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 March 31, 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 May 2, 2022, was 146,452,013 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 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;
- 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 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 March 31,	
	2022	2021
Revenue:		
Product, net	$ 2,066.3	$ 2,211.7
Revenue from anti-CD20 therapeutic programs	399.4	389.0
Other	66.1	93.3
Total revenue	2,531.8	2,694.0
Cost and expense:		
Cost of sales, excluding amortization and impairment of acquired intangible assets	753.9	478.1
Research and development	551.7	514.2
Selling, general and administrative	634.9	595.0
Amortization and impairment of acquired intangible assets	66.9	98.1
Collaboration profit (loss) sharing	(117.3)	68.5
(Gain) loss on fair value remeasurement of contingent consideration	(7.1)	(33.8)
Restructuring charges	38.1	—
Total cost and expense	1,921.1	1,720.1
Income from operations	610.7	973.9
Other income (expense), net	(263.3)	(506.9)
Income before income tax expense and equity in loss of investee, net of tax	347.4	467.0
Income tax (benefit) expense	125.6	44.2
Equity in (income) loss of investee, net of tax	3.3	18.2
Net income	218.5	404.6
Net income (loss) attributable to noncontrolling interests, net of tax	(85.3)	(5.6)
Net income attributable to Biogen Inc.	$ 303.8	$ 410.2
Net income per share:		
Basic earnings per share attributable to Biogen Inc.	$ 2.06	$ 2.70
Diluted earnings per share attributable to Biogen Inc.	$ 2.06	$ 2.69
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	147.1	151.9
Diluted earnings per share attributable to Biogen Inc.	147.6	152.3

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 March 31,	
	2022	2021
Net income attributable to Biogen Inc.	$ 303.8	$ 410.2
Other comprehensive income:		
Unrealized gains (losses) on securities available for sale, net of tax	(9.7)	(0.8)
Unrealized gains (losses) on cash flow hedges, net of tax	15.9	149.6
Gains (losses) on net investment hedges, net of tax	6.2	22.4
Unrealized gains (losses) on pension benefit obligation, net of tax	0.9	2.0
Currency translation adjustment	(21.8)	(48.5)
Total other comprehensive income (loss), net of tax	(8.5)	124.7
Comprehensive income (loss) attributable to Biogen Inc.	295.3	534.9
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	(85.3)	(4.9)
Comprehensive income (loss)	$ 210.0	$ 530.0

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	As of March 31, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,749.3	$ 2,261.4
Marketable securities	2,002.4	1,541.1
Accounts receivable, net	1,632.0	1,549.4
Due from anti-CD20 therapeutic programs	389.4	412.3
Inventory	1,215.4	1,351.5
Other current assets	927.4	740.8
Total current assets	7,915.9	7,856.5
Marketable securities	1,001.6	892.0
Property, plant and equipment, net	3,372.8	3,416.4
Operating lease assets	359.0	375.4
Intangible assets, net	2,150.8	2,221.3
Goodwill	5,758.0	5,761.1
Deferred tax asset	1,288.8	1,415.1
Investments and other assets	1,767.5	1,939.5
Total assets	$ 23,614.4	$ 23,877.3
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$ 999.5	$ 999.1
Taxes payable	317.3	174.7
Accounts payable	398.7	589.2
Accrued expense and other	2,231.1	2,535.2
Total current liabilities	3,946.6	4,298.2
Notes payable	6,275.7	6,274.0
Deferred tax liability	571.2	694.5
Long-term operating lease liabilities	312.3	330.4
Other long-term liabilities	1,287.9	1,320.5
Total liabilities	12,393.7	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	119.0	68.2
Accumulated other comprehensive income (loss)	(115.2)	(106.7)
Retained earnings	14,215.5	13,911.7
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	11,242.3	10,896.2
Noncontrolling interests	(21.6)	63.5
Total equity	11,220.7	10,959.7
Total liabilities and equity	$ 23,614.4	$ 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 Three Months Ended March 31,	
	2022	2021
Cash flow from operating activities:		
Net income	$ 218.5	$ 404.6
Adjustments to reconcile net income to net cash flow from operating activities:		
Depreciation and amortization	143.1	102.6
Impairment of intangible assets	—	44.3
Excess and obsolescence charges related to inventory	281.5	11.9
Share-based compensation	67.6	70.0
Contingent consideration	(7.1)	(33.8)
Deferred income taxes	1.0	(15.0)
(Gain) loss on strategic investments	191.1	437.6
(Gain) loss on equity method investments	3.3	18.2
Other	43.3	59.8
Changes in operating assets and liabilities, net:		
Accounts receivable	(87.5)	37.2
Due from anti-CD20 therapeutic programs	22.9	43.8
Inventory	(142.6)	(112.5)
Accrued expense and other current liabilities	(461.6)	(283.6)
Income tax assets and liabilities	101.9	64.8
Other changes in operating assets and liabilities, net	(213.6)	(80.9)
Net cash flow provided by (used in) operating activities	161.8	769.0
Cash flow from investing activities:		
Purchases of property, plant and equipment	(57.9)	(92.6)
Proceeds from sales and maturities of marketable securities	543.6	819.2
Purchases of marketable securities	(1,133.5)	(913.3)
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	—	28.1
Proceeds from the sales of strategic investments	—	91.2
Other	(0.2)	2.7
Net cash flow provided by (used in) investing activities	(648.0)	(64.7)
Cash flow from financing activities:		
Purchases of treasury stock	—	(600.0)
Payments related to issuance of stock for share-based compensation arrangements, net	(20.8)	(27.1)
Repayment of borrowings and premiums paid on debt exchange	—	(169.3)
Net (distribution) contribution to noncontrolling interest	0.2	—
Other	4.1	11.4
Net cash flow provided by (used in) financing activities	(16.5)	(785.0)
Net increase (decrease) in cash and cash equivalents	(502.7)	(80.7)
Effect of exchange rate changes on cash and cash equivalents	(9.4)	(33.0)
Cash and cash equivalents, beginning of the period	2,261.4	1,331.2
Cash and cash equivalents, end of the period	$ 1,749.3	$ 1,217.5

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, 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	—	—	—	—	—	—	303.8	—	—	303.8	(85.3)	218.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	(8.5)	—	—	—	(8.5)	—	(8.5)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	0.2	0.2
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	18.9	—	—	—	—	18.9	—	18.9
Issuance of common stock under stock award plan	—	—	0.4	—	(39.7)	—	—	—	—	(39.7)	—	(39.7)
Compensation related to share-based payments	—	—	—	—	70.4	—	—	—	—	70.4	—	70.4
Other	—	—	—	—	1.2	—	—	—	—	1.2	—	1.2
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

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	—	—	—	—	—	—	410.2	—	—	410.2	(5.6)	404.6
Other comprehensive income (loss), net of tax	—	—	—	—	—	124.7	—	—	—	124.7	0.7	125.4
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	0.1	0.1
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(2.2)	(600.0)	(600.0)	—	(600.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(2.2)	—	(93.8)	—	(506.2)	2.2	600.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	19.7	—	—	—	—	19.7	—	19.7
Issuance of common stock under stock award plan	—	—	0.3	—	—	—	(46.8)	—	—	(46.8)	—	(46.8)
Compensation related to share-based payments	—	—	—	—	72.6	—	—	—	—	72.6	—	72.6
Other	—	—	—	—	1.5	—	—	—	—	1.5	—	1.5
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

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 are providing 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. We have also secured the exclusive rights to commercialize BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, which was approved in the U.S., the European Union (E.U.) and the United Kingdom (U.K.) during the third quarter of 2021. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to these unaudited condensed consolidated financial statements (condensed consolidated financial statements).

Basis of Presentation

In the opinion of management, our condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair statement of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The information included in this quarterly report on Form 10-Q should be read in conjunction with our audited consolidated financial statements and the accompanying notes included in our 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 months ended March 31, 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 Russia's invasion of 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.

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.

2. 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 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 $100.0 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 months ended March 31, 2022, we recognized $27.7 million of employee related costs, primarily related to severance. 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. We are marketing the space for sublease. Our decision to cease using the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility, which we do not believe can be adequately recovered in a sublease. As a result, for the three months ended March 31, 2022, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in restructuring charges in our condensed consolidated statements of income.

