimated fair values of the first and second payments were approximately $788.1 million and $406.8 million, respectively, and have been classified as level 3 measurements reflected in other current assets and investments and other assets, respectively, in our condensed consolidated balance sheets.

As part of the transaction, we are also eligible to receive up to an additional $50.0 million upon the achievement of certain commercial milestones. Our policy for contingent payments of this nature is to recognize them in the period that they become realizable, which is generally the same period in which they are earned.

If any payments due to us remain outstanding after the second anniversary of the closing of the transaction, we may elect to receive shares of Samsung BioLogics common stock at a 5.0% discount in lieu of a cash payment for the remaining amount due. Currently, we believe that the likelihood of Samsung BioLogics failing to make timely payments to us for the amounts due is remote.

Additionally, for the three and six months ended June 30, 2022, we recorded a discrete tax expense of approximately $269.5 million related to this transaction, which is reflected in income tax (benefit) expense in our condensed consolidated statements of income.

3. RESTRUCTURING, BUSINESS TRANSFORMATION AND OTHER COST SAVING INITIATIVES

2022 Cost Saving Initiatives

In December 2021 and May 2022 we announced our plans to implement a series of cost-reduction measures during 2022. These savings are being achieved through a number of initiatives, including reductions to our workforce, the substantial elimination of our commercial ADUHELM infrastructure, the consolidation of certain real estate locations and operating efficiencies across our selling, general and administrative and research and development functions.

Under these initiatives, we expect to incur restructuring charges ranging from approximately $130.0 million to $150.0 million. These amounts are primarily related to severance and are expected to be substantially incurred and paid by the end of 2022.

For the three and six months ended June 30, 2022, we recognized approximately $70.6 million and $108.7 million, respectively, of pre-tax restructuring charges related to our 2022 cost saving initiatives, of which approximately $60.9 million and $88.6 million, respectively, consisted of employee severance costs. These costs were recorded in restructuring charges in our condensed consolidated statements of income. Our restructuring reserve is included in accrued expense and other in our condensed consolidated balance sheets.

Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, North Carolina. Our decision to cease use of the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility. As a result, for the six months ended June 30, 2022, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in restructuring charges in our condensed consolidated statements of income. In May 2022 we entered into a lease assignment agreement whereby we assigned our remaining lease obligations to an external third party. As a result of the lease assignment, we derecognized the related operating lease obligation and right-of-use asset as of June 30, 2022.

For the three and six months ended June 30, 2022, we recorded other restructuring costs of approximately $9.7 million, which were recorded in restructuring charges in our condensed consolidated statements of income. Other restructuring costs includes items such as facility closure costs, employee non-severance expense, asset write-offs and other costs.

The following table summarizes the charges and spending related to our 2022 workforce reductions for the three and six months ended June 30, 2022:

(In millions)	Total
Restructuring reserve as of December 31, 2021	$ —
Expense	27.7
Payment	(6.2)
Restructuring reserve as of March 31, 2022	$ 21.5
Expense	60.9
Payment	(29.7)
Adjustment	(0.5)
Restructuring reserve as of June 30, 2022	$ 52.2

4. REVENUE

Product Revenue

Revenue by product is summarized as follows:

	For the Three Months Ended June 30,					
	2022			2021		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 120.7	$ 277.2	$ 397.9	$ 178.4	$ 309.2	$ 487.6
VUMERITY[1]	129.9	6.9	136.8	90.7	0.2	90.9
Total Fumarate	250.6	284.1	534.7	269.1	309.4	578.5
AVONEX	171.0	87.7	258.7	214.0	96.9	310.9
PLEGRIDY	40.2	51.3	91.5	43.4	46.1	89.5
Total Interferon	211.2	139.0	350.2	257.4	143.0	400.4
TYSABRI	291.9	224.3	516.2	299.8	224.4	524.2
FAMPYRA	—	25.5	25.5	—	26.1	26.1
Subtotal: MS	753.7	672.9	1,426.6	826.3	702.9	1,529.2
Spinal Muscular Atrophy:						
SPINRAZA	139.8	291.3	431.1	149.3	350.4	499.7
Biosimilars:						
BENEPALI	—	115.8	115.8	—	121.5	121.5
IMRALDI	—	57.6	57.6	—	55.6	55.6
FLIXABI	—	20.5	20.5	—	25.3	25.3
BYOOVIZ[2]	0.5	—	0.5	—	—	—
Subtotal: Biosimilars	0.5	193.9	194.4	—	202.4	202.4
Other:						
FUMADERM	—	2.7	2.7	—	3.1	3.1
ADUHELM	0.1	—	0.1	1.6	—	1.6
Total product revenue	$ 894.1	$ 1,160.8	$ 2,054.9	$ 977.2	$ 1,258.8	$ 2,236.0

[1] VUMERITY became commercially available in the European Union (E.U.) during the fourth quarter of 2021.
[2] BYOOVIZ launched in the United States (U.S.) in June 2022 and will be commercially available in July 2022.

BIOGEN INC. AND SUBSIDIARIES
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(unaudited, continued)

	For the Six Months Ended June 30,					
	2022			2021		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 237.8	$ 570.0	$ 807.8	$ 340.8	$ 626.0	$ 966.8
VUMERITY[1]	255.1	9.7	264.8	164.3	0.3	164.6
Total Fumarate	492.9	579.7	1,072.6	505.1	626.3	1,131.4
AVONEX	319.0	169.3	488.3	423.2	198.8	622.0
PLEGRIDY	74.5	97.0	171.5	76.0	102.9	178.9
Total Interferon	393.5	266.3	659.8	499.2	301.7	800.9
TYSABRI	576.4	460.6	1,037.0	573.1	454.4	1,027.5
FAMPYRA	—	51.7	51.7	—	52.7	52.7
Subtotal: MS	1,462.8	1,358.3	2,821.1	1,577.4	1,435.1	3,012.5
Spinal Muscular Atrophy:						
SPINRAZA	303.1	600.5	903.6	298.0	722.2	1,020.2
Biosimilars:						
BENEPALI	—	230.5	230.5	—	243.2	243.2
IMRALDI	—	114.7	114.7	—	113.5	113.5
FLIXABI	—	43.0	43.0	—	50.8	50.8
BYOOVIZ[2]	0.5	—	0.5	—	—	—
Subtotal: Biosimilars	0.5	388.2	388.7	—	407.5	407.5
Other:						
FUMADERM	—	4.9	4.9	—	5.9	5.9
ADUHELM	2.9	—	2.9	1.6	—	1.6
Total product revenue	$ 1,769.3	$ 2,351.9	$ 4,121.2	$ 1,877.0	$ 2,570.7	$ 4,447.7

[1] VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.
[2] BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022.

We recognized revenue from two wholesalers accounting for 27.4% and 11.2% of gross product revenue for the three months ended June 30, 2022, and 26.8% and 10.8% of gross product revenue for the six months ended June 30, 2022.

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.

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, 2021	$ 137.7	$ 759.6	$ 38.0	$ 935.3
Current provisions relating to sales in current year	337.7	1,346.1	6.4	1,690.2
Adjustments relating to prior years	(1.1)	(58.6)	(4.6)	(64.3)
Payments/credits relating to sales in current year	(243.8)	(833.3)	—	(1,077.1)
Payments/credits relating to sales in prior years	(98.4)	(391.3)	(10.6)	(500.3)
Balance, June 30, 2022	$ 132.1	$ 822.5	$ 29.2	$ 983.8

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

(In millions)	As of June 30, 2022	As of December 31, 2021
Reduction of accounts receivable	$ 137.8	$ 133.2
Component of accrued expense and other	846.0	802.1
Total revenue-related reserves	$ 983.8	$ 935.3

Revenue from Anti-CD20 Therapeutic Programs

Revenue from anti-CD20 therapeutic programs is 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)	2022	2021	2022	2021
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$ 139.9	$ 178.8	$ 283.1	$ 352.9
OCREVUS and other revenue from anti-CD20 therapeutic programs	296.4	261.2	552.6	476.1
Total revenue from anti-CD20 therapeutic programs	$ 436.3	$ 440.0	$ 835.7	$ 829.0

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 2021 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)	2022	2021	2022	2021
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	$ 6.4	$ 5.5	$ 14.4	$ 9.4
Other royalty and corporate revenue:				
Royalty	10.3	6.4	20.9	12.6
Other corporate	81.2	87.1	128.7	170.3
Total other revenue	$ 97.9	$ 99.0	$ 164.0	$ 192.3

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.

5. INVENTORY

The components of inventory are summarized as follows:

(In millions)	As of June 30, 2022	As of December 31, 2021
Raw materials	$ 378.0	$ 349.6
Work in process[1]	706.3	814.0
Finished goods	209.9	187.9
Total inventory	$ 1,294.2	$ 1,351.5

[1] Work in process inventory as of June 30, 2022, includes approximately $71.5 million related to lecanemab.

In April 2022 the Centers for Medicare and Medicaid Services (CMS) released the final National Coverage Decision (NCD) for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. We expect that this decision will reduce future demand for ADUHELM to a minimal level. During the first quarter of 2022 we wrote-off approximately $275.0 million of inventory related to

ADUHELM, as a result of this CMS decision, which was recognized in cost of sales within our condensed consolidated statements of income for the six months ended June 30, 2022. We have recognized approximately $136.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the six months ended June 30, 2022.

During the fourth quarter of 2021 we wrote-off approximately $120.0 million of inventory in excess of forecasted demand related to ADUHELM, which was recognized in cost of sales within our condensed consolidated statements of income. We have recognized approximately $59.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the year ended December 31, 2021.

As of June 30, 2022, our total ADUHELM inventory was de minimis. As of December 31, 2021, we had approximately $223.0 million of ADUHELM inventory. For additional information please read *Note 17, Collaborative and Other Relationships*, to these condensed consolidated financial statements.

6. INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

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

		As of June 30, 2022			As of December 31, 2021		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,415.0	$ (5,522.9)	$ 1,892.1	$ 7,413.1	$ (5,388.5)	$ 2,024.6
In-process research and development	Indefinite until commercialization	119.2	—	119.2	132.7	—	132.7
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 7,598.2	$ (5,522.9)	$ 2,075.3	$ 7,609.8	$ (5,388.5)	$ 2,221.3

Amortization and Impairments

For the three and six months ended June 30, 2022, amortization and impairment of acquired intangible assets totaled $67.5 million and $134.4 million, respectively, compared to $604.1 million and $702.2 million, respectively, in the prior year comparative periods. For the three and six months ended June 30, 2022, we had no impairment charges.

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).

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

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. 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, 2022, relates to the IPR&D programs we acquired in connection with our acquisition of Convergence Pharmaceuticals Holdings Ltd. (Convergence).

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 are now performing an additional clinical trial of vixotrigine, which is expected to be completed by the end of 2022.

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, 2022, the carrying value associated with the remaining IPR&D intangible asset for DPN was $119.2 million and the fair value of this asset was not significantly in excess of its carrying value. We will reassess the carrying value of this program upon conclusion of the ongoing clinical trial or sooner if there is a reevaluation event and may record an impairment charge related to this asset.

BIIB111 and BIIB112

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 intangible 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 intangible asset from $220.0 million to $28.4 million.

In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the year ended December 31, 2021, we recognized additional impairment charges related to BIIB111 and BIIB112, reducing the remaining book values of these IPR&D intangible assets to zero.

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, 2022
2022 (remaining six months)	$ 130.0
2023	210.0
2024	195.0
2025	195.0
2026	180.0
2027	165.0

Goodwill

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

(In millions)	As of June 30, 2022
Goodwill, December 31, 2021	$ 5,761.1
Other	(11.5)
Goodwill, June 30, 2022	$ 5,749.6

As of June 30, 2022, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

7. FAIR VALUE MEASUREMENTS

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

	Fair Value Measurements on a Recurring Basis			
	As of June 30, 2022			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 2,144.9	$ —	$ 2,144.9	$ —
Marketable debt securities:				
Corporate debt securities	1,890.3	—	1,890.3	—
Government securities	1,156.9	—	1,156.9	—
Mortgage and other asset backed securities	207.0	—	207.0	—
Marketable equity securities	785.6	668.7	116.9	—
Other current assets:				
Receivable from Samsung BioLogics[1]	788.1	—	—	788.1
Other assets:				
Derivative contracts	180.0	—	180.0	—
Plan assets for deferred compensation	31.9	—	31.9	—
Receivable from Samsung BioLogics[1]	406.8	—	—	406.8
Total	$ 7,591.5	$ 668.7	$ 5,727.9	$ 1,194.9
Liabilities:				
Derivative contracts	$ 23.3	$ —	$ 23.3	$ —
Contingent consideration obligations	197.5	—	—	197.5
Total	$ 220.8	$ —	$ 23.3	$ 197.5

[1] Represents the fair value of the current and non-current payments due from Samsung BioLogics as a result of the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics during the second quarter of 2022, for which we elected the fair value option. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

	Fair Value Measurements on a Recurring Basis			
	As of December 31, 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	$ 1,632.2	$ —	$ 1,632.2	$ —
Marketable debt securities:				
Corporate debt securities	1,108.2	—	1,108.2	—
Government securities	1,192.7	—	1,192.7	—
Mortgage and other asset backed securities	132.2	—	132.2	—
Marketable equity securities	1,048.5	181.7	866.8	—
Derivative contracts	80.9	—	80.9	—
Plan assets for deferred compensation	33.4	—	33.4	—
Total	$ 5,228.1	$ 181.7	$ 5,046.4	$ —
Liabilities:				
Derivative contracts	$ 10.8	$ —	$ 10.8	$ —
Contingent consideration obligations	209.1	—	—	209.1
Total	$ 219.9	$ —	$ 10.8	$ 209.1

There have been no material impairments of our assets measured and carried at fair value as of June 30, 2022 and December 31, 2021. In addition, there have been no changes in valuation techniques as of June 30, 2022 and December 31, 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 a portion of our investment in the common stock of Sage Therapeutics, Inc. (Sage) and is valued using an option pricing valuation model as the investment is subject to certain holding period restrictions. This initial holding period restriction for a portion of our investment in the common stock of Sage expired during the second quarter of 2022 and is reflected as a Level 1 measurement as of June 30, 2022.

The initial holding period restriction for a portion of our investment in the common stock of Sangamo Therapeutics, Inc. (Sangamo) expired during the second quarter of 2021 and the remaining portion expired during the second quarter of 2022. The holding period restriction for our investment in the common stock of Denali Therapeutics Inc. (Denali) expired during the first quarter of 2022. As of June 30, 2022, the fair values of our investments in Sangamo and Denali common stock were classified as Level 1 measurements. Prior to the expiration of these holding period restrictions the investments were classified as level 2 instruments.

For additional information on our investments in Sangamo, Denali and Sage common stock, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2021 Form 10-K.

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 2021 Form 10-K.

Level 3 Assets and Liabilities Held at Fair Value

The following table presents quantitative information, as of the dates indicated, about the valuation techniques and significant unobservable inputs used in the valuation of our level 3 financial assets and liabilities measured at fair value on a recurring basis:

	Quantitative Information about Level 3 Fair Value Measurements						
	Fair Value					Weighted Average	
(In millions)	June 30, 2022	December 31, 2021	Valuation Technique	Significant Unobservable Input(s)	Range	June 30, 2022	December 31, 2021
Liabilities:							
Contingent consideration obligations	$ 197.5	$ 209.1	Discounted cash flow	Discount rate	3.96%	3.96 %	1.30 %
				Expected timing of achievement of development milestones	2023 to 2028	—	—

The weighted average discount rates were calculated based on the relative fair value of our contingent consideration obligations. In addition, we apply various probabilities of technological and regulatory success to the valuation models to estimate the fair values of our contingent consideration obligations, which ranged from 10.9% to certain probability as of June 30, 2022 and December 31, 2021.

There were no transfers of assets or liabilities into or out of Level 3 as of June 30, 2022 and December 31, 2021.

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 are classified as Level 3 measurements:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2022	2021	2022	2021
Fair value, beginning of period	$ 202.0	$ 226.0	$ 209.1	$ 259.8
Changes in fair value	(4.5)	0.3	(11.6)	(33.5)
Fair value, end of period	$ 197.5	$ 226.3	$ 197.5	$ 226.3

As of June 30, 2022 and December 31, 2021, approximately $197.5 million and $209.1 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 any remaining balances reflected as a component of accrued expense and other. Changes in the fair values of our contingent consideration obligations are recorded in (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, 2022, changes in the fair value of our contingent consideration obligations were primarily due to increases in the discount rates used to revalue these obligations and 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, 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.