The following table summarizes the charges and spending related to our 2022 cost saving initiatives for the three months ended March 31, 2022:

(In millions)	Workforce Reduction	Total
Restructuring reserve as of December 31, 2021	$ —	$ —
Expense	27.7	27.7
Payment	(6.2)	(6.2)
Restructuring reserve as of March 31, 2022	$ 21.5	$ 21.5

3. REVENUE

Product Revenue

Revenue by product is summarized as follows:

	For the Three Months Ended March 31,					
	2022			2021		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate[1]	$ 242.3	$ 295.6	$ 537.9	$ 236.0	$ 316.9	$ 552.9
Interferon[2]	182.3	127.3	309.6	241.8	158.7	400.5
TYSABRI	284.5	236.3	520.8	273.3	230.0	503.3
FAMPYRA	—	26.2	26.2	—	26.6	26.6
Subtotal: MS	709.1	685.4	1,394.5	751.1	732.2	1,483.3
Spinal Muscular Atrophy:						
SPINRAZA	163.3	309.2	472.5	148.7	371.8	520.5
Alzheimer's disease:						
ADUHELM[3]	2.8	—	2.8	—	—	—
Biosimilars:						
BENEPALI	—	114.7	114.7	—	121.7	121.7
IMRALDI	—	57.1	57.1	—	57.9	57.9
FLIXABI	—	22.5	22.5	—	25.5	25.5
Subtotal: Biosimilars	—	194.3	194.3	—	205.1	205.1
Other:						
FUMADERM	—	2.2	2.2	—	2.8	2.8
Total product revenue	$ 875.2	$ 1,191.1	$ 2,066.3	$ 899.8	$ 1,311.9	$ 2,211.7

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

We recognized revenue from two wholesalers accounting for 26.3% and 10.5% of gross product revenue for the three months ended March 31, 2022, and 30.0% and 9.3% of gross product revenue for the three months ended March 31, 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	169.0	659.5	4.0	832.5
Adjustments relating to prior years	(3.9)	(40.2)	(2.5)	(46.6)
Payments/credits relating to sales in current year	(101.2)	(271.6)	(0.5)	(373.3)
Payments/credits relating to sales in prior years	(58.9)	(314.5)	(6.5)	(379.9)
Balance, March 31, 2022	$ 142.7	$ 792.8	$ 32.5	$ 968.0

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

(In millions)	As of March 31, 2022	As of December 31, 2021
Reduction of accounts receivable	$ 136.9	$ 133.2
Component of accrued expense and other	831.1	802.1
Total revenue-related reserves	$ 968.0	$ 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 March 31,	
(In millions)	2022	2021
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$ 143.2	$ 174.1
OCREVUS and other revenue from anti-CD20 therapeutic programs	256.2	214.9
Total revenue from anti-CD20 therapeutic programs	$ 399.4	$ 389.0

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 March 31,	
(In millions)	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	$ 8.0	$ 3.9
Other royalty and corporate revenue:		
Royalty	10.6	6.2
Other corporate	47.5	83.2
Total other revenue	$ 66.1	$ 93.3

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.

4. INVENTORY

The components of inventory are summarized as follows:

(In millions)	As of March 31, 2022	As of December 31, 2021
Raw materials	$ 354.5	$ 349.6
Work in process	655.6	814.0
Finished goods	205.3	187.9
Total inventory	$ 1,215.4	$ 1,351.5

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. 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.

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 during the fourth quarter of 2021.

As of March 31, 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 16, Collaborative and Other Relationships*, to these condensed consolidated financial statements.

5. INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

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

		As of March 31, 2022			As of December 31, 2021		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,413.1	$ (5,455.4)	$ 1,957.7	$ 7,413.1	$ (5,388.5)	$ 2,024.6
In-process research and development	Indefinite until commercialization	129.1	—	129.1	132.7	—	132.7
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 7,606.2	$ (5,455.4)	$ 2,150.8	$ 7,609.8	$ (5,388.5)	$ 2,221.3

Amortization and Impairments

For the three months ended March 31, 2022, amortization and impairment of acquired intangible assets totaled $66.9 million, compared to $98.1 million in the prior year comparative period. For the three months ended March 31, 2022, we had no impairment charges.

For the three months ended March 31, 2021, amortization and impairment of acquired intangible assets reflects the impact of 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 March 31, 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 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 March 31, 2022, the carrying value associated with the remaining IPR&D asset for DPN was $129.1 million and the fair value of this asset was not significantly in excess of its carrying value. Upon the completion of the additional clinical trial we will reevaluate the carrying value of the program.

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 March 31, 2022
2022 (remaining nine months)	$ 200.0
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 March 31, 2022
Goodwill, December 31, 2021	$ 5,761.1
Other	(3.1)
Goodwill, March 31, 2022	$ 5,758.0

As of March 31, 2022, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

6. FAIR VALUE MEASUREMENTS

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

	As of March 31, 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	$ 1,283.7	$ —	$ 1,283.7	$ —
Marketable debt securities:				
Corporate debt securities	1,579.4	—	1,579.4	—
Government securities	1,252.7	—	1,252.7	—
Mortgage and other asset backed securities	171.9	—	171.9	—
Marketable equity securities	860.3	607.0	253.3	—
Derivative contracts	97.2	—	97.2	—
Plan assets for deferred compensation	35.8	—	35.8	—
Total	$ 5,281.0	$ 607.0	$ 4,674.0	$ —
Liabilities:				
Derivative contracts	$ 12.5	$ —	$ 12.5	$ —
Contingent consideration obligations	202.0	—	—	202.0
Total	$ 214.5	$ —	$ 12.5	$ 202.0

	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 March 31, 2022 and December 31, 2021. In addition, there have been no changes in valuation techniques as of March 31, 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 our investments in the common stock of Sangamo Therapeutics, Inc. (Sangamo) and Sage Therapeutics, Inc. (Sage) and are valued using an option pricing valuation model as the investments are each subject to certain holding period restrictions. The holding period restrictions for our investment in the common stock of Denali Therapeutics Inc. (Denali) and a portion of our Sangamo investment expired during the first quarter of 2022 and the second quarter of 2021, respectively. The fair value of our Denali investment and this portion of our Sangamo investment were Level 1 measurements as of March 31, 2022. For additional information on our investments in Sangamo, Denali and Sage common stock, please read *Note 7, Financial Instruments,* to these condensed consolidated financial statements.

For a description of our validation procedures related to prices provided by third-party pricing services and our option pricing valuation model, please read *Note 1, Summary of Significant Accounting Policies - Fair Value Measurements,* to our consolidated financial statements included in our 2021 Form 10-K.

The following tables summarize the significant unobservable inputs in the fair value measurement of our contingent consideration obligations as of March 31, 2022 and December 31, 2021:

	As of March 31, 2022				
(In millions)	Fair Value	Valuation Technique	Unobservable Input(s)	Range	Weighted Average
Liabilities:					
Contingent consideration obligations	$ 202.0	Discounted cash flow	Discount rate	2.89%	2.89%
			Expected timing of achievement of development milestones	2023 to 2027	—

	As of December 31, 2021				
(In millions)	Fair Value	Valuation Technique	Unobservable Input(s)	Range	Weighted Average
Liabilities:					
Contingent consideration obligations	$ 209.1	Discounted cash flow	Discount rate	1.30%	1.30%
			Expected timing of achievement of development milestones	2023 to 2027	—

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. In addition, we apply various probabilities of technological and regulatory success, ranging from 10.9% to certain probability as of March 31, 2022, to the valuation models to estimate the fair values of our contingent consideration obligations.

Debt Instruments

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

	As of March 31, 2022		As of December 31, 2021	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
3.625% Senior Notes due September 15, 2022	$ 1,008.7	$ 999.5	$ 1,020.0	$ 999.1
4.050% Senior Notes due September 15, 2025	1,797.6	1,743.4	1,895.2	1,742.9
2.250% Senior Notes due May 1, 2030	1,341.6	1,492.2	1,475.9	1,492.0
5.200% Senior Notes due September 15, 2045	1,240.0	1,100.0	1,463.0	1,099.9
3.150% Senior Notes due May 1, 2050	1,225.3	1,473.3	1,457.7	1,473.2
3.250% Senior Notes due February 15, 2051	581.8	466.8	692.9	466.0
Total	$ 7,195.0	$ 7,275.2	$ 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. 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.

Contingent Consideration Obligations

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

	For the Three Months Ended March 31,	
(In millions)	2022	2021
Fair value, beginning of period	$ 209.1	$ 259.8
Changes in fair value	(7.1)	(33.8)
Fair value, end of period	$ 202.0	$ 226.0

As of March 31, 2022 and December 31, 2021, approximately $202.0 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.

For the three months ended March 31, 2022, changes in the fair value of our contingent consideration obligations were primarily due to an increase in 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 months ended March 31, 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.

7. FINANCIAL INSTRUMENTS

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

(In millions)	As of March 31, 2022	As of December 31, 2021
Commercial paper	$ 278.5	$ 247.6
Overnight reverse repurchase agreements	13.9	200.0
Money market funds	585.0	901.6
Short-term debt securities	406.3	283.0
Total	$ 1,283.7	$ 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:

	As of March 31, 2022			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 1,126.7	$ 0.1	$ (2.2)	$ 1,124.6
Non-current	460.5	0.1	(5.8)	454.8
Government securities:				
Current	878.7	1.0	(2.6)	877.1
Non-current	379.0	0.2	(3.6)	375.6
Mortgage and other asset backed securities:				
Current	0.7	—	—	0.7
Non-current	173.4	—	(2.2)	171.2
Total marketable debt securities	$ 3,019.0	$ 1.4	$ (16.4)	$ 3,004.0
Marketable equity securities				
Marketable equity securities, current	$ 33.9	$ —	$ —	$ 33.9
Marketable equity securities, non-current	1,133.1	4.5	(311.2)	826.4
Total marketable equity securities	$ 1,167.0	$ 4.5	$ (311.2)	$ 860.3

(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 available-for-sale by contractual maturity are summarized as follows:

(In millions)	As of March 31, 2022 Estimated Fair Value	Amortized Cost	As of December 31, 2021 Estimated Fair Value	Amortized Cost
Due in one year or less	$ 2,002.4	$ 2,006.0	$ 1,541.1	$ 1,541.7
Due after one year through five years	982.9	993.7	868.2	870.2
Due after five years	18.7	19.3	23.8	24.0
Total marketable debt securities	$ 3,004.0	$ 3,019.0	$ 2,433.1	$ 2,435.9

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

Proceeds from Marketable Debt Securities

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

(In millions)	For the Three Months Ended March 31, 2022	2021
Proceeds from maturities and sales	$ 543.6	$ 819.2
Realized gains	—	0.2
Realized losses	0.6	0.7

Realized losses for the three months ended March 31, 2022 and 2021, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities.

Strategic Investments

As of March 31, 2022 and December 31, 2021, our strategic investment portfolio was comprised of investments totaling $919.5 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 6, Fair Value Measurements,* to these condensed consolidated financial statements, venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.

The decrease in our strategic investment portfolio for the three months ended March 31, 2022, was 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, Ionis Pharmaceuticals, Inc. (Ionis), 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.

8. DERIVATIVE INSTRUMENTS

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of March 31, 2022 and December 31, 2021, had durations of 1 to 18 months and 1 to 15 months, respectively. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the table below). Realized gains and losses of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized and in operating expense when the expense in the currency being hedged is recorded. We recognize all cash flow hedge reclassifications from accumulated other comprehensive income (loss) and fair value changes of excluded portions in the same line item in our condensed consolidated statements of income that has been impacted by the hedged item.

The notional 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 March 31, 2022**	**As of December 31, 2021**
Euro	$ 1,631.2	$ 1,828.0
British pound	126.6	166.2
Swiss franc	128.6	—
Japanese yen	55.0	72.7
Canadian dollar	44.6	59.9
Total foreign currency forward contracts	$ 1,986.0	$ 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 March 31, 2022**	**As of December 31, 2021**
Unrealized gains	$ 76.4	$ 60.8
Unrealized (losses)	(4.3)	(7.0)
Net unrealized gains (losses)	$ 72.1	$ 53.8

We expect the net unrealized gains of $72.1 million to be settled over the next 18 months, of which $72.0 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 March 31, 2022 and December 31, 2021, credit risk did not materially change the fair value of our foreign currency forward contracts.

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

	For the Three Months Ended March 31,			
	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)		Net Gains/(Losses) Recognized in Operating Income (in millions)	
Location	2022	2021	Location	2022	2021
Revenue	$ 20.9	$ (23.1)	Revenue	$ (6.5)	$ (3.0)
Operating expense	(0.3)	(0.4)	Operating expense	(0.1)	(0.1)

Net Investment Hedges - Hedging Instruments

In February 2012 we entered into a joint venture agreement with Samsung BioLogics establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products. In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5.0% to approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics. Our investment in the equity of Samsung Bioepis is exposed to the currency fluctuations in the South Korean won.

In order to mitigate the currency fluctuations between the U.S. dollar and South Korean won, we have entered into foreign currency forward contracts. Foreign currency forward contracts in effect as of March 31, 2022, had a remaining duration of seven months. These contracts have been designated as net investment hedges. We recognize changes in the spot exchange rate in accumulated other comprehensive income (loss). The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net gains of $20.6 million and $10.6 million as of March 31, 2022 and December 31, 2021, respectively. We exclude fair value changes related to the forward rate from our hedging relationship and will amortize the forward points in other income (expense), net in our condensed consolidated statements of income over the term of the contract. The pre-tax portion of the fair value of the forward points that were included in accumulated other comprehensive income (loss) in total equity reflected net losses of $2.5 million and $3.6 million as of March 31, 2022 and December 31, 2021, respectively. In conjunction with the closing of our sale of equity in Samsung Bioepis to Samsung BioLogics, which occurred in April 2022, we concurrently closed our foreign currency forward contracts.

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

	For the Three Months Ended March 31,					
	Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)		Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)		Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)	
Location	2022	2021	Location	2022	2021	Location	2022	2021
Gains (losses) on net investment hedge	$ 10.1	$ 23.8	Gains (losses) on net investment hedge	$ (3.3)	$ (1.4)	Other income (expense)	$ (1.1)	$ 0.1

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

Foreign Currency Forward Contracts - Other Derivative Instruments

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

The aggregate notional amount of these outstanding foreign currency forward contracts was $1,333.4 million and $1,268.0 million as of March 31, 2022 and December 31, 2021, respectively. Net losses of $12.2 million and $17.4 million related to these contracts were recorded as a component of other income (expense), net for the three months ended March 31, 2022 and 2021, respectively.

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 March 31, 2022	As of December 31, 2021
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 79.8	$ 66.2
	Investments and other assets	1.6	5.5
Liability derivative instruments	Accrued expense and other	2.4	6.6
	Other long-term liabilities	2.2	—
Net Investment Hedging Instruments:			
Asset derivative instruments	Other current assets	10.9	4.1
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	4.9	5.1
Liability derivative instruments	Accrued expense and other	7.9	4.2

9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was $2,082.0 million and $2,006.6 million as of March 31, 2022 and December 31, 2021, respectively. For the three months ended March 31, 2022, depreciation expense totaled $76.3 million compared to $48.8 million in the prior year comparative period.

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 March 31, 2022 and December 31, 2021, we had approximately $682.6 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 remainder of the facility will be operational during the first half of 2023.

10. INDEBTEDNESS

Exchange Offer

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

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

In addition, we redeemed an aggregate principal amount of approximately $8.9 million of our 2045 Senior Notes for aggregate cash payments of approximately $12.1 million, excluding accrued and unpaid interest. The redemption has been accounted for as a debt extinguishment; as such, we recognized a pre-tax charge of

$3.2 million upon the extinguishment of such 2045 Senior Notes. This charge, which was recognized in interest expense in other income (expense), net in our condensed consolidated statements of income for the three months ended March 31, 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 three months ended March 31, 2021.