Financial Instruments Not Carried at Fair Value

Other Financial Instruments

Due to the short-term nature of certain financial instruments, the carrying value reflected in our condensed consolidated balance sheets for current accounts receivable, due from anti-CD20 therapeutic programs, other current assets, accounts payable and accrued expense and other, approximates fair value.

Debt Instruments

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

	As of June 30, 2022		As of December 31, 2021	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
3.625% Senior Notes due September 15, 2022	$ 1,001.1	$ 999.8	$ 1,020.0	$ 999.1
4.050% Senior Notes due September 15, 2025	1,730.1	1,743.8	1,895.2	1,742.9
2.250% Senior Notes due May 1, 2030	1,232.2	1,492.5	1,475.9	1,492.0
5.200% Senior Notes due September 15, 2045	1,066.3	1,100.1	1,463.0	1,099.9
3.150% Senior Notes due May 1, 2050	1,027.9	1,473.4	1,457.7	1,473.2
3.250% Senior Notes due February 15, 2051	489.1	467.6	692.9	466.0
Total	$ 6,546.7	$ 7,277.2	$ 8,004.7	$ 7,273.1

The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. The change in the fair value of our Senior Notes as of June 30, 2022, compared to December 31, 2021, is related to the increase in U.S. treasury yields and wider credit spreads used to value the notes since December 31, 2021. For additional information related to our Senior Notes, please read *Note 12, Indebtedness,* to our consolidated financial statements included in our 2021 Form 10-K.

8. FINANCIAL INSTRUMENTS

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

(In millions)	As of June 30, 2022	As of December 31, 2021
Commercial paper	$ 79.7	$ 247.6
Overnight reverse repurchase agreements	83.8	200.0
Money market funds	1,764.5	901.6
Short-term debt securities	216.9	283.0
Total	$ 2,144.9	$ 1,632.2

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:

(In millions)	As of June 30, 2022 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 1,363.9	$ —	$ (6.3)	$ 1,357.6
Non-current	540.4	0.1	(7.8)	532.7
Government securities:				
Current	798.0	0.1	(4.5)	793.6
Non-current	367.2	0.2	(4.1)	363.3
Mortgage and other asset backed securities:				
Current	0.1	—	—	0.1
Non-current	210.0	—	(3.1)	206.9
Total marketable debt securities	$ 3,279.6	$ 0.4	$ (25.8)	$ 3,254.2
Marketable equity securities				
Marketable equity securities, current	$ 33.9	$ —	$ (9.7)	$ 24.2
Marketable equity securities, non-current	1,103.3	—	(341.9)	761.4
Total marketable equity securities	$ 1,137.2	$ —	$ (351.6)	$ 785.6

(In millions)	As of December 31, 2021 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 723.6	$ 0.1	$ (0.3)	$ 723.4
Non-current	385.4	0.2	(0.8)	384.8
Government securities:				
Current	817.0	—	(0.4)	816.6
Non-current	377.0	0.1	(1.0)	376.1
Mortgage and other asset backed securities:				
Current	1.1	—	—	1.1
Non-current	131.8	—	(0.7)	131.1
Total marketable debt securities	$ 2,435.9	$ 0.4	$ (3.2)	$ 2,433.1
Marketable equity securities				
Marketable equity securities, current	$ 33.9	$ 9.9	$ —	$ 43.8
Marketable equity securities, non-current	1,133.1	151.0	(279.4)	1,004.7
Total marketable equity securities	$ 1,167.0	$ 160.9	$ (279.4)	$ 1,048.5

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

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

	As of June 30, 2022		As of December 31, 2021	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$ 2,151.3	$ 2,135.6	$ 1,541.1	$ 1,541.7
Due after one year through five years	1,089.4	1,130.1	868.2	870.2
Due after five years	13.5	13.9	23.8	24.0
Total marketable debt securities	$ 3,254.2	$ 3,279.6	$ 2,433.1	$ 2,435.9

The average maturity of our marketable debt securities classified as available-for-sale as of June 30, 2022 and December 31, 2021, was approximately 11 months and 10 months, respectively.

Proceeds from Marketable Debt Securities

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	2022	2021	2022	2021
Proceeds from maturities and sales	$ 917.9	$ 633.5	$ 1,461.5	$ 1,452.7
Realized gains	—	0.1	—	0.3
Realized losses	0.8	0.5	1.4	1.2

Realized losses for the three and six months ended June 30, 2022 and 2021, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities.

Strategic Investments

As of June 30, 2022 and December 31, 2021, our strategic investment portfolio was comprised of investments totaling $839.3 million and $1,110.3 million, respectively, which are included in other current assets and investments and other assets in our condensed consolidated balance sheets.

Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies, which are reflected within our disclosures included in *Note 7, Fair Value Measurements,* to these condensed consolidated financial statements, venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.

The decreases in our strategic investment portfolio for the three and six months ended June 30, 2022, were primarily due to decreases in the fair value of our investments in Denali, Sage and Sangamo common stock.

For additional information on our investments in Denali, Sage and Sangamo common stock, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2021 Form 10-K.

9. 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. We enter into foreign currency forward contracts and foreign currency options with financial institutions with the primary objective to mitigate the impact of foreign currency exchange rate fluctuations on our international revenue and operating expense.

Foreign currency forward contracts and foreign currency options in effect as of June 30, 2022 and December 31, 2021, had durations of 1 to 15 months. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the tables below). Realized gains and losses of such contracts are recognized in 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 have been impacted by the hedged item.

The notional amount 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, 2022**	**As of December 31, 2021**
Euro	$ 1,285.4	$ 1,828.0
British pound	87.0	166.2
Swiss franc	78.7	—
Japanese yen	44.6	72.7
Canadian dollar	29.5	59.9
Total foreign currency forward contracts	$ 1,525.2	$ 2,126.8

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 is summarized as follows:

(In millions)	**As of June 30, 2022**	**As of December 31, 2021**
Unrealized gains	$ 140.7	$ 60.8
Unrealized (losses)	(3.1)	(7.0)
Net unrealized gains (losses)	$ 137.6	$ 53.8

We expect the net unrealized gains of approximately $137.6 million to be settled over the next 15 months, of which approximately $133.7 million of these net unrealized gains are expected to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to 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, 2022 and December 31, 2021, 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	**2022**	**2021**	**Location**	**2022**	**2021**
Revenue	$ 44.6	$ (30.7)	Revenue	$ (0.9)	$ (0.8)
Operating expense	(2.4)	0.4	Operating expense	(0.2)	(0.3)

	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	**2022**	**2021**	**Location**	**2022**	**2021**
Revenue	$ 65.5	$ (53.8)	Revenue	$ (7.4)	$ (3.8)
Operating expense	(2.7)	—	Operating expense	(0.3)	(0.4)

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 related to this transaction was 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 entered into foreign currency forward contracts. These contracts were designated as net investment hedges. In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics and closed these foreign currency forward contracts. Upon completing this sale, the cumulative gains on our net investment hedges of $57.0 million were reclassified from accumulated other comprehensive income (loss) and reflected within the total pre-tax gain recognized from the sale, which was recorded in other (income) expense, net in our condensed consolidated statements of income. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

Prior to the sale of our equity interest in Samsung Bioepis we recognized changes in the spot exchange rate of these foreign currency forward contracts 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 $10.6 million as of December 31, 2021. We excluded fair value changes related to the forward rate from our hedging relationship and amortized 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 net losses of $3.6 million as of December 31, 2021.

The following tables summarize the effect of our net investment hedges 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	2022		2021	Location	2022	2021	Location	2022	2021
Gains (losses) on net investment hedges[1]	$ 10.3		$ (2.5)	Gains (losses) on net investment hedges[1]	$ 0.1	$ 0.3	Other (income) expense[1]	$ (3.5)	$ —

	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	2022		2021	Location	2022	2021	Location	2022	2021
Gains (losses) on net investment hedges[1]	$ 20.4		$ 21.3	Gains (losses) on net investment hedges[1]	$ (3.2)	$ (1.1)	Other (income) expense[1]	$ (4.6)	$ 0.1

[1] Beginning in the second quarter of 2022 we no longer held net investment hedges as they were closed with the sale of our 49.9% equity interest in Samsung Bioepis in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

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

Foreign Currency Forward Contracts - Other Derivative Instruments

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

The aggregate notional amount of these outstanding foreign currency forward contracts was $1,230.4 million and $1,268.0 million as of June 30, 2022 and December 31, 2021, respectively. Net losses of $37.1 million and $49.3 million related to these contracts were recorded as a component of other (income) expense, net for the three and six months ended June 30, 2022, respectively, compared to net gains of $4.8 million and net losses of $12.6 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, 2022	As of December 31, 2021
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 142.3	$ 66.2
	Investments and other assets	4.1	5.5
Liability derivative instruments	Accrued expense and other	5.2	6.6
Net Investment Hedging Instruments:[(1)]			
Asset derivative instruments	Other current assets	21.4	4.1
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	12.2	5.1
Liability derivative instruments	Accrued expense and other	18.1	4.2

[(1)] Beginning in the second quarter of 2022 we no longer held net investment hedges as they were closed with the sale of our 49.9% equity interest in Samsung Bioepis in April 2022. Amount represents unsettled balance of our closed net investment hedges. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

10. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was $2,131.0 million and $2,006.6 million as of June 30, 2022 and December 31, 2021, respectively. For the three and six months ended June 30, 2022, depreciation expense totaled $67.2 million and $143.5 million, respectively, compared to $54.7 million and $103.5 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, 2022 and December 31, 2021, we had approximately $691.7 million and $677.0 million, 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 $1.2 billion of fixed assets being placed in service during the second quarter of 2021. In April 2022 the FDA approved the Prior Approval Supplement for the Solothurn facility for ADUHELM. We estimate the second manufacturing suite will be operational during the second half of 2023.

11. INDEBTEDNESS

3.625% Senior Notes due September 15, 2022

On September 15, 2015, we issued $1.0 billion aggregate principal amount of our 3.625% Senior Notes due September 15, 2022, at 99.920% of par. Our 3.625% Senior Notes were senior unsecured obligations. In July 2022 we redeemed our 3.625% Senior Notes prior to their maturity and will recognize a net pre-tax charge of approximately $2.4 million upon the extinguishment of these notes, which primarily reflects the payment of an early call premium as well as the write-off of remaining unamortized original debt issuance costs and discount balances. These charges

will be recognized as interest expense in other (income) expense, net in our condensed consolidated statements of income during the third quarter of 2022.

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.

12. EQUITY

Share Repurchases

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $500.0 million during the three and six months ended June 30, 2022. During the three and six months ended June 30, 2021, 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, respectively. Approximately $2.3 billion remained available under our 2020 Share Repurchase Program as of June 30, 2022.

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 Hedges, Net of Tax[1]	Unrealized gains (losses) on pension benefit obligation, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2021	$ (2.2)	$ 53.8	$ 25.5	$ (44.8)	$ (139.0)	$ (106.7)
Other comprehensive income (loss) before reclassifications	(19.1)	129.5	12.6	2.7	(94.9)	30.8
Amounts reclassified from accumulated other comprehensive income (loss)	1.1	(56.4)	(38.1)	—	58.9	(34.5)
Net current period other comprehensive income (loss)	(18.0)	73.1	(25.5)	2.7	(36.0)	(3.7)
Balance, June 30, 2022	$ (20.2)	$ 126.9	$ —	$ (42.1)	$ (175.0)	$ (110.4)

[1] Beginning in the second quarter of 2022 we no longer held net investment hedges as they were closed with the sale of our 49.9% equity interest in Samsung Bioepis in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

(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 Hedges, Net of Tax	Unrealized gains (losses) on pension benefit obligation, 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)

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	2022	2021	2022	2021
Gains (losses) on securities available for sale	Other (income) expense	$ (0.8)	$ (0.4)	$ (1.4)	$ (0.9)
	Income tax benefit (expense)	0.2	0.1	0.3	0.2
Gains (losses) on cash flow hedges	Revenue	44.6	(30.7)	65.5	(53.8)
	Operating expense	(2.4)	0.4	(2.7)	—
	Other (income) expense	(0.1)	(0.1)	(0.2)	0.1
	Income tax benefit (expense)	(4.2)	3.0	(6.2)	5.3
Gains (losses) on net investment hedges[1]	Other (income) expense	39.2	0.1	38.1	0.1
Currency Translation Adjustments	Other (income) expense	(58.9)	—	(58.9)	—
Total reclassifications, net of tax		$ 17.6	$ (27.6)	$ 34.5	$ (49.0)

[1] Beginning in the second quarter of 2022 we no longer held net investment hedges as they were closed with the sale of our 49.9% equity interest in Samsung Bioepis in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

13. 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)	2022	2021	2022	2021
Numerator:				
Net income attributable to Biogen Inc.	$ 1,058.0	$ 448.5	$ 1,361.8	$ 858.7
Denominator:				
Weighted average number of common shares outstanding	145.9	149.7	146.5	150.8
Effect of dilutive securities:				
Time-vested restricted stock units	0.2	0.2	0.2	0.2
Market stock units	—	0.1	—	0.1
Performance stock units settled in stock	0.1	0.1	0.1	0.1
Dilutive potential common shares	0.3	0.4	0.3	0.4
Shares used in calculating diluted earnings per share	146.2	150.1	146.8	151.2

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

14. SHARE-BASED PAYMENTS

Share-based Compensation Expense

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Research and development	$ 22.4	$ 19.1	$ 48.1	$ 52.7
Selling, general and administrative	36.7	40.3	82.8	85.2
Subtotal	59.1	59.4	130.9	137.9
Capitalized share-based compensation costs	(2.3)	(1.7)	(5.1)	(4.3)
Share-based compensation expense included in total cost and expense	56.8	57.7	125.8	133.6
Income tax effect	(10.2)	(10.9)	(23.0)	(24.9)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 46.6	$ 46.8	$ 102.8	$ 108.7

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)	**2022**	**2021**	**2022**	**2021**
Market stock units	$ 1.5	$ 9.3	$ 7.4	$ 25.8
Time-vested restricted stock units	50.4	40.4	101.7	83.2
Performance stock units settled in stock	3.3	3.0	11.6	9.3
Performance stock units settled in cash	1.1	3.4	2.5	9.4
Employee stock purchase plan	2.8	3.3	7.7	10.2
Subtotal	59.1	59.4	130.9	137.9
Capitalized share-based compensation costs	(2.3)	(1.7)	(5.1)	(4.3)
Share-based compensation expense included in total cost and expense	$ 56.8	$ 57.7	$ 125.8	$ 133.6

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.

15. INCOME TAXES

Tax Rate

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Statutory rate	21.0 %	21.0 %	21.0 %	21.0 %
State taxes	0.6	1.3	0.4	1.1
Taxes on foreign earnings	(3.8)	(7.7)	(5.3)	(9.1)
Tax credits	(1.4)	(2.9)	(1.6)	(3.3)
Purchased intangible assets	0.1	(0.8)	0.2	(0.1)
GILTI	0.2	1.5	0.2	1.3
Sale of Samsung Bioepis	(3.7)	—	(2.9)	—
Litigation agreement in principle	8.5	—	6.7	—
Neurimmune tax impacts	—	(83.1)	5.2	(46.3)
International reorganization	(4.0)	—	(3.1)	—
Other	(0.4)	0.4	0.4	0.6
Effective tax rate	17.1 %	(70.3)%	21.2 %	(34.8)%

Changes in Tax Rate

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the increases in our effective tax rate were primarily due to the overall current year unfavorable tax rate impact on the sale of our equity interest in Samsung Bioepis in April 2022, the litigation agreement in principle and the tax benefit recorded in the second quarter of 2021 related to the Neurimmune SubOne AG (Neurimmune) deferred tax asset matter, as discussed below. These effective tax rate increases were partially offset by the non-cash tax effects of changes in the value of our equity instruments and the current year tax benefits recorded in the second quarter of 2022 related to an international reorganization to align with global tax developments.

For the six months ended June 30, 2022, compared with the same period in 2021, our effective tax rate also increased as a result of the Neurimmune valuation allowance recorded in the first quarter of 2022.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM. During the fourth quarter of 2021, due to reduced future expected revenue associated with ADUHELM, we recorded a valuation allowance of approximately $390.0 million.

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an additional valuation allowance of approximately $85.0 million to reduce the net value of this deferred tax asset to zero. These adjustments to our deferred tax assets and their valuation allowances are each recorded 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 the litigation agreement in principle, please read *Note 19, Litigation*, to these condensed consolidated financial statements.

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

Accounting for Uncertainty in Income Taxes

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

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 $500.0 million, including approximately $455.0 million related to the unrecognized tax benefits related to Neurimmune's tax basis in ADUHELM, in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations. Any changes to our gross unrecognized tax benefits related to Neurimmune's tax basis in ADUHELM would result in a zero net impact to net income attributable to Biogen, Inc., as we have recorded a full valuation allowance against the relevant deferred tax assets.

16. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAIL

Other (Income) Expense, Net

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Gain on sale of equity interest in Samsung Bioepis[1]	$ (1,505.4)	$ —	$ (1,505.4)	$ —
Litigation agreement in principle	900.0	—	900.0	—
Interest income	(12.6)	(2.7)	(15.5)	(5.6)
Interest expense	65.8	56.4	131.9	121.1
Gains (losses) on investments, net	78.2	(153.9)	269.3	282.7
Foreign exchange gains (losses), net	19.2	0.8	27.5	9.4
Other, net	26.2	3.0	26.9	2.9
Total other (income) expense, net	$ (428.6)	$ (96.4)	$ (165.3)	$ 410.5

[1] Reflects the pre-tax gain, net of transaction costs, recognized from the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

Gains (losses) 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.

During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million, plus estimated fees and expenses, related to an agreement in principle to resolve a qui tam litigation relating to conduct prior to 2015. This charge is included within other (income) expense, net in our condensed consolidated statements of income for the three and six months ended June 30, 2022. For additional information on the litigation agreement in principle, please read *Note 19, Litigation*, to these condensed consolidated financial statements.

The following table summarizes our gains (losses) on investments, net that relate to our equity securities held during the following periods:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(In millions)	**2022**	**2021**	**2022**	**2021**
Net gains (losses) recognized on equity securities	$ (77.2)	$ 154.3	$ (267.9)	$ (281.8)
Less: Net gains (losses) realized on equity securities	(0.7)	0.4	(0.5)	6.6
Net unrealized gains (losses) recognized on equity securities	$ (76.5)	$ 153.9	$ (267.4)	$ (288.4)

The net unrealized losses recognized during the three months ended June 30, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Sangamo and Denali common stock of approximately $75.3 million.

The net unrealized losses recognized during the six months ended June 30, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sangamo and Sage common stock of approximately $277.1 million.

Accrued Expense and Other

Accrued expense and other consists of the following:

(In millions)	As of June 30, 2022	As of December 31, 2021
Litigation agreement in principle[1]	$ 900.0	$ —
Revenue-related reserves for discounts and allowances	846.0	802.1
Collaboration expense	261.8	324.7
Royalties and licensing fees	216.2	234.7
Employee compensation and benefits	281.5	345.1
Other	793.0	828.6
Total accrued expense and other	$ 3,298.5	$ 2,535.2

[1] During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million, plus estimated fees and expenses, related to an agreement in principle to resolve a qui tam litigation relating to conduct prior to 2015. For additional information on the litigation agreement in principle, please read *Note 19, Litigation*, to these condensed consolidated financial statements.

Other Long-term Liabilities

Other long-term liabilities were $1,167.8 million and $1,320.5 million as of June 30, 2022 and December 31, 2021, respectively, and included accrued income taxes totaling $499.6 million and $664.5 million, respectively.

17. 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 lead of lecanemab development and regulatory submissions globally with both companies co-commercializing and co-promoting the product, and Eisai having final decision-making authority. 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 March 2022 we extended our supply agreement related to lecanemab from five years to ten years, and we will manufacture the lecanemab drug substance.

In May 2022 Eisai completed the submission of a Biologics License Application (BLA) to the FDA for the accelerated approval of lecanemab. In July 2022 the FDA accepted the BLA and granted Priority Review with a Prescription Drug User Fee Act action date of January 6, 2023.

The Lecanemab Collaboration also provided Eisai with an option to jointly develop and commercialize ADUHELM (aducanumab) (ADUHELM 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 (the ADUHELM Collaboration Agreement).

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)	2022	2021	2022	2021
Total development expense incurred by the collaboration related to the advancement of lecanemab and elenbecestat	$ 78.6	$ 62.2	$ 155.6	$ 117.7
Biogen's share of lecanemab and elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	39.3	31.1	77.8	58.8
Total sales and marketing expense incurred by the Lecanemab Collaboration	23.4	4.3	39.3	10.0
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	11.7	2.1	19.7	5.0

For additional information on our Lecanemab Collaboration, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2021 Form 10-K.

ADUHELM Collaboration Agreement

Under our initial ADUHELM Collaboration Agreement, we would lead the ongoing development of ADUHELM, and we and Eisai would co-promote ADUHELM with a region-based profit split. Beginning January 1, 2019, Eisai was reimbursing us for 45.0% of development costs incurred by the collaboration for the advancement of ADUHELM (ADUHELM development expense).

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, which was recorded in collaboration profit (loss) sharing in our condensed consolidated statements of income.

In March 2022 we amended our ADUHELM Collaboration Agreement with Eisai. Effective March 2022 we have sole decision making and commercialization rights worldwide on ADUHELM and beginning January 1, 2023, Eisai will receive a tiered royalty based on net sales of ADUHELM, rather than sharing global profits and losses. Eisai's share of development, commercialization and manufacturing expense is limited to $335.0 million for the period from January 1, 2022 to December 31, 2022. As of June 30, 2022, Eisai's portion of these expenses was approximately $275.0 million. Once this limit is achieved, we will be responsible for all ADUHELM related development costs. After the tiered royalty model commences on January 1, 2023, Eisai will not participate in ADUHELM's economics beyond these royalties.

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)	2022	2021	2022	2021
Total ADUHELM development expense	$ 37.2	$ 42.1	$ 81.4	$ 89.1
Biogen's share of ADUHELM development expense reflected in research and development expense in our condensed consolidated statements of income	20.5	23.2	44.8	49.0
Total ADUHELM sales and marketing expense incurred by the ADUHELM Collaboration Agreement	40.8	125.6	135.8	237.4
Biogen's share of ADUHELM sales and marketing expense reflected in selling, general and administrative expense and collaboration profit (loss) sharing in our condensed consolidated statements of income	21.1	67.6	72.0	127.9
Total ADUHELM collaboration third-party milestones	—	100.0	—	100.0
Biogen's share of reimbursement from Eisai of ADUHELM milestone payments reflected in collaboration profit (loss) sharing in our condensed consolidated statements of income	—	45.0	—	45.0

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 (loss) sharing in our condensed consolidated statements of income. For the three and six months ended June 30, 2022, we recognized a net reduction to our operating expense of $28.9 million and $210.6 million, respectively, to reflect Eisai's 45.0% share of net collaboration losses in the U.S., compared to $40.1 million in each of the prior year comparative periods.

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.

During the first quarter of 2022 we recorded approximately $275.0 million of gross charges associated with inventory and purchase commitments in excess of forecasted demand related to ADUHELM, as well as approximately $45.0 million of gross idle capacity charges, which were recognized in cost of sales within our condensed consolidated statements of income for the six months ended June 30, 2022. We have recognized approximately $160.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the six months ended June 30, 2022.

Amounts receivable from Eisai related to the agreements discussed above were $250.8 million and $285.4 million as of June 30, 2022 and December 31, 2021, respectively. Amounts payable to Eisai related to the agreements discussed above were $56.0 million and $46.5 million as of June 30, 2022 and December 31, 2021, respectively.

For additional information on the ADUHELM Collaboration Agreement, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2021 Form 10-K.

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)	**2022**	**2021**	**2022**	**2021**
Total UCB collaboration development expense	$ 15.6	$ 16.1	$ 33.2	$ 33.0
Biogen's share of UCB development expense reflected in research and development expense in our condensed consolidated statements of income	7.8	8.1	16.6	16.5

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.

Under this collaboration, 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)	2022	2021	2022	2021
Total Sage collaboration development expense	$ 50.8	$ 54.0	$ 89.5	$ 93.8
Biogen's share of Sage development expense reflected in research and development expense in our condensed consolidated statements of income	25.3	27.0	44.7	46.9
Total Sage sales and marketing expense incurred by the collaboration	23.0	10.5	41.4	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	11.5	5.2	20.7	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. Under this collaboration, both companies share responsibility and costs for global development based on specified percentages as well as profits and losses for commercialization in the U.S. and China. Outside the U.S. and China we are responsible for commercialization and may pay Denali potential tiered royalties.

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 ATV-enabled therapeutics for indications within specific neurodegenerative diseases, should Denali decide to seek a collaboration for such programs.

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)	2022	2021	2022	2021
Total Denali collaboration development expense	$ 23.2	$ 10.4	$ 38.1	$ 18.7
Biogen's share of Denali development expense reflected in research and development expense in our condensed consolidated statements of income	13.2	6.2	22.1	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 to modulate the expression of key genes involved in neurological diseases.

Under this collaboration, we may pay Sangamo tiered royalties on potential net sales of any products developed under this collaboration in the high single digit to sub-teen percentages.

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)	2022	2021	2022	2021
Total Sangamo collaboration development expense	$ 2.6	$ 5.4	$ 10.9	$ 10.2
Biogen's share of Sangamo development expense reflected in research and development expense in our condensed consolidated statements of income	1.6	3.4	7.1	7.6

InnoCare Pharma Limited

In July 2021 we entered into a collaboration and license 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 collaboration, we 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 retains

exclusive worldwide rights to orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan).

In connection with the closing of this transaction in August 2021 we made an upfront payment of $125.0 million that was recorded as research and development expense in our condensed consolidated statements of income. We may also pay InnoCare up to approximately $812.5 million in potential development milestones and potential commercial payments should this collaboration achieve certain development, commercial milestones and sales thresholds. In addition, we may pay InnoCare tiered royalties on potential net sales of any products developed under this collaboration in the low to high 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, 2022, we recorded $18.0 million and $37.5 million, respectively, as research and development expense in our condensed consolidated statements of income related to other research and discovery related arrangements, compared to $77.2 million in each of 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 April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics. Under the terms of this transaction, we received approximately $1.0 billion in cash at closing and expect to receive approximately $1.3 billion in cash to be deferred over two payments of approximately $812.5 million due at the first anniversary and approximately $437.5 million due at the second anniversary of the closing of the transaction.

As part of the transaction, we are also eligible to receive up to an additional $50.0 million upon the achievement of certain commercial milestones. Our policy for contingent payments of this nature is to recognize them in the period that they become realizable, which is generally the same period in which they are earned.

Prior to this sale, we recognized 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 became available, which was reflected as equity in (income) loss of investee, net of tax in our condensed consolidated statements of income.

Upon investment, the equity method of accounting required 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 were being amortized over their economic life until the completion of the sale in April 2022, as discussed above. The total basis difference was approximately $675.0 million and related 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 were being amortized, net of tax, over their estimated useful lives of 15 years.

For the three and six months ended June 30, 2022, we recognized net income on our investment of $5.9 million and $2.6 million, respectively, reflecting our share of Samsung Bioepis' operating profits, net of tax totaling $13.0 million and $17.0 million, respectively, offset by amortization of basis differences totaling $7.1 million and $14.4 million, respectively. These amounts reflect our share of results prior to the sale of Samsung Bioepis as the results are recognized one quarter in arrears. Following the sale of Samsung Bioepis we no longer recognize gains or losses associated with Samsung Bioepis' results of operations and amortization related to basis differences.

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 income, net of tax totaling $41.6 million and $30.6 million, respectively, and amortization of basis differences totaling $7.3 million and $14.5 million, respectively.

As of December 31, 2021, the carrying value of our investment in Samsung Bioepis totaled 713.3 billion South Korean won ($599.9 million), which is classified as a component of investments and other assets in our condensed consolidated balance sheets. In connection with the sale of Samsung Bioepis, the carrying value of our investment was reduced to zero.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to these condensed consolidated financial statements.

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, BYOOVIZ (ranibizumab-nuna), a 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 at a pre-specified gross margin of approximately 45.0%.

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 our condensed consolidated statements of income in 2019 and $37.0 million was recorded as intangible assets, net in our condensed consolidated balance sheets in 2019.

During the third quarter of 2021 we accrued $15.0 million in milestone payments related to the approval of BYOOVIZ in the U.S., the E.U. and the United Kingdom (U.K.), that were capitalized within intangible assets, net in our condensed consolidated balance sheets. We may also pay Samsung Bioepis up to approximately $180.0 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 (loss) sharing in our condensed consolidated statements of income. For the three and six months ended June 30, 2022, we recognized net profit-sharing expense of $58.3 million and $122.7 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits, compared to a net profit-sharing expense of $69.9 million and $138.4 million, respectively, in the prior year comparative periods.

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 is reflected in revenue from collaborative and other relationships as a component of other revenue in our condensed consolidated statements of income.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were $3.1 million and $4.1 million as of June 30, 2022 and December 31, 2021, respectively. Amounts payable to Samsung Bioepis related to the agreements discussed above were $121.1 million and $148.7 million as of June 30, 2022 and December 31, 2021, 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 2021 Form 10-K.

18. INVESTMENTS IN VARIABLE INTEREST ENTITIES

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

We have a collaboration and license agreement with Neurimmune 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 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 (loss) sharing in our condensed consolidated statements of income.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM. During the fourth quarter of 2021, due to reduced future expected revenue associated with ADUHELM, we recorded a valuation allowance of approximately $390.0 million. During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an additional valuation allowance of approximately $85.0 million to reduce the net value of this deferred tax asset to zero. These adjustments to our deferred tax assets and their valuation allowances are each recorded 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.

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

Unconsolidated Variable Interest Entities

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

As of June 30, 2022 and December 31, 2021, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $23.5 million and $24.6 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 previous 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 2021 Form 10-K.

19. LITIGATION

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read *Note 1, Summary of Significant Accounting Policies,* to our consolidated financial statements included in our 2021 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 actions filed by shareholders on November 13, 2020 (the November 2020 Securities Action) and February 7, 2022 (the February 2022 Securities Action), and pending in the U.S. District Court for the District of Massachusetts. The actions allege violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seek declarations of the actions as class actions and monetary relief. We have filed a motion to dismiss the November 2020 Securities Action, which is pending. An estimate of the possible loss or range of loss in these actions cannot be made at this time.

Derivative Action

We and members of the Board of Directors are named as defendants in an action filed by a shareholder on February 9, 2022, in the U.S. District Court for the District of Massachusetts. The action alleges violations of federal securities laws under 15 U.S.C. §78n(a) and 17 C.F.R. §240 14.a-9, breaches of fiduciary duties and waste of corporate assets, and seeks declaratory and injunctive relief, monetary relief to Biogen, and attorneys' fees and costs to the plaintiff. The court has stayed the case pending the resolution of the February 2022 Securities Action. An estimate of the possible loss or range of loss cannot be made at this time.

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 (the French proceeding) and in November 2018 against Biogen GmbH in the D✔sseldorf Regional Court (the German proceeding), alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis that Biogen has commercialized in Europe, infringes national counterparts of European Patent No. 3 148 510 (the EP '510 Patent, expiring in May 2035). Fresenius Kabi later added European Patent 3 145 488 (the EP '488 Patent, expiring in May 2035) to both actions and no hearing has been set in either. In June 2022 the Technical Boards of Appeal (TBA) of the European Patent Office (EPO) affirmed the revocation of the EP '510 Patent. The EPO has scheduled a hearing on the validity of the EP '488 Patent for October 2022.

In June 2020 Fresenius Kabi commenced proceedings in Denmark's Maritime and Commercial High Court alleging that IMRALDI infringes the Danish counterpart of the EP '488 Patent and a Danish utility model. In September 2021 the Court ruled that the patent and utility model are invalid and not infringed. Fresenius Kabi has appealed to the High Court of Eastern Denmark and the appeal is pending.

In July 2020 the Danish Patent Board of Appeal revoked the Danish utility models that Fresenius Kabi had asserted against Biogen and Fresenius Kabi has appealed to the Danish Maritime and Commercial High Court. No hearing has been scheduled.

In July 2019 Gedeon Richter Nyrt commenced proceedings for damages and injunctive relief against Biogen GmbH in the D✔sseldorf Regional Court alleging infringement of the German counterpart of European Patent No. 3 212 667, which expires in October 2035. The case has been stayed pending proceedings in the EPO seeking to invalidate the patent. In November 2020 Gedeon Richter Nyrt commenced additional proceedings against Biogen GmbH in the D✔sseldorf Regional Court alleging infringement of a German utility model. In October 2021 Biogen filed cancellation proceedings in respect of the German utility model and the infringement proceedings have been stayed pending the outcome of the cancellation proceedings.

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

Biogen has reached an agreement in principle to resolve previously disclosed litigation pending in the U.S. District Court for the District of Massachusetts alleging violations of the federal False Claims Act and state law counterparts. The litigation was filed by Michael Bawduniak on behalf of the U.S. and certain states and unsealed in 2015. The U.S. has not intervened in the case. The agreement in principle contemplates Biogen making a payment of $900.0 million. The agreement in principle does not include any admission of liability and is subject to the negotiation of final settlement documents and agreements with the named government entities.