11. EQUITY

Share Repurchases

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 2.2 million shares of our common stock at a cost of approximately $600.0 million during the three months ended March 31, 2021. There were no share repurchases of our common stock during the three months ended March 31, 2022. Approximately $2.8 billion remained available under our 2020 Share Repurchase Program as of March 31, 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 Hedge, Net of Tax	Unfunded Status of Postretirement Benefit Plans, 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	(10.2)	34.4	5.1	0.9	(21.8)	8.4
Amounts reclassified from accumulated other comprehensive income (loss)	0.5	(18.5)	1.1	—	—	(16.9)
Net current period other comprehensive income (loss)	(9.7)	15.9	6.2	0.9	(21.8)	(8.5)
Balance, March 31, 2022	$ (11.9)	$ 69.7	$ 31.7	$ (43.9)	$ (160.8)	$ (115.2)

(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedge, Net of Tax	Unfunded Status of Postretirement Benefit Plans, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2020	$ 1.4	$ (179.0)	$ (8.5)	$ (66.3)	$ (46.6)	$ (299.0)
Other comprehensive income (loss) before reclassifications	(1.2)	128.6	22.4	2.0	(48.5)	103.3
Amounts reclassified from accumulated other comprehensive income (loss)	0.4	21.0	—	—	—	21.4
Net current period other comprehensive income (loss)	(0.8)	149.6	22.4	2.0	(48.5)	124.7
Balance, March 31, 2021	$ 0.6	$ (29.4)	$ 13.9	$ (64.3)	$ (95.1)	$ (174.3)

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 March 31,	
(In millions)	Income Statement Location	2022	2021
Gains (losses) on securities available for sale	Other income (expense)	$ (0.6)	$ (0.5)
	Income tax benefit (expense)	0.1	0.1
Gains (losses) on cash flow hedges	Revenue	20.9	(23.1)
	Operating expense	(0.3)	(0.4)
	Other income (expense)	(0.1)	0.2
	Income tax benefit (expense)	(2.0)	2.3
Gains (losses) on net investment hedge	Other income (expense)	(1.1)	—
Total reclassifications, net of tax		$ 16.9	$ (21.4)

12. EARNINGS PER SHARE

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

	For the Three Months Ended March 31,	
(In millions)	2022	2021
Numerator:		
Net income attributable to Biogen Inc.	$ 303.8	$ 410.2
Denominator:		
Weighted average number of common shares outstanding	147.1	151.9
Effect of dilutive securities:		
Time-vested restricted stock units	0.3	0.2
Market stock units	0.1	0.1
Performance stock units settled in stock	0.1	0.1
Dilutive potential common shares	0.5	0.4
Shares used in calculating diluted earnings per share	147.6	152.3

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

13. SHARE-BASED PAYMENTS

Share-based Compensation Expense

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

	For the Three Months Ended March 31,	
(In millions)	2022	2021
Research and development	$ 25.7	$ 33.6
Selling, general and administrative	46.1	44.9
Subtotal	71.8	78.5
Capitalized share-based compensation costs	(2.8)	(2.6)
Share-based compensation expense included in total cost and expense	69.0	75.9
Income tax effect	(12.8)	(14.0)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 56.2	$ 61.9

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

	For the Three Months Ended March 31,	
(In millions)	2022	2021
Market stock units	$ 5.9	$ 16.5
Time-vested restricted stock units	51.3	42.8
Performance stock units settled in stock	8.3	6.3
Performance stock units settled in cash	1.4	6.0
Employee stock purchase plan	4.9	6.9
Subtotal	71.8	78.5
Capitalized share-based compensation costs	(2.8)	(2.6)
Share-based compensation expense included in total cost and expense	$ 69.0	$ 75.9

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

14. INCOME TAXES

Tax Rate

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

	For the Three Months Ended March 31,	
	2022	2021
Statutory rate	21.0 %	21.0 %
State taxes	(0.4)	0.8
Taxes on foreign earnings	(10.8)	(10.9)
Tax credits	(2.5)	(3.7)
Purchased intangible assets	0.6	0.8
GILTI	0.3	0.9
Neurimmune tax impacts	24.2	(0.6)
Other	3.8	1.2
Effective tax rate	36.2 %	9.5 %

Changes in Tax Rate

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune SubOne AG's (Neurimmune) 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 the three months ended March 31, 2022, compared to the same period in 2021, the increase in our effective tax rate was primarily due to a deferred tax expense related to a valuation allowance, as discussed above, and the non-cash tax effects of changes in the value of our equity investments. The tax effects of this change in value of our equity investments were recorded discretely, since changes in value of equity investments cannot be forecasted.

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

Tax Basis in Samsung Bioepis

As of March 31, 2022 and December 31, 2021, the carrying value of our investment in Samsung Bioepis totaled 709.4 billion South Korean won ($586.4 million) and 713.3 billion South Korean won ($599.9 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets. As of March 31, 2022, we have not recorded deferred taxes of approximately $70.0 million on our tax over book basis related to this joint venture.

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.

15. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAIL

Other Income (Expense), Net

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

	For the Three Months Ended March 31,	
(In millions)	**2022**	**2021**
Interest income	$ 2.9	$ 2.9
Interest expense	(66.1)	(64.7)
Gains (losses) on investments, net	(191.1)	(436.6)
Foreign exchange gains (losses), net	(8.3)	(8.6)
Other, net	(0.7)	0.1
Total other income (expense), net	$ (263.3)	$ (506.9)

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.

The following table summarizes our gains (losses) on investments, net that relates to our equity securities held as of March 31, 2022 and 2021:

	For the Three Months Ended March 31,	
(In millions)	**2022**	**2021**
Net gains (losses) recognized during the period on equity securities	$ (190.7)	$ (436.1)
Less: Net gains (losses) realized during the period on equity securities	0.2	6.2
Unrealized gains (losses) recognized during the period on equity securities	$ (190.9)	$ (442.3)

The net unrealized losses recognized during the three months ended March 31, 2022, primarily reflect decreases in the aggregate fair value of our investments in Denali, Sage and Sangamo common stock of approximately $205.5 million.

Accrued Expense and Other

Accrued expense and other consists of the following:

(In millions)	As of March 31, 2022	As of December 31, 2021
Revenue-related reserves for discounts and allowances	$ 831.1	$ 802.1
Collaboration expense	266.2	324.7
Royalties and licensing fees	216.0	234.7
Employee compensation and benefits	206.6	345.1
Other	711.2	828.6
Total accrued expense and other	$ 2,231.1	$ 2,535.2

Other Long-term Liabilities

Other long-term liabilities were $1,287.9 million and $1,320.5 million as of March 31, 2022 and December 31, 2021, respectively, and included accrued income taxes totaling $640.5 million and $664.5 million, respectively.

16. COLLABORATIVE AND OTHER RELATIONSHIPS

Eisai Co., Ltd.

Lecanemab Collaboration

We have a collaboration agreement with Eisai Co., Ltd. (Eisai) to jointly develop and commercialize lecanemab (BAN2401), an anti-amyloid antibody, and elenbecestat, the oral BACE (base amyloid cleaving enzyme) inhibitor, two Eisai product candidates for the potential treatment of Alzheimer's disease (the Lecanemab Collaboration). In September 2019 we and Eisai discontinued the global Phase 3 studies of elenbecestat in early Alzheimer's disease.

Eisai serves as the 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 our Solothurn manufacturing facility.

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 (aducanumab) (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 March 31,	
(In millions)	2022	2021
Total development expense incurred by the collaboration related to the advancement of lecanemab and elenbecestat	$ 77.0	$ 55.5
Biogen's share of lecanemab and elenbecestat development expense reflected in research and development expense in our condensed consolidated statements of income	38.5	27.7
Total sales and marketing expense incurred by the Lecanemab Collaboration	15.9	5.7
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	8.0	2.9

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. 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 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. Once 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 March 31,	
(In millions)	**2022**	**2021**
Total ADUHELM development expense	$ 44.2	$ 47.0
Biogen's share of ADUHELM development expense reflected in research and development expense in our condensed consolidated statements of income	24.3	25.8
Total ADUHELM sales and marketing expense incurred by the ADUHELM Collaboration Agreement	95.0	111.8
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	50.9	60.3

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 months ended March 31, 2022, we recognized a net reduction to our operating expense of $181.7 million to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

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. 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.