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.

ERISA Class Action Litigation

In September 2020 the U.S. District Court for the District of Massachusetts consolidated two cases filed against us in July and August 2020 by participants in the Biogen 401(k) Savings Plan alleging breach of fiduciary duty under ERISA. Plaintiffs seek a declaration of the action as a class action and monetary and other relief. An estimate of the possible loss or range of loss cannot be made at this time.

Humana Patient Assistance Litigation

In September 2021 Humana Inc. (Humana) filed suit against us in the U.S. District Court for the District of Massachusetts alleging damages related to our providing MS patients with free medications and making charitable contributions to non-profit organizations that assist MS patients. Humana alleges violation of the federal RICO Act and state laws and seeks statutory treble damages, attorneys' fees and costs. We filed a motion to dismiss, which is pending. An estimate of the possible loss cannot be made at this time.

Other Matters

Government Investigations

The U.S. House of Representatives Committees on Oversight and Reform and Energy and Commerce and the Office of Inspector General of the U.S. Department of Health and Human Services have announced investigations relating to ADUHELM. In addition, the Company has received a civil investigative demand from the Federal Trade Commission and a subpoena from the Securities and Exchange Commission seeking information relating to ADUHELM, including healthcare sites, ADUHELM’s approval and ADUHELM’s marketing.

TECFIDERA Patent Matters

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 (the West Virginia Action) in the U.S. District Court for the Northern District of West Virginia (the West Virginia Court).

In November 2021 the Federal Circuit affirmed the West Virginia Court judgment that the asserted claims of our U.S. Patent No. 8,399,514 (the '514 Patent) are invalid for lack of written description and in June 2022 we filed a petition for a writ of certiorari to the United States Supreme Court seeking review of the Federal Circuit's decision.

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. The appeals in the Delaware Actions are stayed pending any final action by the United States Supreme Court with respect to the judgment in the West Virginia Action.

In July 2018 Mylan Pharmaceuticals, Inc. (Mylan) filed a petition with the U.S. Patent Trial and Appeal Board (PTAB) for *inter partes* review of the '514 Patent. In November 2021 the Federal Circuit ruled that the PTAB decision upholding the patentability of the ‘514 patent was moot, but in April 2022 the Federal Circuit vacated that ruling and stayed the appeal pending any final action by the United States Supreme Court with respect to the judgment in the West Virginia Action.

TYSABRI Patent Revocation Matters

In November 2017 Swiss Pharma International AG, affiliated with the Polpharma Group, filed an action in the Commercial Court of Rome to invalidate the Italian counterpart of the European Patent No. 1 485 127 (the EP '127 Patent) which covers administration of natalizumab (TYSABRI) to treat MS and expires in February 2023. A hearing has been set for November 2022.

In August 2020 Polpharma Biologics S.A., also affiliated with the Polpharma Group, brought an action in the Polish Patent Office to revoke our Polish Patent No. 215263, which corresponds to the EP '127 Patent and expires in February 2023. The action was suspended by the Polish Patent Office in April 2021 pending examination of our amended patent claims.

In June 2021 Polpharma Biologics S.A., Sandoz B.V. and Sandoz AG filed an action in the District Court of the Hague, Netherlands to invalidate the Dutch counterpart of our European Patent 2 676 967 (the EP '967 Patent), which expires in 2027 and covers methods of treatment using natalizumab (TYSABRI) and pre-treatment testing of patients. A hearing has been set for September 2022.

In July 2021 the EPO revoked the EP ‘967 Patent. A hearing on our appeal to the TBA of the EPO is set for December 2022.

In September 2021 Polpharma Biologics S.A., Sandoz AG, Sandoz Limited and Sandoz GmbH filed an action in the English High Court to revoke the U.K. counterpart of the EP ‘967 Patent and seeking a declaration that the patent would not be infringed by the marketing of Polpharma’s proposed natalizumab biosimilar. A hearing has been set for February 2023.

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

Pharmaceutical Works Polpharma SA (Polpharma) and Mylan Ireland Ltd. (Mylan Ireland) each filed actions in the General Court of the European Union (Polpharma in October 2018 and Mylan Ireland in November 2020) to annul the European Medicines Agency's (EMA) decision not to validate their applications to market generic versions of TECFIDERA on the grounds that TECFIDERA benefits from regulatory data protection. On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to Polpharma. We have appealed the 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.

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, 2021 (2021 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. We have a leading portfolio of medicines to treat multiple sclerosis (MS), have introduced the first approved treatment for spinal muscular atrophy (SMA) and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. We also commercialize biosimilars of advanced biologics and focus on advancing our pipeline in neuroscience and specialized immunology. Lastly, we are focused on accelerating our efforts in digital health to support our commercial and pipeline programs while also creating opportunities for potential digital therapeutics. 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 (PPMS) and relapsing MS (RMS); and other potential anti-CD20 therapies, including mosunetuzumab, 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 2021 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 collaboration with Samsung Bioepis Co., Ltd. (Samsung Bioepis) 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, as well as BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 17, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

We seek to ensure an uninterrupted supply of medicines to patients around the world. To that end, we continually review our manufacturing capacity, capabilities, processes and facilities. In order to support our future growth and drug development pipeline, we are expanding our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland. 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). In April 2022 the United States (U.S.) Food and Drug Administration (FDA) approved the Prior Approval Supplement for the Solothurn facility for ADUHELM. We estimate the second manufacturing suite will be operational during the second half of 2023. We believe that the Solothurn facility will support our anticipated near-term needs for the manufacturing of biologic assets. If we are unable to fully utilize our manufacturing facilities, due to lower than forecasted demand for our products, we will incur excess capacity charges which will have a negative effect on our financial condition and results of operations.

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 and/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, geopolitical events, foreign currency exchange fluctuations, changes in intellectual property legal protections and changes in trade regulations and procedures.

For a detailed discussion on our business environment, please read *Item 1. Business*, in our 2021 Form 10-K. For additional information on our competition and pricing risks that could negatively impact our product sales, please read *Item 1A. Risk Factors* included in this report.

ADUHELM (aducanumab)

U.S.

In June 2021 the FDA granted accelerated approval of ADUHELM, which we are collaborating on 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 are required to 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 of ADUHELM, 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.

In January 2022 the Centers for Medicare and Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) decision memorandum, stating the proposed NCD would cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease for people with Medicare only if they are enrolled in qualifying clinical trials.

In April 2022 CMS released the final NCD for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. We expect that this decision will reduce future demand for ADUHELM to a minimal level. During the first quarter of 2022 we recorded approximately $275.0 million of gross charges associated with inventory and purchase commitments in excess of forecasted demand related to ADUHELM, as well as approximately $45.0 million of gross idle capacity charges, which were recognized in cost of sales within our condensed consolidated

statements of income for the six months ended June 30, 2022. We have recognized approximately $160.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the six months ended June 30, 2022.

Additionally, as a result of the final NCD we have substantially eliminated our commercial infrastructure supporting ADUHELM, retaining minimal resources to manage patient access programs, including a continued free drug program for patients currently on treatment in the U.S.

We expect to continue funding certain regulatory and research and development activities for ADUHELM, including the continuation of the EMBARK re-dosing study and the initiation of the Phase 4 post-marketing requirement study, ENVISION. Additional actions regarding ADUHELM may be informed by upcoming data readouts expected for this class of antibodies, as well as further engagement with the FDA and CMS.

In March 2022 we amended our ADUHELM Collaboration Agreement with Eisai. Effective March 2022 we have sole decision making and commercialization rights worldwide on ADUHELM and beginning January 1, 2023, Eisai will receive a tiered royalty based on net sales of ADUHELM, rather than sharing global profits and losses. Eisai's share of development, commercialization and manufacturing expense is limited to $335.0 million for the period from January 1, 2022 to December 31, 2022. As of June 30, 2022, Eisai's portion of these expenses was approximately $275.0 million. Once this limit is achieved, we will be responsible for all ADUHELM related development costs. After the tiered royalty model commences on January 1, 2023, Eisai will not participate in ADUHELM’s economics beyond these royalties.

Rest of World

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

In December 2021 the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a negative opinion on the MAA for aducanumab in Europe. We sought re-examination of the opinion by the CHMP. In April 2022 we announced our decision to withdraw our MAA for aducanumab in Europe.

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 2020 U.S. federal courts in West Virginia and Delaware entered judgments in favor of the defendants in patent infringement proceedings relating to TECFIDERA Orange-Book listed patents. We appealed both decisions. In late 2021 the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) affirmed the judgment of the West Virginia federal court. The appeals in the actions in Delaware are stayed pending any final action by the United States Supreme Court with respect to the judgment in the West Virginia Action.

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 continue to have a substantial and increasing negative impact on our U.S. TECFIDERA revenue in the future.

In May 2021 the European General Court annulled the EMA's decision not to validate applications for approval of TECFIDERA generics on the basis that the EMA conducted the wrong assessment when determining TECFIDERA's entitlement to regulatory data and marketing protection. Our Company, the EMA and the European Commission (EC) have each appealed the General Court’s decision as wrongly decided and the appeal is pending.

In November 2021 the CHMP of the EMA issued an ad hoc opinion referencing the General Court’s decision which concluded that "the totality of the available data cannot establish that [monoethyl fumarate] exerts a clinically relevant therapeutic contribution within FUMADERM," and in May 2022 the EC approved applications to market generic TECFIDERA. Generic TECFIDERA is now for sale in the E.U. and we expect generic sales to have an adverse impact on our TECFIDERA sales in the E.U. and our results of operations. In June 2022 the European Patent Office granted Biogen a patent that relates to TECFIDERA and expires in 2028. We intend to enforce this new patent.

For additional information, please read *Note 19, 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 and Other Disruptions

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, the supply chain, manufacturing, clinical trials, research and development costs and employee-related costs, 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.

Conflict in Ukraine

The ongoing geopolitical tensions related to Russia's invasion of Ukraine have resulted in global business disruptions and economic volatility, including sanctions and other restrictions levied on the government and businesses in Russia. Although we do not have affiliates or employees, in either Russia or Ukraine, we do provide various therapies to patients in Russia through a distributor and are currently involved in clinical trials with sites in Ukraine and Russia. The timing and costs of these trials may be impacted as a result of the conflict. For example, the development of orelabrutinib, an oral small molecule Bruton’s tyrosine kinase inhibitor for the potential treatment of MS, that we are developing with InnoCare has been delayed and will require the establishment of new clinical sites in other geographies.

The impact of the conflict on our operations and financial performance remains uncertain and will depend on future developments, including the severity and duration of the conflict, its impact on regional and global economic conditions and whether the conflict spreads or has effects on countries outside Ukraine and Russia. Revenue generated from sales in these regions represented less than 2.0% of total product revenue for the three and six months ended June 30, 2022 and the year ended December 31, 2021.

We will continue to monitor the ongoing conflict between Russia and Ukraine and assess any potential impacts on our business, supply chain, partners or customers, as well as any factors that could have an adverse effect on our results of operations.

Factors such as the COVID-19 pandemic, adverse weather events, geopolitical events, labor or raw material shortages and other supply chain disruptions could result in product shortages or other difficulties and delays or increased costs in manufacturing our products.

For additional information on the various risks posed by the COVID-19 pandemic and the conflict in Ukraine, please read *Item 1A. Risk Factors* included in this report.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was $7.24 for the three months ended June 30, 2022, representing a increase of 142.1% compared to $2.99 in the same period in 2021.

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, 2022, compared to the three months ended June 30, 2021, reflects the following:

Revenue

- Total revenue was $2,589.1 million for the second quarter of 2022, representing a $185.9 million, or 6.7%, decrease compared to $2,775.0 million in the same period in 2021.
- Product revenue, net totaled $2,054.9 million for the second quarter of 2022, representing a $181.1 million, or 8.1%, decrease compared to $2,236.0 million in the same period in 2021. This decrease was primarily due to a $102.6 million, or 6.7%, decrease in MS product revenue and a $68.6 million, or 13.7%, decrease in SPINRAZA product revenue.
    - The decrease in MS product revenue was primarily due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market and a decrease in Interferon demand due to competition.
    - The decrease in SPINRAZA revenue was primarily due to a decrease in demand as a result of increased competition in certain established markets, particularly Germany, and the timing of shipments, as well as unfavorable pricing and the

unfavorable impact of foreign currency exchange.

- Revenue from anti-CD20 therapeutic programs totaled $436.3 million for the second quarter of 2022, representing a $3.7 million, or 0.8%, decrease compared to $440.0 million in the same period in 2021. This decrease was primarily due to a $39.2 million, or 24.6%, decrease in RITUXAN revenue, partially offset by a $34.8 million, or 13.6%, increase in royalty revenue on sales of OCREVUS. Sales of RITUXAN have been adversely affected by the onset of biosimilars competition.
- Other revenue totaled $97.9 million for the second quarter of 2022, representing a $1.1 million, or 1.1%, decrease compared to $99.0 million in the same period in 2021.

Expense

- Total cost and expense was $1,319.6 million for the second quarter of 2022, representing a $873.3 million, or 39.8%, decrease compared to $2,192.9 million in the same period in 2021.
    - The decrease in amortization and impairment of acquired intangible assets is primarily due to impairment charges recorded during the three months ended June 30, 2021 totaling $541.6 million.
    - Other (income) expense, net for the second quarter of 2022 reflected a pre-tax gain of approximately $1.5 billion related to the sale of our 49.9% equity interest in Samsung Bioepis, partially offset by a pre-tax charge of $900.0 million related to an agreement in principle to resolve a qui tam litigation relating to conduct prior to 2015.

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

- We generated $898.3 million of net cash flow from operations for the six months ended June 30, 2022.
- Cash, cash equivalents and marketable securities totaled approximately $5,900.8 million as of June 30, 2022.
- We repurchased and retired approximately 2.4 million shares of our common stock at a cost of approximately $500.0 million during the second quarter of 2022 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 $2.3 billion remained available under our 2020 Share Repurchase Program as of June 30, 2022.

Collaborative and Other Relationships

For additional information on our collaborative and other relationships discussed below, please read *Note 17, Collaborative and Other Relationships*, and *Note 18, Investments in Variable Interest Entities*, to our condensed consolidated financial statements included in this report.

Samsung Bioepis - Biogen's Joint Venture with Samsung BioLogics

In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics. Under the terms of this transaction, we received approximately $1.0 billion in cash at closing and expect to receive approximately $1.3 billion in cash to be deferred over two payments of approximately $812.5 million due at the first anniversary and approximately $437.5 million due at the second anniversary of the closing of the transaction.

We are also eligible to receive up to an additional $50.0 million upon the achievement of certain commercial milestones. Our policy for contingent payments of this nature is to recognize them in the period that they become realizable, which is generally the same period in which they are earned.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to our condensed consolidated financial statements included in this report.

Eisai Collaboration Agreements

ADUHELM Collaboration Agreement

In March 2022 we amended our ADUHELM Collaboration Agreement with Eisai. Effective March 2022 we have sole decision making and commercialization rights worldwide on ADUHELM and beginning January 1, 2023, Eisai will receive a tiered royalty based on net sales of ADUHELM, rather than sharing global profits and losses. Eisai's share of development, commercialization and manufacturing expense is limited to $335.0 million for the period from January 1, 2022 to December 31, 2022. As of June 30, 2022, Eisai's portion of these expenses was approximately $275.0 million. Once this limit is achieved, we will be responsible for all ADUHELM related development costs. After the tiered royalty model commences on January 1, 2023, Eisai will not participate in ADUHELM’s economics beyond these royalties.

Lecanemab Collaboration

In March 2022 we extended our supply agreement related to lecanemab from 5 years to 10 years, and we will manufacture the lecanemab drug substance.

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

Other Key Developments

2022 Cost Saving Initiatives

In December 2021 and May 2022 we announced our plans to implement a series of cost-reduction measures during 2022. These savings are expected to be achieved through a number of initiatives, including reductions to our workforce, primarily within our global Alzheimer's infrastructure, the consolidation of certain real estate locations and operating efficiency gains across our selling, general and administrative and research and development functions.

Under these initiatives, we expect to incur restructuring charges ranging from approximately $130.0 million to $150.0 million. These amounts are primarily related to severance and are expected to be substantially incurred and paid by the end of 2022.

For additional information on our 2022 cost saving initiatives, please read *Note 3, Restructuring, Business Transformation and Other Cost Saving Initiatives*, to our condensed consolidated financial statements included in this report.

BIIB125 (zuranolone)

In May 2022 we and our collaboration partner Sage Therapeutics, Inc. (Sage) initiated a rolling submission of a New Drug Application (NDA) to the FDA for BIIB125 (zuranolone) for the potential treatment of major depressive disorder (MDD). We have submitted the nonclinical module of the NDA to the FDA and plan to submit the remaining components for the MDD filing in the second half of 2022.

In June 2022 we and Sage announced that the Phase 3 SKYLARK Study of zuranolone, which is being evaluated in women with postpartum depression, met its primary and all key secondary endpoints. Subsequently, we decided to submit a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD. We expect to complete the submission of this single NDA in the second half of 2022, and to seek priority review of the filing.

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

Lecanemab

In May 2022 we and our collaboration partner Eisai announced the completed submission of a Biologics License Application (BLA) to the FDA for the accelerated approval of lecanemab, an anti-amyloid antibody candidate for the potential treatment of Alzheimer's disease. In July 2022 the FDA accepted the BLA and granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of January 6, 2023.

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

Mosunetuzumab

In June 2022 our collaboration partner Genentech announced that mosunetuzumab, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas, was approved in the E.U.

In July Genentech announced that the FDA accepted the company's BLA and granted Priority Review for mosunetuzumab, with a PDUFA action date of December 29, 2022.

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 2021 Form 10-K.

RESULTS OF OPERATIONS

Revenue

Revenue is summarized as follows:

	For the Three Months Ended June 30,					
(In millions, except percentages)	**2022**		**2021**		**$ Change**	**% Change**
Product revenue, net:						
United States	$ 894.1	34.5 %	$ 977.2	35.2 %	$ (83.1)	(8.5)%
Rest of world	1,160.8	44.8	1,258.8	45.4	(98.0)	(7.8)
Total product revenue, net	2,054.9	79.3	2,236.0	80.6	(181.1)	(8.1)
Revenue from anti-CD20 therapeutic programs	436.3	16.9	440.0	15.9	(3.7)	(0.8)
Other revenue	97.9	3.8	99.0	3.5	(1.1)	(1.1)
Total revenue	$ 2,589.1	100.0 %	$ 2,775.0	100.0 %	$ (185.9)	(6.7)%

	For the Six Months Ended June 30,					
(In millions, except percentages)	**2022**		**2021**		**$ Change**	**% Change**
Product revenue, net:						
United States	$ 1,769.3	34.6 %	$ 1,877.0	34.3 %	$ (107.7)	(5.7)%
Rest of world	2,351.9	45.9	2,570.7	47.0	(218.8)	(8.5)
Total product revenue, net	4,121.2	80.5	4,447.7	81.3	(326.5)	(7.3)
Revenue from anti-CD20 therapeutic programs	835.7	16.3	829.0	15.2	6.7	0.8
Other revenue	164.0	3.2	192.3	3.5	(28.3)	(14.7)
Total revenue	$ 5,120.9	100.0 %	$ 5,469.0	100.0 %	$ (348.1)	(6.4)%

Product Revenue

Product revenue is summarized as follows:

(In millions, except percentages)	For the Three Months Ended June 30, 2022		2021		$ Change	% Change
Multiple Sclerosis (MS):						
TECFIDERA	$ 397.9	19.4 %	$ 487.6	21.8 %	$ (89.7)	(18.4)%
VUMERITY[1]	136.8	6.7	90.9	4.1	45.9	50.5
Total Fumarate	534.7	26.1	578.5	25.9	(43.8)	(7.6)
AVONEX	258.7	12.6	310.9	13.9	(52.2)	(16.8)
PLEGRIDY	91.5	4.5	89.5	4.0	2.0	2.2
Total Interferon	350.2	17.0	400.4	17.9	(50.2)	(12.5)
TYSABRI	516.2	25.1	524.2	23.4	(8.0)	(1.5)
FAMPYRA	25.5	1.2	26.1	1.2	(0.6)	(2.3)
Subtotal: MS	1,426.6	69.4	1,529.2	68.4	(102.6)	(6.7)
Spinal Muscular Atrophy:						
SPINRAZA	431.1	21.0	499.7	22.3	(68.6)	(13.7)
Biosimilars:						
BENEPALI	115.8	5.6	121.5	5.4	(5.7)	(4.7)
IMRALDI	57.6	2.8	55.6	2.5	2.0	3.6
FLIXABI	20.5	1.0	25.3	1.2	(4.8)	(19.0)
BYOOVIZ[2]	0.5	—	—	—	0.5	nm
Subtotal: Biosimilars	194.4	9.4	202.4	9.1	(8.0)	(4.0)
Other:						
FUMADERM	2.7	0.1	3.1	0.1	(0.4)	(12.9)
ADUHELM	0.1	—	1.6	0.1	(1.5)	(93.8)
Total product revenue, net	$ 2,054.9	100.0 %	$ 2,236.0	100.0 %	$ (181.1)	(8.1)%

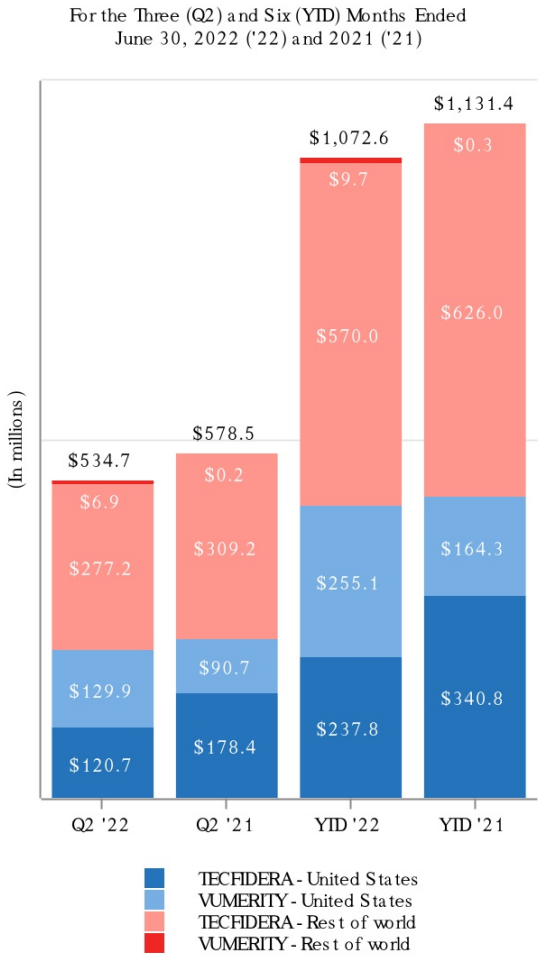
[1] VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.
[2] BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022.
nm Not meaningful

(In millions, except percentages)	For the Six Months Ended June 30, 2022		2021		$ Change	% Change
Multiple Sclerosis (MS):						
TECFIDERA	$ 807.8	19.6 %	$ 966.8	21.7 %	$ (159.0)	(16.4)%
VUMERITY[1]	264.8	6.4	164.6	3.7	100.2	60.9
Total Fumarate	1,072.6	26.0	1,131.4	25.4	(58.8)	(5.2)
AVONEX	488.3	11.8	622.0	14.0	(133.7)	(21.5)
PLEGRIDY	171.5	4.2	178.9	4.0	(7.4)	(4.1)
Total Interferon	659.8	16.0	800.9	18.0	(141.1)	(17.6)
TYSABRI	1,037.0	25.2	1,027.5	23.1	9.5	0.9
FAMPYRA	51.7	1.3	52.7	1.2	(1.0)	(1.9)
Subtotal: MS	2,821.1	68.5	3,012.5	67.7	(191.4)	(6.4)
Spinal Muscular Atrophy:						
SPINRAZA	903.6	21.9	1,020.2	23.0	(116.6)	(11.4)
Biosimilars:						
BENEPALI	230.5	5.6	243.2	5.5	(12.7)	(5.2)
IMRALDI	114.7	2.8	113.5	2.6	1.2	1.1
FLIXABI	43.0	1.0	50.8	1.1	(7.8)	(15.4)
BYOOVIZ[2]	0.5	—	—	—	0.5	nm
Subtotal: Biosimilars	388.7	9.4	407.5	9.2	(18.8)	(4.6)
Other:						
FUMADERM	4.9	0.1	5.9	0.1	(1.0)	(16.9)
ADUHELM	2.9	0.1	1.6	—	1.3	81.3
Total product revenue, net	$ 4,121.2	100.0 %	$ 4,447.7	100.0 %	$ (326.5)	(7.3)%

[1] VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.
[2] BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022.
nm Not meaningful

Multiple Sclerosis (MS)

Fumarate



Fumarate revenue includes sales from TECFIDERA and VUMERITY. During the fourth quarter of 2021 VUMERITY was approved for the treatment of relapsing-remitting MS (RRMS) in the E.U., Switzerland and the United Kingdom (U.K.).

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases of 6.9% and 2.4%, respectively, in U.S. Fumarate revenue were primarily due to decreases in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market, partially offset by favorable pricing for TECFIDERA driven by discounts and allowances and increases in VUMERITY sales volumes.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases of 8.2% and 7.4%, respectively, in rest of world Fumarate revenue were primarily due to TECFIDERA pricing reductions in certain European countries, the unfavorable impact of foreign currency exchange and decreases in TECFIDERA demand as multiple TECFIDERA generic entrants entered into markets such as Germany and Canada.

In 2020 U.S. federal courts in West Virginia and Delaware entered judgments in favor of the defendants in patent infringement proceedings relating to TECFIDERA Orange-Book listed patents. We appealed both decisions. In late 2021 the Federal Circuit affirmed the judgment of the West Virginia federal court. The appeals in the actions in Delaware are stayed pending any final action by the United States Supreme Court with respect to the judgment in the West Virginia Action.

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 continue to have a substantial and increasing negative impact on our U.S. TECFIDERA revenue in the future.

In May 2021 the European General Court annulled the EMA's decision not to validate applications for approval of TECFIDERA generics on the basis that the EMA conducted the wrong assessment when determining TECFIDERA's entitlement to regulatory data and marketing protection. Our Company, the EMA and the EC have each appealed the General Court's decision as wrongly decided and the appeal is pending.

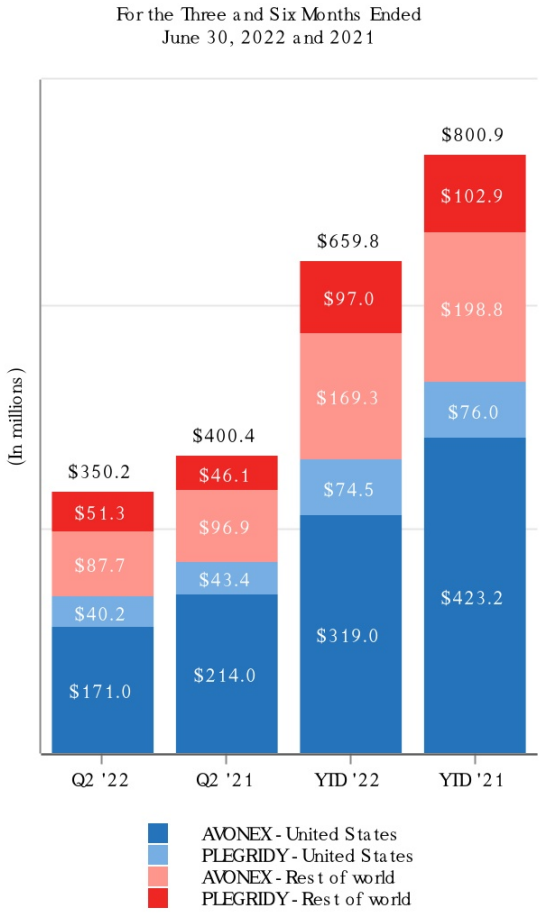
In November 2021 the CHMP of the EMA issued an ad hoc opinion referencing the General Court's decision which concluded that "the totality of the available data cannot establish that [monoethyl fumarate] exerts a clinically relevant therapeutic contribution within FUMADERM," and in May 2022 the EC approved applications to market generic TECFIDERA. Generic TECFIDERA is now for sale in the E.U. and we expect generic sales to have an adverse impact on our TECFIDERA sales in the E.U. and our results of operations. In June 2022 the European Patent Office granted Biogen a patent that relates to TECFIDERA and expires in 2028. We intend to enforce this new patent.

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

We expect that TECFIDERA revenue will continue to decline in 2022, compared to 2021, as a result of generic competition.

We expect an increase in VUMERITY sales volumes in 2022, compared to 2021, mostly due to demand growth in the U.S. and 14 other markets. We are currently working with our contract manufacturing suppliers to address potential supply constraints and have therefore delayed any additional country launches.

Interferon



For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases of 17.9% and 21.2%, respectively, in U.S. Interferon revenue were primarily due to decreases in Interferon sales volumes of 15.5% and 15.1%, respectively, and decreases in pricing of 2.4% and 6.1%, 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, 2022, compared to the same period in 2021, the decrease of 2.8% in rest of world Interferon revenue was primarily due to the unfavorable impact of foreign currency exchange.

For the six months ended June 30, 2022, compared to the same period in 2021, the decrease of 11.7% was primarily due to decreases in Interferon sales volumes resulting from the continued decline of the Interferon market, unfavorable pricing and the unfavorable impact of foreign currency exchange.

We expect that Interferon revenue will continue to decline in both the U.S. and rest of world markets in 2022, compared to 2021, as a result of increasing competition from other MS products, including biosimilars, and further pricing reductions in certain European markets.

TYSABRI

For the three months ended June 30, 2022, compared to the same period in 2021, the decrease of 2.6% in U.S. TYSABRI revenue was primarily due to a decrease in sales volumes, partially offset by an increase in pricing.

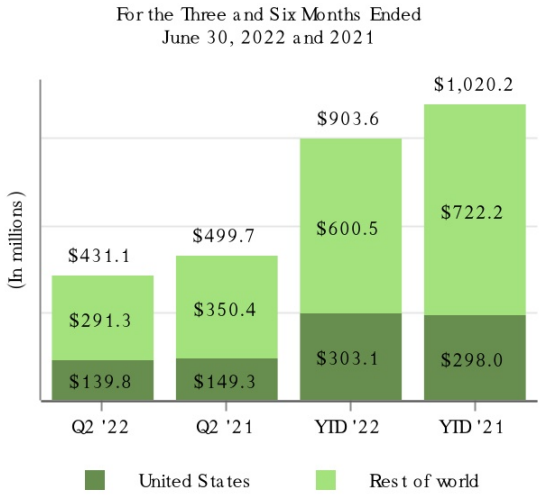
For the six months ended June 30, 2022, compared to the same period in 2021, U.S. TYSABRI revenue remained flat.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, rest of world TYSABRI revenue remained flat.

We anticipate TYSABRI revenue to be relatively flat on a global basis in 2022, compared to 2021, despite increasing competition from additional treatments for MS. We expect to continue to face price reductions in certain European markets. We are also aware of a potential biosimilar entrant of TYSABRI that may enter the market as early as 2023.

Spinal Muscular Atrophy

SPINRAZA



For the three months ended June 30, 2022, compared to the same period in 2021, the decrease of 6.4% in U.S. SPINRAZA revenue was primarily due to a decrease in sales volumes resulting from increased competition and unfavorable pricing driven by higher rebates.

For the six months ended June 30, 2022, compared to the same period in 2021, the increase of 1.7% in U.S. SPINRAZA revenue was primarily due to an increase in sales volumes resulting from favorable channel dynamics in the first quarter of 2022.

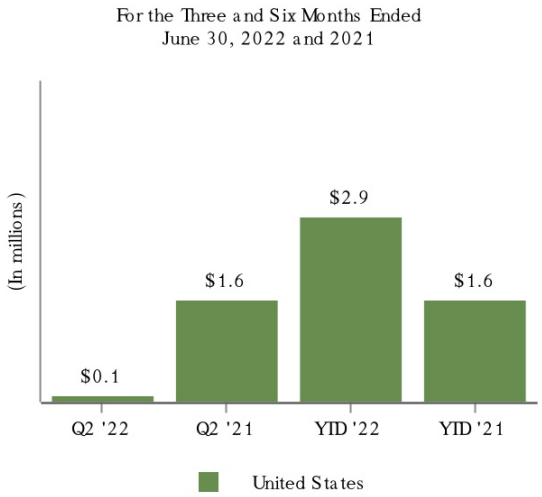
For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases of 16.9% for both periods in rest of world SPINRAZA revenue were primarily due to decreases in pricing of 7.3% and 6.8%, respectively, and decreases in sales volumes of 4.7% and 4.9%, respectively, resulting from increased competition in certain established markets, particularly Germany, and the timing of shipments, as well as the unfavorable impact of foreign currency exchange. The decreases were partially offset by sales volume growth in certain Asian markets.