Amounts receivable from Eisai related to the agreements discussed above were $402.7 million and $285.4 million as of March 31, 2022 and December 31, 2021, respectively. Amounts payable to Eisai related to the agreements discussed above were $36.5 million and $46.5 million as of March 31, 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 March 31,	
(In millions)	**2022**	**2021**
Total UCB collaboration development expense	$ 17.6	$ 16.9
Biogen's share of UCB development expense reflected in research and development expense in our condensed consolidated statements of income	8.8	8.4

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 March 31,	
(In millions)	**2022**	**2021**
Total Sage collaboration development expense	$ 38.7	$ 39.8
Biogen's share of Sage development expense reflected in research and development expense in our condensed consolidated statements of income	19.4	19.9
Total Sage sales and marketing expense incurred by the collaboration	18.4	5.3
Biogen's share of Sage sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	9.2	2.7

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:

(In millions)	For the Three Months Ended March 31, 2022	2021
Total Denali collaboration development expense	$ 14.9	$ 15.4
Biogen's share of Denali development expense reflected in research and development expense in our condensed consolidated statements of income	8.9	9.2

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:

(In millions)	For the Three Months Ended March 31, 2022	2021
Total Sangamo collaboration development expense	$ 8.3	$ 4.8
Biogen's share of Sangamo development expense reflected in research and development expense in our condensed consolidated statements of income	5.5	4.2

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 months ended March 31, 2022, we recorded $19.5 million as research and development expense in our condensed consolidated statements of income related to other research and discovery related arrangements, compared to less than $1.0 million in the prior year comparative period.

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. As of March 31, 2022, our ownership percentage was approximately 49.9%.

We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in (income) loss of investee, net of tax in our condensed consolidated statements of income.

Upon investment, the equity method of accounting requires us to identify and allocate differences between the fair value of our investment and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life. The total basis difference was approximately $675.0 million and relates to inventory, developed technology, IPR&D and deferred tax balances. The basis differences related to inventory were amortized, net of tax, over their estimated useful lives of 1.5 years, and the basis differences related to developed technology and IPR&D for marketed products will be amortized, net of tax, over their estimated useful lives of 15 years.

For the three months ended March 31, 2022, we recognized net losses on our investment of $3.3 million, reflecting our share of Samsung Bioepis' operating profits, net of tax totaling $4.0 million offset by amortization of basis differences totaling $7.3 million.

For the three months ended March 31, 2021, we recognized net losses on our investment of $18.2 million, reflecting our share of Samsung Bioepis' operating losses, net of tax totaling $11.0 million and amortization of basis differences totaling $7.2 million.

As of March 31, 2022 and December 31, 2021, the carrying value of our investment in Samsung Bioepis totaled 709.4 billion South Korean won ($586.4 million) and 713.3 billion South Korean won ($599.9 million), respectively, which is classified as a component of investments and other assets in our condensed consolidated balance sheets.

In January 2022 we entered into an agreement to sell to Samsung BioLogics our equity in Samsung Bioepis, which was completed on April 20, 2022. Under the terms of the transaction, we received approximately $1.0 billion in cash at closing and will receive approximately $1.3 billion to be deferred over two payments of $812.5 million due at the first anniversary and $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.

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 proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. Samsung Bioepis will be responsible for development and will supply both products to us at a pre-specified gross margin.

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 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 months ended March 31, 2022, we recognized net profit-sharing expense of $64.4 million to reflect Samsung

Bioepis' 50.0% sharing of the net collaboration profits, compared to a net profit-sharing expense of $68.5 million in the prior year comparative period.

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 $5.8 million and $4.1 million as of March 31, 2022 and December 31, 2021, respectively. Amounts payable to Samsung Bioepis related to the agreements discussed above were $102.5 million and $148.7 million as of March 31, 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.

17. INVESTMENTS IN VARIABLE INTEREST ENTITIES

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

We have a collaboration and license agreement with Neurimmune for the development and commercialization of antibodies for the potential treatment of Alzheimer's disease, including ADUHELM (as amended, the Neurimmune Agreement). We are responsible for the development, manufacturing and commercialization of all collaboration products. The Neurimmune Agreement is effective for the longer of the duration of certain patents relating to a licensed product or 12 years from the first commercial sale of a licensed product.

We consolidate the results of Neurimmune as we determined that we are the primary beneficiary of Neurimmune because we have the power through the collaboration to direct the activities that most significantly impact the entity’s economic performance and we are required to fund 100.0% of the research and development costs incurred in support of the collaboration.

In 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.

Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay additional milestones to Neurimmune, including $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the ADUHELM Collaboration Agreement.

Research and development costs for which we reimburse Neurimmune are reflected in research and development expense in our condensed consolidated statements of income. During the three months ended March 31, 2022 and 2021, amounts reimbursed were immaterial.

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 16, Collaborative and Other Relationships,* to these condensed consolidated financial statements.

Unconsolidated Variable Interest Entities

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

As of March 31, 2022 and December 31, 2021, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $24.1 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.

18. LITIGATION

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read *Note 1, Summary of Significant Accounting Policies,* to our consolidated financial statements included in our 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 and February 7, 2022, 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 action filed on November 13, 2020, 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. 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 Düsseldorf 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). In May 2020 the European Patent Office (EPO) held the EP '510 Patent invalid. Fresenius Kabi has appealed to the EPO's Technical Boards of Appeal, a hearing has been set for June 2022, and the German and French proceedings have been stayed pending the decision on appeal.

In June 2020 Fresenius Kabi commenced proceedings in Denmark's Maritime and Commercial High Court alleging that IMRALDI infringes the Danish counterpart of European Patent No. 3 145 488 (the EP '488 Patent, expiring in May 2035) 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. The EPO has scheduled a hearing on the validity of the EP '488 Patent for October 2022.

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 Düsseldorf 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 Düsseldorf 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

In July 2015 a qui tam action filed by Michael Bawduniak on behalf of the U.S. and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts and seeks damages of $981.1 million plus statutory trebling of damages, civil penalties, attorneys' fees and costs. The U.S. has not made an intervention decision. A trial is scheduled for the third quarter of 2022. An estimate of the possible loss cannot be made at this time.

Dispute with Former Convergence Shareholders

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

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.

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.

In July 2018 Mylan Pharmaceuticals, Inc. (Mylan) also 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 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 June 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. We have appealed to the EPO’s Technical Boards of Appeal. A hearing date has not been set.

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 November 2022.

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

Pharmaceutical Works Polpharma SA (Polpharma) and Mylan Ireland Ltd. (Mylan Ireland) each filed 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.

19. SUBSEQUENT EVENTS

On May 3, 2022, Biogen Inc. (the "Company") announced that it had begun a search for a new Chief Executive Officer ("CEO"). The Company has agreed with its current CEO, Michel Vounatsos, that he will continue to serve as CEO during the interim period. Mr. Vounatsos will remain on the Board of Directors of Biogen until he steps down from his CEO position.

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 are providing 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 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. We have also secured the exclusive rights to commercialize BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, which was approved in the United States (U.S.), the European Union (E.U.) and the United Kingdom (U.K.) during the third quarter of 2021. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

We seek to ensure an uninterrupted supply of medicines to 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 U.S. Food and Drug Administration (FDA) approved the Prior Approval Supplement for the Solothurn facility for ADUHELM. We estimate the remainder of the facility will be operational during the first half of 2023. We believe that the Solothurn facility will support our anticipated near-term needs for the manufacturing of biologic assets. In addition, we believe that the Solothurn facility may provide us with the ability to further expand if we need additional large scale manufacturing capacity to support future clinical and commercial manufacturing requirements. 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 wrote-off approximately $275.0 million of gross charges associated with inventory and purchase commitments related to ADUHELM and recognized approximately $45.0 million of gross idle capacity charges, as a result of this CMS decision, which were recognized in cost of sales within our condensed consolidated statements of income. 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.

Additionally, as a result of the final NCD we will substantially eliminate 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. Once 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.

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." The EC will decide TECFIDERA's entitlement to regulatory data and market protection. If data and market protection is not upheld, we could face generic competition in the E.U. as early as the first half of 2022, which would have an adverse impact on our TECFIDERA sales in the E.U. and our results of operations.

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

Business Update Regarding COVID-19 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. To help mitigate the impact of the COVID-19 pandemic to our clinical trials, we are pursuing innovative approaches such as remote monitoring, remote patient visits and supporting home infusions. These alternative measures have resulted in an immaterial increase to the cost of the clinical trials underway.

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 months ended March 31, 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 Russia's invasion of Ukraine, please read *Item 1A. Risk Factors* included in this report.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. was $2.06 for the three months ended March 31, 2022, representing a decrease of 23.4% compared to $2.69 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 March 31, 2022, compared to the three months ended March 31, 2021, reflects the following:

Revenue

- Total revenue was $2,531.8 million for the first quarter of 2022, representing a $162.2 million, or 6.0%, decrease compared to $2,694.0 million in the same period in 2021.
- Product revenue, net totaled $2,066.3 million for the first quarter of 2022, representing a $145.4 million, or 6.6%, decrease compared to $2,211.7 million in the same period in 2021. This decrease was primarily due to an $88.8 million, or 6.0%, decrease in MS product revenue and a $48.0 million, or 9.2%, decrease in SPINRAZA product revenue.
    - The decrease in MS product revenue was primarily due to a decrease in

rest of world Interferon demand due to increasing competition from our other MS products as well as other treatments for MS, including biosimilars. The decrease was also due to a decrease in U.S. TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.

- 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 the unfavorable impact of foreign currency exchange.

- Revenue from anti-CD20 therapeutic programs totaled $399.4 million for the first quarter of 2022, representing a $10.4 million, or 2.7%, increase compared to $389.0 million in the same period in 2021. This increase was primarily due to a $43.0 million, or 20.5%, increase in royalty revenue on sales of OCREVUS, partially offset by a $31.0 million, or 19.5%, decrease in RITUXAN revenue. Sales of RITUXAN have been adversely affected by the onset of biosimilars competition.

- Other revenue totaled $66.1 million for the first quarter of 2022, representing a $27.2 million, or 29.2% decrease from $93.3 million in the same period in 2021.

Expense

- Total cost and expense was $1,921.1 million for the first quarter of 2022, representing a $201.0 million, or 11.7%, increase compared to $1,720.1 million in the same period in 2021.
  - This increase was primarily due to a $275.8 million, or 57.7%, increase in cost of sales, driven by 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.
  - The increase in cost and expense for the first quarter of 2022 also reflects an increase in selling, general and administrative expense due to ADUHELM commercialization expense of approximately $80.0 million and restructuring charges of approximately $38.1 million related to our 2022 cost saving initiatives.

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

- We generated $161.8 million of net cash flow from operations for the three months ended March 31, 2022.
- Cash, cash equivalents and marketable securities totaled approximately $4,753.3 million as of March 31, 2022.
- There were no share repurchases of our common stock during the first 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 $2.8 billion remained available under our 2020 Share Repurchase Program as of March 31, 2022.

Collaborative and Other Relationships

For additional information on our collaborative and other relationships discussed below, please read *Note 16, Collaborative and Other Relationships*, and *Note 17, 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 January 2022 we entered into an agreement to sell to Samsung BioLogics our equity in Samsung Bioepis, which was completed on April 20, 2022. Under the terms of the transaction, we received approximately $1.0 billion in cash at closing and will receive approximately $1.3 billion to be deferred over two payments of $812.5 million due at the first anniversary and $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.

For additional information on the transaction and our collaboration arrangements with Samsung Bioepis, please read *Note 16, Collaborative and Other Relationships,* 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. Once 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 in our Solothurn manufacturing facility.

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

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 $100.0 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 2, Restructuring, Business Transformation and Other Cost Saving Initiatives,* to our condensed consolidated financial statements included in this report.

RESULTS OF OPERATIONS

Revenue

Revenue is summarized as follows:

	For the Three Months Ended March 31,					
(In millions, except percentages)	**2022**		**2021**		**$ Change**	**% Change**
Product revenue, net:						
United States	$ 875.2	34.6 %	$ 899.8	33.4 %	$ (24.6)	(2.7)%
Rest of world	1,191.1	47.0	1,311.9	48.7	(120.8)	(9.2)
Total product revenue, net	2,066.3	81.6	2,211.7	82.1	(145.4)	(6.6)
Revenue from anti-CD20 therapeutic programs	399.4	15.8	389.0	14.4	10.4	2.7
Other revenue	66.1	2.6	93.3	3.5	(27.2)	(29.2)
Total revenue	$ 2,531.8	100.0 %	$ 2,694.0	100.0 %	$ (162.2)	(6.0)%

Product Revenue

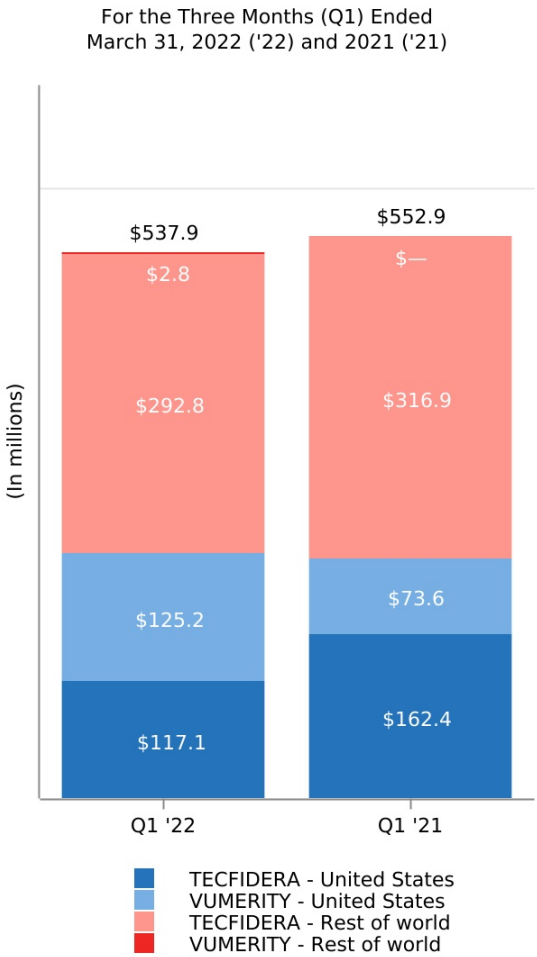
Product revenue is summarized as follows:

	For the Three Months Ended March 31,					
(In millions, except percentages)	**2022**		**2021**		**$ Change**	**% Change**
Multiple Sclerosis (MS):						
Fumarate[1]	$ 537.9	26.0 %	$ 552.9	25.0 %	$ (15.0)	(2.7)%
Interferon[2]	309.6	15.0	400.5	18.1	(90.9)	(22.7)
TYSABRI	520.8	25.2	503.3	22.8	17.5	3.5
FAMPYRA	26.2	1.3	26.6	1.2	(0.4)	(1.5)
Subtotal: MS	1,394.5	67.5	1,483.3	67.1	(88.8)	(6.0)
Spinal Muscular Atrophy:						
SPINRAZA	472.5	22.9	520.5	23.5	(48.0)	(9.2)
Alzheimer's disease:						
ADUHELM[3]	2.8	0.1	—	—	2.8	nm
Biosimilars:						
BENEPALI	114.7	5.5	121.7	5.5	(7.0)	(5.8)
IMRALDI	57.1	2.8	57.9	2.6	(0.8)	(1.4)
FLIXABI	22.5	1.1	25.5	1.2	(3.0)	(11.8)
Subtotal: Biosimilars	194.3	9.4	205.1	9.3	(10.8)	(5.3)
Other:						
FUMADERM	2.2	0.1	2.8	0.1	(0.6)	(21.4)
Total product revenue, net	$ 2,066.3	100.0 %	$ 2,211.7	100.0 %	$ (145.4)	(6.6)%

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

Multiple Sclerosis (MS)

Fumarate



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

For the three months ended March 31, 2022, compared to the same period in 2021, the 2.7% increase in U.S. Fumarate revenue was primarily due to a favorable adjustment of prior year estimates on Medicaid-related sales of VUMERITY. The increase was also due to an increase in VUMERITY sales volumes in the U.S., partially offset by a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market.