We face competition from a gene therapy product and an oral product. In 2022 we expect that SPINRAZA revenue will be subject to increased competition likely resulting in continued patient 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.

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 2021 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.

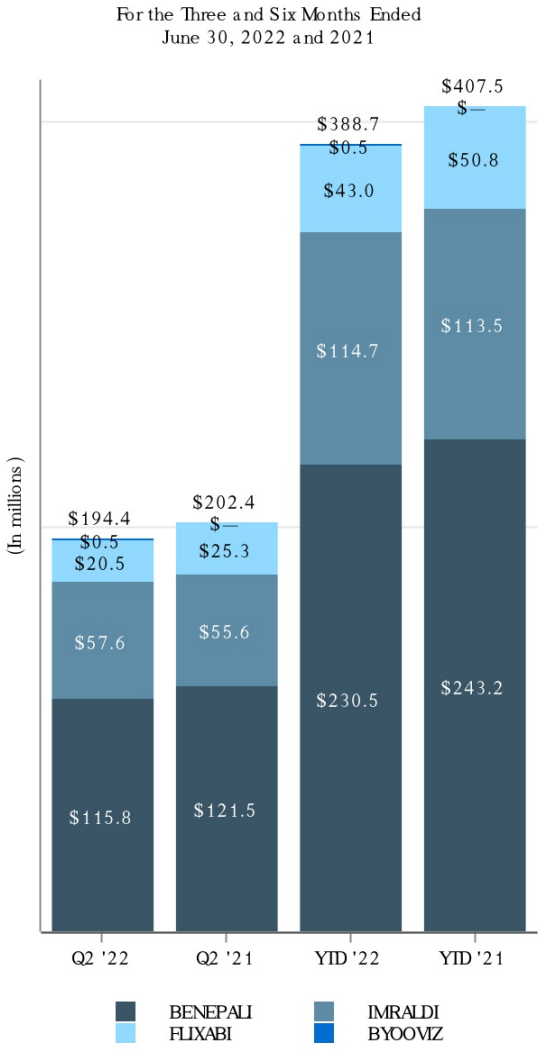
In April 2022 the CMS released the final NCD for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. We expect that this decision will reduce future demand for ADUHELM to a minimal level.

Additionally, as a result of the final NCD we have substantially eliminated our commercial infrastructure supporting ADUHELM, retaining minimal resources to manage patient access programs, including a continued free drug program for patients currently on treatment in the U.S.

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

Biosimilars

BENEPALI, IMRALDI, FLIXABI and BYOOVIZ



During the third quarter of 2021 BYOOVIZ, a biosimilar referencing LUCENTIS, was approved in the U.S., the E.U. and the U.K. BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022 through major distributors in the U.S.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases of 4.0% and 4.6%, respectively, in biosimilar revenue were primarily due to decreases in pricing in certain markets and the unfavorable impact of foreign currency exchange, partially offset by increases in sales volumes.

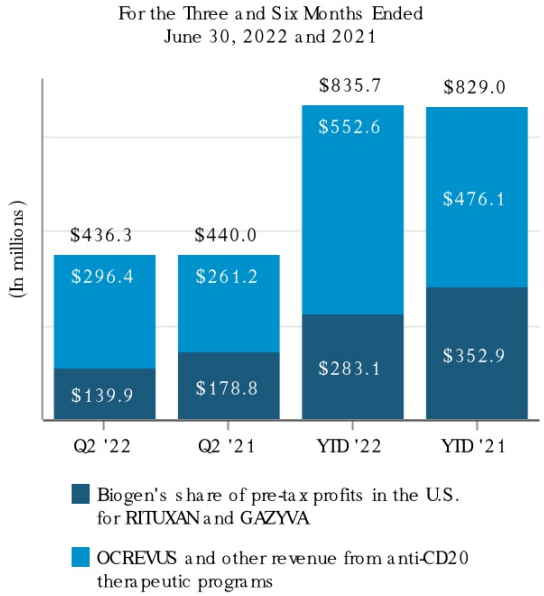
We anticipate a slight decline in revenue from our biosimilars business in 2022, despite the launch of BYOOVIZ in the U.S., and an anticipated modest increase in sales volumes as we continue to face price reductions in certain markets.

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

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)	**2022**	**2021**
Product revenue, net	$ 443.1	$ 554.1
Cost and expense	70.1	77.9
Pre-tax profits in the U.S.	373.0	476.2
Biogen's share of pre-tax profits	$ 139.9	$ 178.8

	For the Six Months Ended June 30,	
(In millions)	**2022**	**2021**
Product revenue, net	$ 898.1	$ 1,105.5
Cost and expense	129.9	152.1
Pre-tax profits in the U.S.	768.2	953.4
Biogen's share of pre-tax profits	$ 283.1	$ 352.9

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in U.S. product revenue, net were primarily due to decreases in sales volumes of RITUXAN in the U.S. of 30.9% and 30.6%, respectively, primarily due to the onset of competition from multiple biosimilar products and decreases in GAZYVA sales volumes of 4.0% and 3.8%, respectively.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in collaboration costs and expense were primarily due to lower cost of sales, selling and marketing expense and distribution costs related to RITUXAN.

We are aware of several other anti-CD20 molecules, including biosimilar products, that have been approved and are competing with RITUXAN and GAZYVA in the oncology and other markets. Biosimilar products referencing RITUXAN have 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, 2022, compared to the same periods in 2021, 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, 2022, totaled $291.8 million and $544.1 million, respectively, compared to $257.0 million and $466.3 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 2021 Form 10-K.

Other Revenue

Other revenue is summarized as follows:

	For the Three Months Ended June 30,					
(In millions, except percentages)	2022		2021		$ Change	% Change
Revenue from collaborative and other relationships	$ 6.4	6.5 %	$ 5.5	5.6 %	$ 0.9	16.4 %
Other royalty and corporate revenue	91.5	93.5	93.5	94.4	(2.0)	(2.1)
Total other revenue	$ 97.9	100.0 %	$ 99.0	100.0 %	$ (1.1)	(1.1)%

	For the Six Months Ended June 30,					
(In millions, except percentages)	2022		2021		$ Change	% Change
Revenue from collaborative and other relationships	$ 14.4	8.8 %	$ 9.4	4.9 %	$ 5.0	53.2 %
Other royalty and corporate revenue	149.6	91.2	182.9	95.1	(33.3)	(18.2)
Total other revenue	$ 164.0	100.0 %	$ 192.3	100.0 %	$ (28.3)	(14.7)%

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 17, 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.

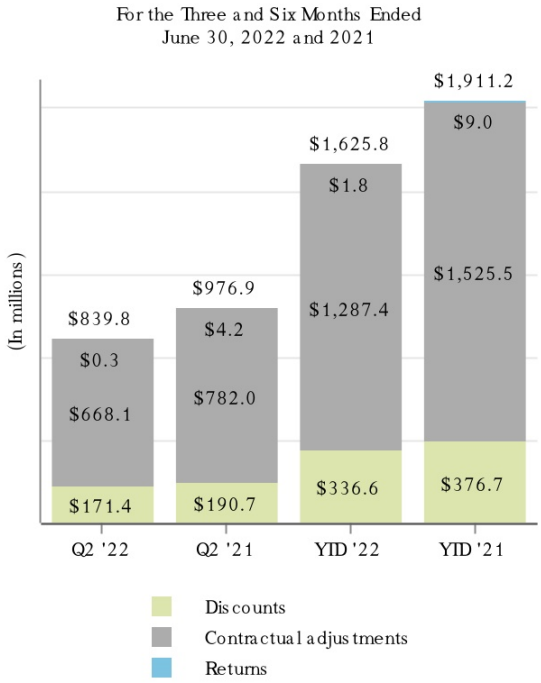
For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in other corporate revenue were primarily due to lower contract manufacturing revenue related to the timing of batch releases.

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, 2022, reserves for discounts and allowances as a percentage of gross product revenue were 29.2% and 28.1%, respectively, compared to 29.2% and 28.6%, respectively, in the prior year comparative periods.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in discounts were primarily driven by decreases in gross sales.

Contractual Adjustments

Contractual adjustments primarily relate to Medicaid and managed care rebates in the U.S., pharmacy rebates, co-payment (copay) assistance, Veterans Administration, 340B discounts, specialty pharmacy program fees and other government rebates or applicable allowances.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in contractual adjustments were primarily driven by lower TECFIDERA sales in the U.S., resulting in lower pharmacy rebates, Medicaid rebates and managed care rebates, as well as lower Medicaid rebates in the U.S. driven by a favorable change in estimates for VUMERITY.

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, 2022, compared to the same periods in 2021, return reserves were relatively consistent.

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

Cost and Expense

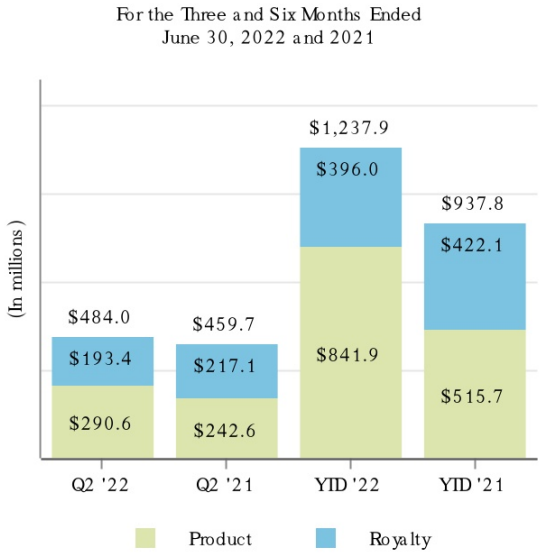
A summary of total cost and expense is as follows:

	For the Three Months Ended June 30,			
(In millions, except percentages)	**2022**	**2021**	**% Change**	**$ Change**
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 484.0	$ 459.7	5.3 %	$ 24.3
Research and development	528.6	585.1	(9.7)	(56.5)
Selling, general and administrative	572.6	637.3	(10.2)	(64.7)
Amortization and impairment of acquired intangible assets	67.5	604.1	(88.8)	(536.6)
Collaboration profit (loss) sharing	29.4	(15.2)	(293.4)	44.6
(Gain) loss on fair value remeasurement of contingent consideration	(4.5)	0.3	nm	(4.8)
Acquired in-process research and development	—	18.0	nm	(18.0)
Restructuring charges	70.6	—	nm	70.6
Other (income) expense, net	(428.6)	(96.4)	344.6	(332.2)
Total cost and expense	$ 1,319.6	$ 2,192.9	(39.8)%	$ (873.3)

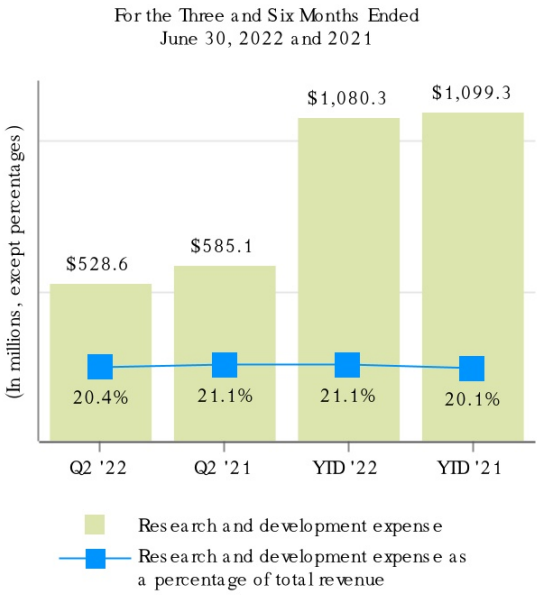
	For the Six Months Ended June 30,			
(In millions, except percentages)	**2022**	**2021**	**% Change**	**$ Change**
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 1,237.9	$ 937.8	32.0 %	$ 300.1
Research and development	1,080.3	1,099.3	(1.7)	(19.0)
Selling, general and administrative	1,207.5	1,232.3	(2.0)	(24.8)
Amortization and impairment of acquired intangible assets	134.4	702.2	(80.9)	(567.8)
Collaboration profit (loss) sharing	(87.9)	53.3	(264.9)	(141.2)
(Gain) loss on fair value remeasurement of contingent consideration	(11.6)	(33.5)	(65.4)	21.9
Acquired in-process research and development	—	18.0	nm	(18.0)
Restructuring charges	108.7	—	nm	108.7
Other (income) expense, net	(165.3)	410.5	(140.3)	(575.8)
Total cost and expense	$ 3,504.0	$ 4,419.9	(20.7)%	$ (915.9)

[nm] Not meaningful

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



Research and Development



Product Cost of Sales

For the three months ended June 30, 2022, compared to the same period in 2021, the increase in product cost of sales was primarily due to product mix and higher cost of sales associated with contract manufacturing agreements.

For the six months ended June 30, 2022, compared to the same period in 2021, the increase in product cost of sales was primarily due to the write-off of ADUHELM inventory during the first quarter of 2022. During the first quarter of 2022 we recorded approximately $275.0 million of gross charges associated with inventory and purchase commitments in excess of forecasted demand related to ADUHELM, as well as approximately $45.0 million of gross idle capacity charges. We have recognized approximately $160.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the six months ended June 30, 2022.

During 2022 we recorded approximately $72.0 million of gross idle capacity charges. We have recognized approximately $32.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our condensed consolidated statements of income for the six months ended June 30, 2022.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in royalty cost of sales were primarily due to lower royalties payable on lower sales of SPINRAZA, TYSABRI and AVONEX, partially offset by higher royalties payable on higher sales of VUMERITY.

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 months ended June 30, 2022, compared to the same period in 2021, the decrease in research and development expense was primarily due to higher milestone payments in 2021.

For the six months ended June 30, 2022, compared to the same period in 2021, the decrease in research and development expense was primarily due to higher milestone payments in 2021, partially offset by an increase in spending related to lecanemab, the advancement of BIIB059 (anti-BDCA2) for the potential treatment of systemic lupus erytheatosus (SLE), the development of mosunetuzumab, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas, the development of BIIB124 (SAGE-324) for the potential treatment of essential tremor, which we are developing in collaboration with Sage, 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 development of BIIB135 (orelabrutinib) for the potential treatment of MS.

In 2021 we recorded significant upfront payments related to our new collaborations as part of research and development expense. Excluding upfront payments, we expect our core research and development expense in 2022 to be consistent with 2021 as we continue to invest in our pipeline. We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where a drug candidate has the potential to be highly differentiated.

Early Stage Programs

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the decreases in spending related to our early stage programs were primarily due to decreases in costs associated with:

- the discontinuation of BIIB054 (cinpanemab) in Parkinson's disease;
- the discontinuation of gosuranemab (BIIB092) in Alzheimer's disease;
- the discontinuation of BIIB112 (cotoretigene toliparvovec) in X-linked retinitis pigmentosa; and
- the advancement of BIIB059 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 for the potential treatment of Parkinson's disease;
- an increase in spending in the development of BIIB135 for the potential treatment of MS; and
- an increase in spending in the development of BIIB059 for the potential treatment of cutaneous lupus erythematosus (CLE).

Late Stage Programs

For the three months ended June 30, 2022, compared to the same period in 2021, the increase in spending associated with our late stage programs was primarily due to an increase in costs associated with:

- the increase in spending related to lecanemab; and
- an increase in spending related to mosunetuzumab, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas.

The increase was partially offset by a decrease in costs associated with:

- the discontinuation of BIIB111 (timrepigene emparvovec) in choroideremia.

For the six months ended June 30, 2022, compared to the same period in 2021, the decrease in spending associated with our late stage programs was primarily due to a decrease in costs associated with:

- the advancement of ADUHELM from late stage to marketed upon the accelerated approval of ADUHELM in the U.S.; and
- the discontinuation of BIIB111 (timrepigene emparvovec) in choroideremia.

The decrease was partially offset by an increase in costs associated with:

- the advancement of BIIB059 for the potential treatment of SLE into late stage;
- an increase in spending related to lecanemab; and
- an increase in spending related to mosunetuzumab.

Marketed Programs

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the increases in spending associated with our marketed programs were primarily due to increases in costs associated with:

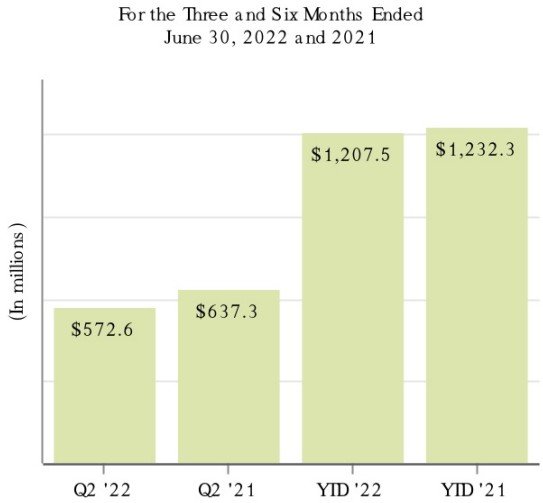
- the advancement of ADUHELM from late stage to marketed upon the accelerated approval of ADUHELM in the U.S.