For the three months ended March 31, 2022, compared to the same period in 2021, the 6.7% decrease in rest of world Fumarate revenue was primarily due to TECFIDERA pricing reductions in certain European countries.

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.

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.

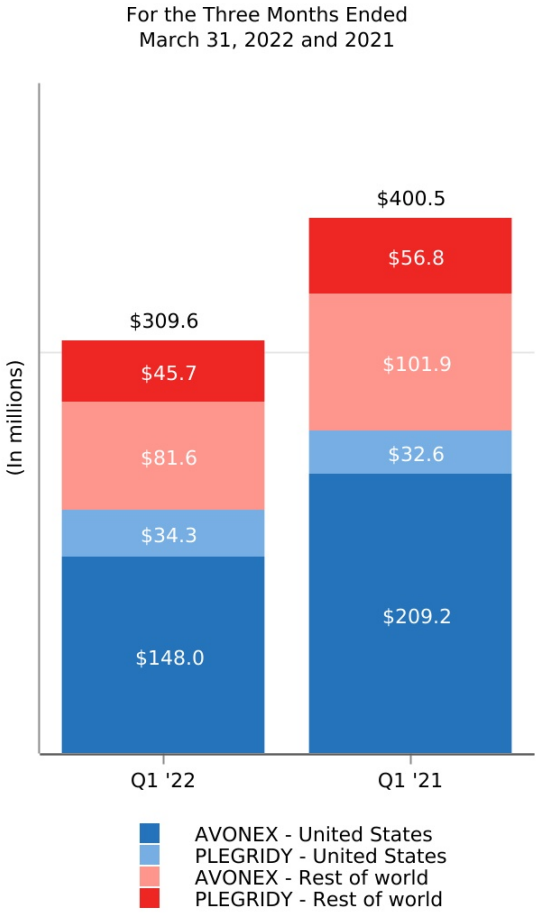
In November 2021 the CHMP of the EMA issued an ad hoc opinion referencing the General Court's decision which concluded that "the totality of the available data cannot establish that [monoethyl fumarate] exerts a clinically relevant therapeutic contribution within FUMADERM." The EC will decide TECFIDERA's entitlement to regulatory data and market protection. If data and market protection is not upheld, we could face generic competition in the E.U. as early as the first half of 2022, which would have an adverse impact on our TECFIDERA sales in the E.U. and our results of operations.

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

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

We expect an increase in VUMERITY sales volumes in 2022, compared to 2021, mostly due to demand growth, including the continued launch of VUMERITY in the E.U.

Interferon

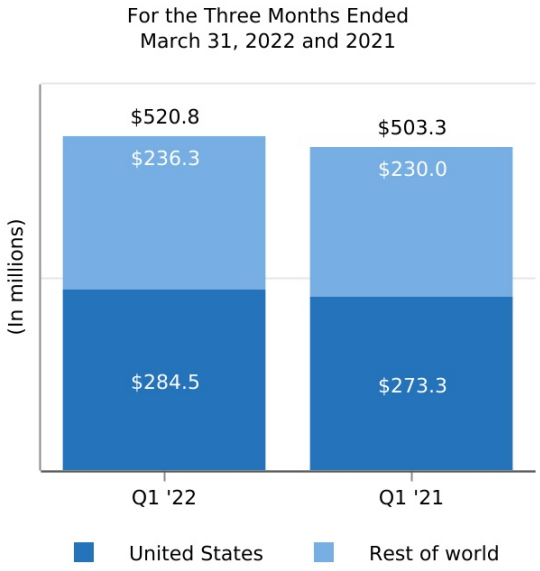


For the three months ended March 31, 2022, compared to the same period in 2021, the 24.6% decrease in U.S. Interferon revenue was primarily due to a decrease in Interferon sales volumes of 14.6% and a decrease in pricing of 10.0%. The net decline in sales volumes reflects the continued decline of the Interferon market as patients transition to other higher efficacy and oral MS therapies.

For the three months ended March 31, 2022, compared to the same period in 2021, the 19.8% decrease in rest of world Interferon revenue was primarily due to a decrease in Interferon sales volumes resulting from the continued decline of the Interferon market.

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



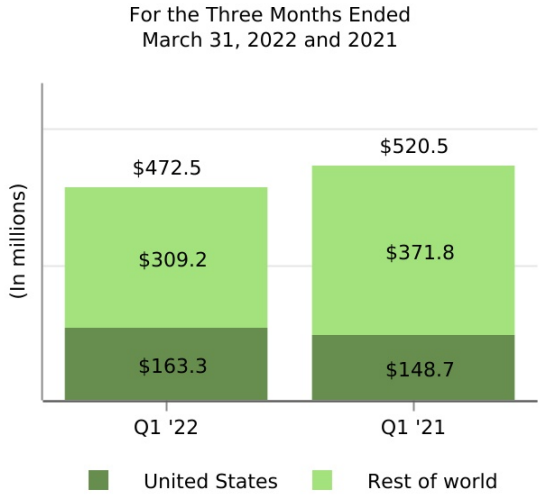
For the three months ended March 31, 2022, compared to the same period in 2021, the 4.1% increase in U.S. TYSABRI revenue was primarily due to price increases, partially offset by a decrease in sales volumes.

For the three months ended March 31, 2022, compared to the same period in 2021, the 2.7% increase in rest of world TYSABRI revenue was primarily due to favorable volume impacts, partially offset by a decrease in pricing.

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.

Spinal Muscular Atrophy

SPINRAZA



For the three months ended March 31, 2022, compared to the same period in 2021, the 9.8% increase in U.S. SPINRAZA revenue was primarily due to an increase in sales volumes resulting from favorable channel dynamics.

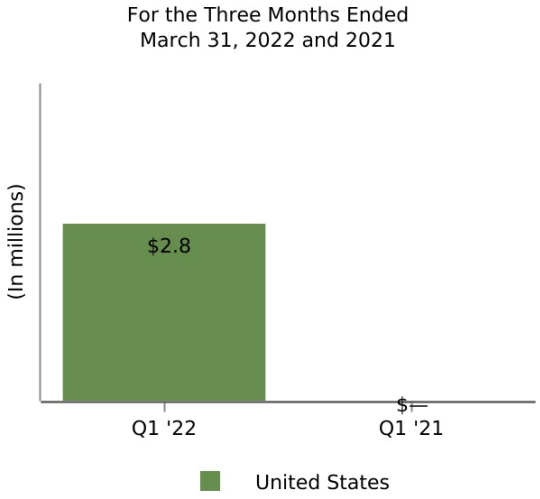
For the three months ended March 31, 2022, compared to the same period in 2021, the 16.8% decrease in rest of world SPINRAZA revenue was primarily due to a decrease in sales volumes of 10.0% resulting from increased competition in certain established markets, particularly Germany, and the timing of shipments, as well as the unfavorable impact of foreign currency exchange. The decrease was 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.

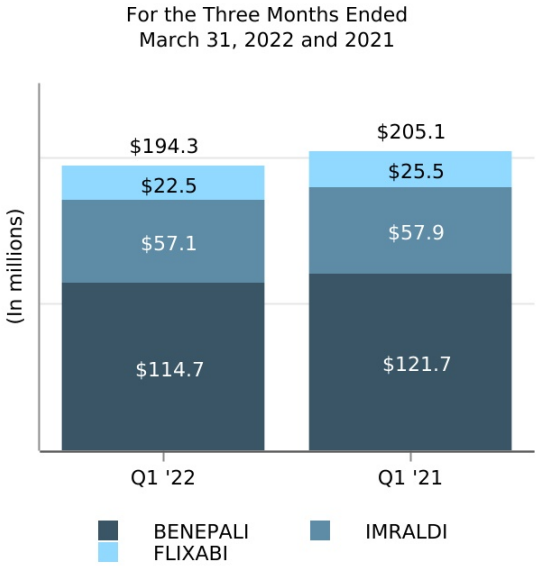
In April 2022 the CMS released the final NCD for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. We expect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

Additionally, as a result of the final NCD we will substantially eliminate 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 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

Biosimilars

BENEPALI, IMRALDI and FLIXABI



For the three months ended March 31, 2022, compared to the same period in 2021, the 5.3% decrease in biosimilar revenue was primarily due to a decrease in pricing in certain markets and unfavorable foreign currency impact, partially offset by an increase in sales volumes.