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 lead of lecanemab development and regulatory submissions globally with both companies co-commercializing and co-promoting the product, and Eisai having final decision-making authority. All costs, including research, development, sales and marketing expense, are shared equally between us and Eisai. In July 2022 Eisai completed the submission of a BLA to the FDA for the accelerated approval of lecanemab.

As of June 30, 2022, we had approximately $71.5 million of work-in-process inventory related to lecanemab. We plan to continue producing inventory and are also procuring raw materials associated with this production. If the lecanemab Phase 3 study receives a negative readout, or if the program does not receive regulatory approval, we would expect to expense inventory on hand at that time as research and development expense and, under the terms of the collaboration arrangement with Eisai to jointly develop and commercialize lecanemab, we and Eisai would share the costs equally.

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

Selling, General and Administrative



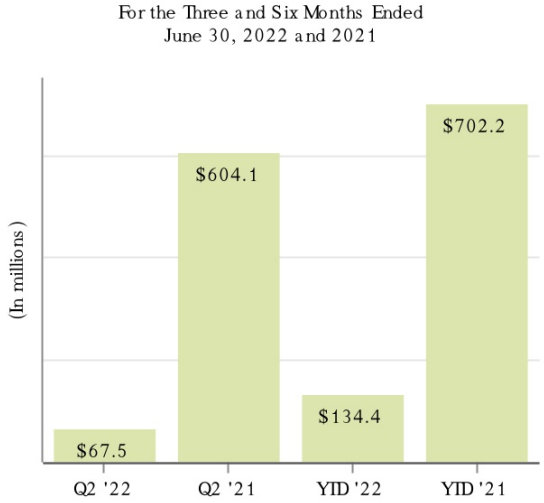
For the three and six months ended June 30, 2022, compared to the same periods in 2021, selling, general and administrative expense decreased by approximately 10.2% and 2.0%, respectively, primarily due cost-reduction measures realized during 2022, partially offset by gross ADUHELM commercialization expense of approximately $27.0 million and $107.0 million, respectively.

As a result of the final NCD we have substantially eliminated our commercial infrastructure supporting ADUHELM, retaining minimal resources to manage patient access programs, including a continued free drug program for patients currently on treatment in the U.S.

Beginning in the second quarter of 2021 reimbursement from Eisai for its share of U.S. ADUHELM selling, general and administrative expense is recognized in collaboration profit (loss) sharing in our condensed consolidated statements of income.

In 2022 we expect selling, general and administrative costs to decline versus 2021 primarily driven by the implementation of our cost savings initiatives, which include the substantial elimination of our commercial infrastructure supporting ADUHELM as well as other cost-reduction measures.

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, 2022, compared to the same periods in 2021, the decreases in amortization and impairment of acquired intangible assets were primarily related to impairment charges recorded in 2021. For the three and six months ended June 30, 2022, we had no impairment charges.

For the three 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).

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 are now performing an additional clinical trial of vixotrigine, which is expected to be completed by the end of 2022.

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, 2022, the carrying value associated with the remaining IPR&D intangible asset for DPN was $119.2 million and the fair value of this asset was not significantly in excess of its carrying value. We will reassess the carrying value of this program upon conclusion of the ongoing clinical trial or sooner if there is a reevaluation event and may record an impairment charge related to this asset.

BIIB111 and BIIB112

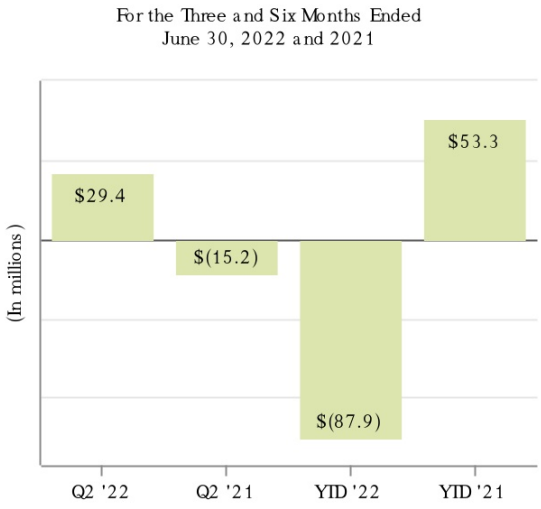
During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 did not meet its primary or key secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of $350.0 million during the second quarter of 2021, which resulted in a reduction of the IPR&D intangible 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 intangible asset from $220.0 million to $28.4 million.

In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the year ended December 31, 2021, we recognized additional impairment charges related to BIIB111 and BIIB112, reducing the remaining book values of these IPR&D intangible assets to zero.

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

Collaboration Profit (Loss) Sharing



Collaboration profit (loss) sharing primarily includes Samsung Bioepis' 50.0% 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 expense in the U.S. related to the ADUHELM Collaboration Agreement.

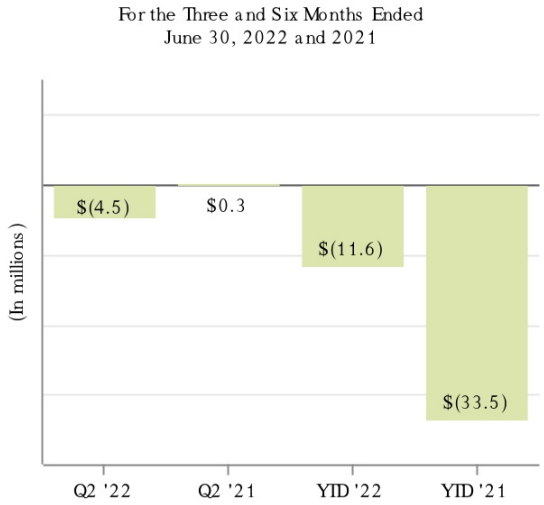
For the three and six months ended June 30, 2022, we recognized net profit-sharing expense of $58.3 million and $122.7 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits compared to a net profit-sharing expense of $69.9 million and $138.4 million, respectively, in the prior year comparative periods.

For the three and six months ended June 30, 2022, we recognized a net reduction to our operating expense of $28.9 million and $210.6 million, respectively, to reflect Eisai's 45.0% share of net collaboration losses in the U.S., compared to $40.1 million in each of 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.

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

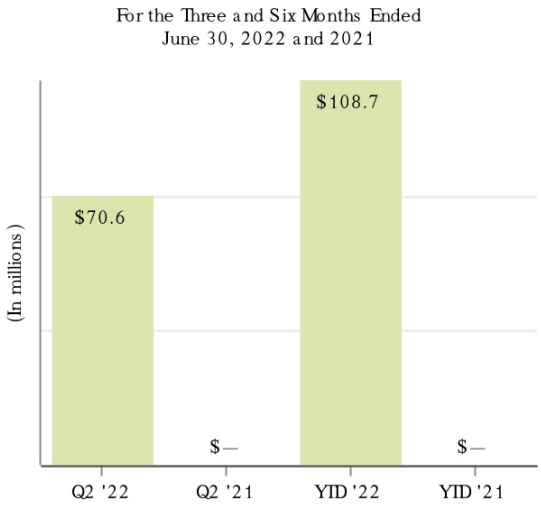
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration



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, 2022, compared to the same periods in 2021, changes in the fair value of our contingent consideration obligations were primarily due to increases in the discount rates used to revalue these obligations and delays in the expected timing of the achievement of certain remaining developmental milestones related to our vixotrigine programs.

Restructuring Charges



2022 Cost Saving Initiatives

In December 2021 and May 2022 we announced our plans to implement a series of cost-reduction measures during 2022. These savings are being achieved through a number of initiatives, including reductions to our workforce, the substantial elimination of our commercial ADUHELM infrastructure, the consolidation of certain real estate locations and operating efficiencies across our selling, general and administrative and research and development functions.

Under these initiatives, we expect to incur restructuring charges ranging from approximately $130.0 million to $150.0 million. These amounts are primarily related to severance and are expected to be substantially incurred and paid by the end of 2022.

For the three and six months ended June 30, 2022, we recognized approximately $70.6 million and $108.7 million, respectively, of pre-tax restructuring charges related to our 2022 cost saving initiatives, of which approximately $60.9 million and $88.6 million, respectively, consisted of employee severance costs. These costs were recorded in restructuring charges in our condensed consolidated statements of income. Our restructuring reserve is included in accrued expense and other in our condensed consolidated balance sheets.

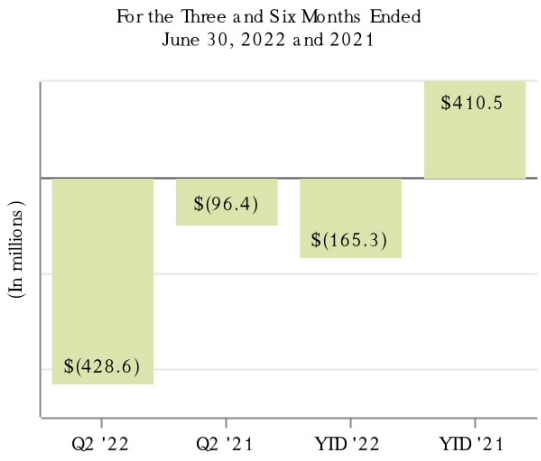
Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, North Carolina. Our decision to cease use of the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility. As a result, for the six months ended June 30, 2022, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in restructuring charges in our condensed consolidated statements of income. In May 2022 we entered into a lease assignment agreement whereby we assigned our remaining lease obligations to an external third party. As a result of the lease assignment, we derecognized the related operating lease obligation and right-of-use asset as of June 30, 2022.

For the three and six months ended June 30, 2022, we recorded other restructuring costs of approximately $9.7 million, which were recorded in restructuring charges in our condensed consolidated statements of income. Other restructuring costs includes items such as facility closure costs, employee non-severance expense, asset write-offs and other costs.

The following table summarizes the charges and spending related to our 2022 workforce reductions for the three and six months ended June 30, 2022:

(In millions)	Total
Restructuring reserve as of December 31, 2021	$ —
Expense	27.7
Payment	(6.2)
Restructuring reserve as of March 31, 2022	21.5
Expense	60.9
Payment	(29.7)
Adjustment	(0.5)
Restructuring reserve as of June 30, 2022	$ 52.2

Other (Income) Expense, Net



For the three and six months ended June 30, 2022, compared to the same periods in 2021, the changes in other (income) expense, net primarily reflect a pre-tax gain of approximately $1.5 billion related to the sale of our 49.9% equity interest in Samsung Bioepis during the second quarter of 2022, partially offset by a pre-tax charge in connection with a litigation agreement in principle, as discussed below.

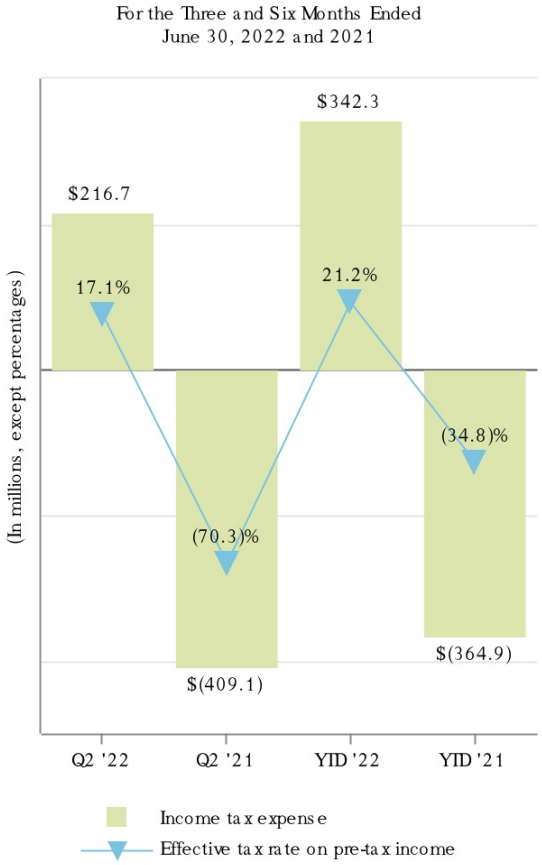
During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million, plus estimated fees and expenses, related to an agreement in principle to resolve a qui tam litigation relating to conduct prior to 2015. This charge is included within other (income) expense, net in our condensed consolidated statements of income for the three and six months ended June 30, 2022. In the period paid, the settlement amount plus all related fees and expenses will have a material adverse impact on our cash flow. For additional information on the litigation agreement in principle, please read *Note 19, Litigation*, to our condensed consolidated financial statements included in this report.

For the three months ended June 30, 2022, net unrealized losses and realized losses on our holdings in equity securities were approximately $76.5 million and $0.7 million, respectively, compared to net unrealized gains and realized gains of approximately $153.9 million and $0.4 million, respectively, in the prior year comparative period. The net unrealized losses recognized during the three months ended June 30, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Sangamo Therapeutics, Inc. (Sangamo) and Denali common stock of approximately $75.3 million.

For the six months ended June 30, 2022, net unrealized losses and realized losses on our holdings in equity securities were approximately $267.4 million and $0.5 million, respectively, compared to net unrealized losses and realized gains of $288.4 million and $6.6 million, respectively, in the prior year comparative period. The net unrealized losses recognized during the six months ended June 30, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sangamo and Sage common stock of approximately $277.1 million.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to our condensed consolidated financial statements included in this report.

Income Tax Provision



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

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the increases in our effective tax rate were primarily due to the overall current year unfavorable tax rate impact

on the sale of our equity interest in Samsung Bioepis in April 2022, the litigation agreement in principle and the tax benefit recorded in the second quarter of 2021 related to the Neurimmune SubOne AG (Neurimmune) deferred tax asset matter, as discussed below. These effective tax rate increases were partially offset by the non-cash tax effects of changes in the value of our equity instruments and the current year tax benefits recorded in the second quarter of 2022 related to an international reorganization to align with global tax developments.

For the six months ended June 30, 2022, compared to the same period in 2021, our effective tax rate also increased as a result of the Neurimmune valuation allowance recorded in the first quarter of 2022.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM. During the fourth quarter of 2021, due to reduced future expected revenue associated with ADUHELM, we recorded a valuation allowance of approximately $390.0 million.

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an additional valuation allowance of approximately $85.0 million to reduce the net value of this deferred tax asset to zero. These adjustments to our deferred tax assets and their valuation allowances are each recorded 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 the litigation agreement in principle, please read *Note 19, Litigation*, to our condensed consolidated financial statements included in this report.

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

For additional information on our income taxes please read *Note 15, Income Taxes,* to our condensed consolidated financial statements included in this report.

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

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

In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics. Following the sale of Samsung Bioepis we no longer recognize gains or losses associated with Samsung Bioepis' results of operations and amortization related to basis differences.

Prior to this sale, we recognized 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 became available, which was reflected as equity in (income) loss of investee, net of tax in our condensed consolidated statements of income. We recognized amortization on certain basis differences resulting from our November 2018 investment.

For the three and six months ended June 30, 2022, we recognized net income on our investment of $5.9 million and $2.6 million, respectively, reflecting our share of Samsung Bioepis' operating profits, net of tax totaling $13.0 million and $17.0 million, respectively, offset by amortization of basis differences totaling $7.1 million and $14.4 million, respectively. These amounts reflect our share of results prior to the sale of Samsung Bioepis as the results are recognized one quarter in arrears.

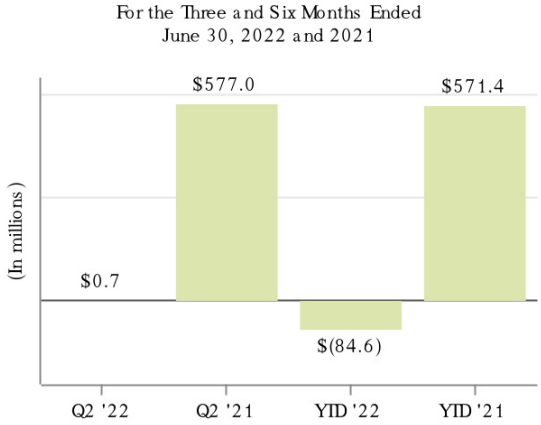
For the three and six months ended June 30, 2021, we recognized net income on our investment of $34.3 million and $16.1 million, respectively, reflecting our share of Samsung Bioepis' operating income, net of tax totaling $41.6 million and $30.6 million, respectively, and amortization of basis

differences totaling $7.3 million and $14.5 million, respectively.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to our condensed consolidated financial statements included in this report.

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

Noncontrolling Interests, Net of Tax



Our condensed consolidated financial statements include the financial results of our variable interest entity, Neurimmune, as we determined that we are the primary beneficiary.

For the three and six months ended June 30, 2022, compared to the same periods in 2021, the changes in net income (loss) attributable to noncontrolling interests, net of tax were primarily due to a deferred tax benefit recorded in the second quarter of 2021, as discussed below.

During the second quarter of 2021 we recorded a 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 $490.0 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 interest, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

During the first quarter of 2022 we recorded a valuation allowance of approximately $85.0 million related to this deferred tax asset. There is 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 were 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 additional information on our collaboration agreement with Neurimmune, please read *Note 18, 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 15, 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, 2022	As of December 31, 2021	Change %
Financial assets:			
Cash and cash equivalents	$ 2,646.6	$ 2,261.4	17.0 %
Marketable securities — current	2,151.3	1,541.1	39.6
Marketable securities — non-current	1,102.9	892.0	23.6
Total cash, cash equivalents and marketable securities	$ 5,900.8	$ 4,694.5	25.7 %
Borrowings:			
Current portion of notes payable	$ 999.8	$ 999.1	0.1 %
Notes payable	6,277.4	6,274.0	0.1
Total borrowings	$ 7,277.2	$ 7,273.1	0.1 %
Working capital:			
Current assets	$ 9,740.9	$ 7,856.5	24.0 %
Current liabilities	(5,018.0)	(4,298.2)	16.7
Total working capital	$ 4,722.9	$ 3,558.3	32.7 %

For the six months ended June 30, 2022, certain significant cash flows were as follows:

- $990.3 million in net proceeds received from the sale of our equity interest in Samsung Bioepis;
- $898.3 million in net cash flow provided by operating activities;
- $500.0 million used for share repurchases;
- $443.2 million in total net payments for income taxes; and
- $94.8 million used for purchases of property, plant and equipment.

Overview

We have historically financed and expect to continue to fund our operating and capital expenditures primarily through cash flow earned through our operations as well as our existing cash resources. We believe generic competition for TECFIDERA in the U.S. and other markets will continue to reduce our cash flow from operations in 2022 and will have a significant adverse impact on our future cash flow from operations. During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million, plus estimated fees and expenses, related to an agreement in principle to resolve a qui tam litigation relating to conduct prior to 2015. In the period paid, the settlement amount plus all related fees and expenses will have a material adverse impact on our cash flow. Additionally, in July 2022 we redeemed our 3.625% Senior Notes due September 15, 2022, with an aggregate principal amount of $1.0 billion.

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 the litigation agreement in principle, please read *Note 19, Litigation*, to our condensed consolidated financial statements included in this report.

For additional information on certain risks that could negatively impact our financial position or future results of operations, please read *Item 1A. Risk Factors* and *Item 3. Quantitative and Qualitative Disclosures About Market Risk* 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, 2022, we had cash, cash equivalents and marketable securities totaling approximately $5.9 billion compared to approximately

$4.7 billion as of December 31, 2021. The change in cash, cash equivalents and marketable securities at June 30, 2022, from December 31, 2021, was primarily due to proceeds received from the sale of our equity interest in Samsung Bioepis and net cash flow provided by operating activities, partially offset by share repurchases.

Investments and other assets in our condensed consolidated balance sheets as of December 31, 2021, include the carrying value of our investment in Samsung Bioepis of $599.9 million. In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics. Under the terms of this transaction, we received approximately $1.0 billion in cash at closing and expect to receive approximately $1.3 billion in cash to be deferred over two payments of approximately $812.5 million due at the first anniversary and approximately $437.5 million due at the second anniversary of the closing of the transaction.

We are also eligible to receive up to an additional $50.0 million upon the achievement of certain commercial milestones. If any payments due to us remain outstanding after the second anniversary of the closing of the transaction, we may elect to receive shares of Samsung BioLogics common stock at a 5.0% discount in lieu of a cash payment for the remaining amount due. Currently, we believe that the likelihood of Samsung BioLogics failing to make timely payments to us for the amounts due is remote.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to our condensed consolidated financial statements included in this report.

The following table summarizes the fair value of our significant common stock investments:

(In millions)	June 30, 2022	December 31, 2021
Denali	$ 391.7	$ 550.7
Sangamo	100.0	173.7
Sage	187.4	231.9
Ionis	106.5	87.5
	$ 785.6	$ 1,043.8

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

For additional information on our collaboration arrangements with Ionis, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2021 Form 10-K.

Capital Expenditures

In March 2021 we announced our plans to build a new gene therapy manufacturing facility in RTP, North Carolina to support our gene therapy pipeline across multiple therapeutic areas. The new facility is expected to be operational by the end of 2023, with an estimated total investment of approximately $200.0 million. Construction for this new facility began during the fourth quarter of 2021.

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, 2022 and December 31, 2021, please read *Note 7, 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, 2022 and December 31, 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. Working capital was $4.7 billion and $3.6 billion as of June 30, 2022 and December 31, 2021, respectively. The change in working capital reflects an increase in total current assets of approximately $1,884.4 million and a increase in total current liabilities of approximately $719.8 million.

The increase in total current assets was primarily driven by the receipt of approximately $990.3 million in cash, net of expenses, and the recording of a receivable from Samsung BioLogics for approximately $788.1 million as part of the sale of our equity interest in Samsung Bioepis in the second quarter of 2022.

The increase in current liabilities was primarily due to an increase in accrued expense and other resulting from a pre-tax charge of $900.0 million in connection with a litigation agreement in principle reached during the second quarter of 2022.

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 2.4 million shares of our common stock at a cost of approximately $500.0 million during the three and six months ended June 30, 2022. During the three and six months ended June 30, 2021, 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, respectively. Approximately $2.3 billion remained available under our 2020 Share Repurchase Program as of June 30, 2022.

Cash Flow

The following table summarizes our cash flow activity:

	For the Six Months Ended June 30,		
(In millions, except percentages)	**2022**	**2021**	**% Change**
Net cash flow provided by (used in) operating activities	$ 898.3	$ 1,996.3	(55.0)%
Net cash flow provided by (used in) investing activities	45.5	(217.4)	120.9
Net cash flow provided by (used in) financing activities	(488.0)	(1,349.5)	(63.8)

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, 2022, compared to the same period in 2021, the decrease in net cash flow provided by operating activities was primarily due to to lower net income in 2022, timing of payments and higher net income tax payments in 2022 as compared to the same period in 2021.

Investing Activities

For the six months ended June 30, 2022, compared to the same period in 2021, the increase in net cash flow provided by investing activities was primarily due to proceeds received from the sale of our equity interest in Samsung Bioepis of $990.3

million, net of expenses, during the second quarter of 2022.

Financing Activities

For the six months ended June 30, 2022, compared to the same period in 2021, the decrease in net cash flow used in financing activities was primarily due to a greater number of shares repurchased in 2021 as compared to the comparative period in 2022. Additionally, we executed our Exchange Offer in the first quarter of 2021, which resulted in net cash outflows of $170.0 million.

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, 2021.

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. During the fourth quarter of 2021 VUMERITY was approved for the treatment of RRMS in the E.U., Switzerland and the U.K. Under our agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), we make royalty payments to Alkermes on worldwide net sales of VUMERITY using a royalty rate of 15.0%, which are recognized 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 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 2021 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 their fair value on the acquisition date and revalue these obligations 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, 2022, we could trigger potential future milestone payments to third parties of up to approximately $9.6 billion, including approximately $1.9 billion in development milestones, approximately $0.8 million in regulatory milestones and approximately $6.9 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of June 30, 2022, 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 $39.7 million in milestones in 2022 under our current agreements.

For additional information on our collaboration arrangements with Eisai, please read *Note 17, Collaborative and Other Relationships,* to our

condensed consolidated financial statements included in this report.

Other Funding Commitments

As of June 30, 2022, 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 $18.8 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of June 30, 2022. We have approximately $986.5 million in cancellable future commitments based on existing CRO contracts as of June 30, 2022.

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 2021 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, 2022, we have approximately $104.7 million of liabilities associated with uncertain tax positions.

As of June 30, 2022 and December 31, 2021, we have accrued income tax liabilities of approximately $558.0 million and $633.0 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, 2022, approximately $137.8 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 2021 Form 10-K. There have been no material changes to our critical accounting estimates since our 2021 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 equity price exposure as well as changes in economic conditions in the markets in which we operate as a result of the COVID-19 pandemic and the conflict in Ukraine. 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, 2022, 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 and foreign currency options to manage foreign currency risk, with the majority of our forward contracts and options used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 15 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read *Note 9, Derivative Instruments,* to our condensed consolidated financial statements included in this report.

Our ability to mitigate the impact of foreign currency exchange rate changes on 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, 2022 and December 31, 2021, 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 $245.5 million and $333.1 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 was 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. In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis

to Samsung BioLogics and closed these foreign currency forward contracts.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 2, Dispositions,* to our condensed consolidated financial statements included in this report.

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, 2022 and December 31, 2021, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $9.9 million and $14.3 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.

Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash and cash equivalents, investments, derivatives and accounts receivable. We attempt to minimize the risks related to cash and cash equivalents and investments by investing in a broad and diverse range of financial instruments. We have established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. We minimize credit risk resulting from derivative instruments by choosing only highly rated financial institutions as counterparties.

We operate in certain countries where weakness in economic conditions, including the effects of the COVID-19 pandemic and the conflict in Ukraine, 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, 2022 and December 31, 2021.

Equity Price Risk

Our strategic investment portfolio includes investments in equity securities of certain biotechnology companies. While we are holding such securities, we are subject to equity price risk, and this may increase the volatility of our income in future periods due to changes in the fair value of equity investments. We may sell such equity securities based on our business considerations, which may include limiting our price risk.

Changes in the fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. The potential change in fair value for equity price sensitive instruments has been assessed on a hypothetical 10.0% adverse movement. As of June 30, 2022 and December 31, 2021, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $78.6 million and $104.8 million, respectively.

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, 2022. 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, 2022, 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, 2022, please read *Note 19, Litigation,* to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 1A. RISK FACTORS

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, greater acceptance or more favorable reimbursement 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.

In June 2021 the FDA granted accelerated approval of ADUHELM in the U.S. In addition to risks associated with new products and the other factors described in these Risk Factors, our ability to successfully commercialize ADUHELM may be adversely affected due to:

- concern regarding the accelerated approval of ADUHELM and its data;
- our ability to obtain and maintain reimbursement for ADUHELM;
- the impact of the final NCD by CMS for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM; and
- the lack of market acceptance of ADUHELM.

As part of the accelerated approval, we are required to 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;
- our ability to receive reimbursement for our products or our ability to receive comparable reimbursement to that of competing products; 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. 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, payment of development or commercial costs, 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 former 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.

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 expense 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 our 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 that may receive greater acceptance or more favorable reimbursement. 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, requiring confirmatory trials and risk evaluation and mitigation strategies. For example, 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 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 third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or 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 safety warnings that may be required to be included in the label 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 create 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 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. The COVID-19 pandemic has caused us to modify our business practices in ways that heighten this dependence, including changing the requirement that most of our office-based employees in the U.S. and our other key markets work from the office, with a number of our employees now working in hybrid or full-remote positions. 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). Breakdowns, invasions, corruptions, destructions and/or breaches of our technology systems or those of our business partners, including our cloud technologies, and/or unauthorized access to our data and information could subject us to liability, negatively impact our business operations, and/or require replacement of technology and/or ransom payments. Our technology systems, including our cloud technologies, continue to increase in multitude and complexity, increasing our vulnerability when breakdowns, malicious intrusions and random attacks occur. Data privacy or security breaches also pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, 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, when they impact vendors, customers or companies, including vendors, suppliers and other companies in our supply chain. 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 careless or malicious intent. Geopolitical instability, including that related to Russia's invasion of Ukraine may increase cyber-attacks. Cyber-attacks include 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 also include manufacturing, hardware or software supply chain attacks, which could cause a delay in the manufacturing of products or products produced for contract manufacturing or lead to a data privacy or security breach. 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 heightens these and other operational risks, and any failure by cloud or other 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. Regulators are considering new cyber security regulations. For example, the SEC has proposed amendments to its disclosure rules regarding cyber security risk management, strategy, governance and incident reporting by public companies. These proposed regulations may impact the manner in which we operate. Failure to comply with new laws 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.

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

Changes in management (including our CEO), other personnel and our overall retention rate may 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 or retain them. We may face difficulty in attracting and retaining talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more marketed or late stage programs, recruitment by competitors or changes in the overall labor market. In addition, changes in our organizational structure or in our flexible working arrangements could impact employees' productivity and morale as well as our ability to attract, retain and motivate employees. 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 approvals of products in a timely manner;
- limitations and additional pressures on our ability to obtain and maintain product pricing or receive price increases, including those resulting from governmental or regulatory requirements;

- increased cost of goods due to factors such as inflation and supply chain disruptions;
- additional complexity in manufacturing internationally;
- delays in clinical trials relating to geopolitical instability related to Russia's invasion of Ukraine;
- 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 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 may continue to occur and would have a negative effect on our financial condition and results of operations.

Although the Solothurn facility was approved by the FDA for ADUHELM, there can be no assurance that the regulatory authorities will approve the Solothurn facility for the manufacturing of other products.

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 including VUMERITY. In some cases, due to the unique manner in which our products are manufactured, we

rely on single source providers of raw materials and manufacturing supplies. These third-parties are independent entities subject to their own unique operational and financial risks that are outside of our control. These third-parties may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations, and they may be unable or unwilling to increase production capacity commensurate with demand for our existing or future products. Finding alternative providers could take a significant amount of time and involve significant expense due to the specialized nature of the services and the need to obtain regulatory approval of any significant changes to our suppliers or manufacturing methods. We cannot be certain that we could reach agreement with alternative providers or that the FDA or other regulatory authorities would approve our use of such alternatives. Furthermore, factors such as the COVID-19 pandemic, weather events, labor or raw material shortages and other supply chain disruptions could result in difficulties and delays in manufacturing our products, which could have an adverse impact on our results in operations or result in product shortages.

- *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 or raw material shortages, public health epidemics, natural disasters, power failures, cyber-attacks and many other factors.
- *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.
- *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.

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

Our business has and could continue to 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. 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. Customer-facing professionals interactions in healthcare settings have changed as a result of the COVID-19

pandemic. 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.

Changes in flexible working arrangements could impact employee retention, 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 has been and may continue to be adversely affected, directly or indirectly, by the COVID-19 pandemic. 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, legislation has been enacted aimed at providing emergency assistance and health care for individuals, families and businesses and broadly supporting the U.S. economy. 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 and have a financial impact on our business that we cannot predict.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will continue to 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, supply chain and distribution systems, 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 expense 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 in-process research and development (IPR&D) and other intangible assets;
- inventory write-downs for failed quality specifications, recurring 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 expense, 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, negative company-specific news, biotechnology market sentiment, 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 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 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 (including those related to the impact of the Tax Cuts and Jobs Act of 2017), 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 enactment of some or all of the recommendations set forth or that may be forthcoming in the Organization for Economic Cooperation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities and economic blocs in the countries in which we operate, could unfavorably impact our effective tax rate. These initiatives focus on common international principles for the entitlement to taxation of global corporate profits and minimum global tax rates.

Our 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 2022:

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 2022	900,000	$ 215.27	900,000	$ 2,606.3
May 2022	1,535,074	$ 199.51	1,535,074	$ 2,300.0
June 2022	—	$ —	—	$ 2,300.0
Total	2,435,074	$ 205.33		

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 2.4 million shares of our common stock at a cost of approximately $500.0 million during the three and six months ended June 30, 2022. During the three and six months ended June 30, 2021, 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, respectively. Approximately $2.3 billion remained available under our 2020 Share Repurchase Program as of June 30, 2022.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1*	Letter regarding employment arrangement of Michel Vounatsos dated May 2, 2022. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on May 3, 2022.
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, 2022, 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, 2022, formatted in Inline XBRL.

* Management contract or compensatory plan or arrangement

\+ Filed herewith

++ Furnished herewith

SIGNATURES

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

BIOGEN INC.

/s/ Michael R. McDonnell
Michael R. McDonnell
Chief Financial Officer
(principal financial officer)

July 20, 2022

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 20, 2022

/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 20, 2022

/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, 2022 (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 20, 2022

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

Date: July 20, 2022

/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.