During the third quarter of 2021 BYOOVIZ, a biosimilar referencing LUCENTIS, was approved in the U.S., the E.U. and the U.K.

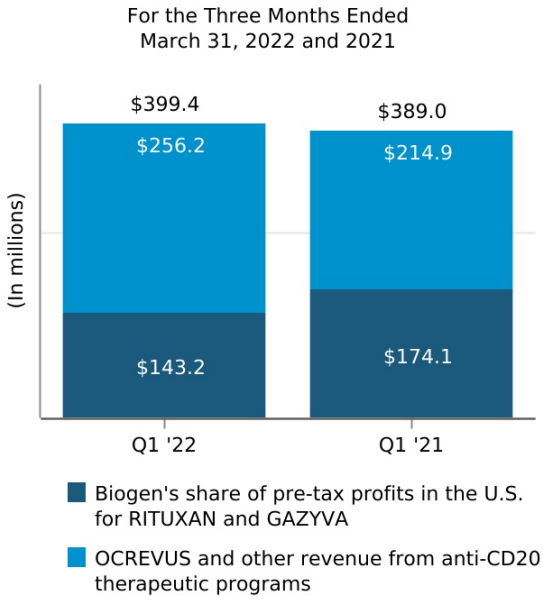
We anticipate a slight decline in revenue from our biosimilars business in 2022, compared to 2021, despite the launch of BYOOVIZ in the U.S. and an anticipated modest increase in sales volumes in 2022, as we continue to face price reductions in certain markets.

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

Revenue from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

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



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

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

	For the Three Months Ended March 31,	
(In millions)	**2022**	**2021**
Product revenue, net	$ 455.0	$ 551.4
Cost and expense	59.8	74.2
Pre-tax profits in the U.S.	395.2	477.2
Biogen's share of pre-tax profits	$ 143.2	$ 174.1

For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in U.S. product revenue, net was primarily due to a decrease in sales volumes of RITUXAN in the U.S. of 30.4%, primarily due to the onset of competition from multiple biosimilar products and a decrease in GAZYVA sales volumes of 3.6%.

For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in collaboration costs and expense was 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. In November 2019, January 2020 and January 2021 biosimilar products referencing RITUXAN were launched in the U.S. and are being offered at lower prices. This competition has had a significant adverse impact on the pre-tax profits of our collaboration arrangements with Genentech, as the sales of RITUXAN have decreased substantially compared to prior periods. We expect that biosimilar competition will continue to increase as these products capture additional market share and that this will have a significant adverse impact on our co-promotion profits in the U.S. in future years.

Other Revenue from Anti-CD20 Therapeutic Programs

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

For the three months ended March 31, 2022, compared to the same period in 2021, the increase in other revenue from anti-CD20 therapeutic programs was primarily due to sales growth of OCREVUS. Royalty revenue recognized on sales of OCREVUS for the three months ended March 31, 2022, totaled $252.3 million compared to $209.3 million in the prior year comparative period.

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:

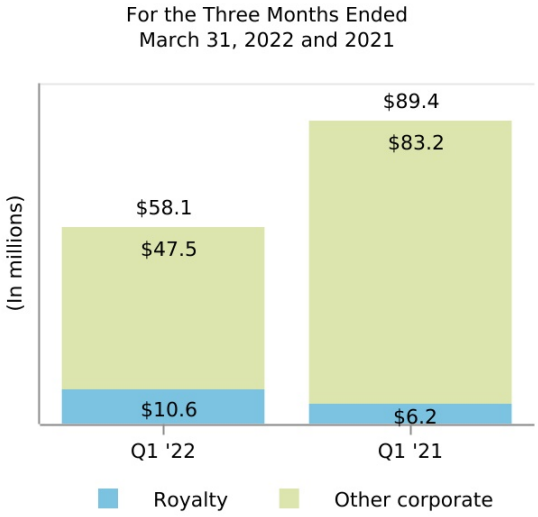
	For the Three Months Ended March 31,					
(In millions, except percentages)	**2022**		**2021**		**% Change**	**$ Change**
Revenue from collaborative and other relationships	$ 8.0	12.1 %	$ 3.9	4.2 %	105.1 %	$ 4.1
Other royalty and corporate revenue	58.1	87.9	89.4	95.8	(35.0)	(31.3)
Total other revenue	$ 66.1	100.0 %	$ 93.3	100.0 %	(29.2)%	$ (27.2)

Revenue from Collaborative and Other Relationships

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

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

Other Royalty and Corporate Revenue



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

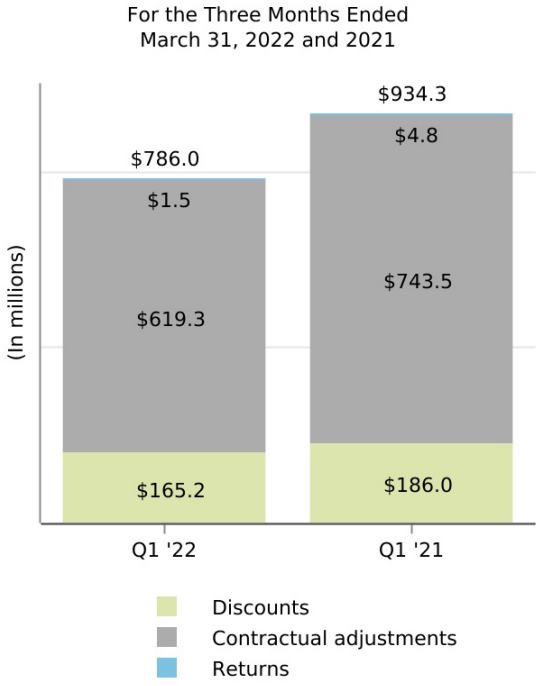
For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in other royalty and corporate revenue was primarily due to lower contract manufacturing revenue related to timing of batch releases.

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 months ended March 31, 2022, reserves for discounts and allowances as a percentage of gross product revenue was 27.0% compared to 29.0% in the prior year comparative period.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in discounts was primarily driven by a decrease in gross sales.

Contractual Adjustments

Contractual adjustments primarily relate to Medicaid and managed care rebates 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 months ended March 31, 2022, compared to the same period in 2021, the decrease in contractual adjustments was primarily driven by lower TECFIDERA sales in the U.S., resulting in lower pharmacy rebates, co-pay assistance 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 months ended March 31, 2022, compared to the same period in 2021, return reserves were relatively consistent.

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

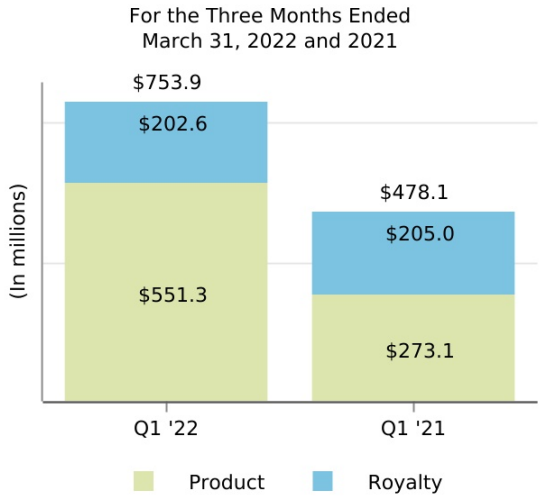
Cost and Expense

A summary of total cost and expense is as follows:

(In millions, except percentages)	For the Three Months Ended March 31, 2022	2021	% Change	$ Change
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 753.9	$ 478.1	57.7 %	$ 275.8
Research and development	551.7	514.2	7.3	37.5
Selling, general and administrative	634.9	595.0	6.7	39.9
Amortization and impairment of acquired intangible assets	66.9	98.1	(31.8)	(31.2)
Collaboration profit (loss) sharing	(117.3)	68.5	(271.2)	(185.8)
(Gain) loss on fair value remeasurement of contingent consideration	(7.1)	(33.8)	(79.0)	26.7
Restructuring charges	38.1	—	nm	38.1
Total cost and expense	$ 1,921.1	$ 1,720.1	11.7 %	$ 201.0

[nm] Not meaningful

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



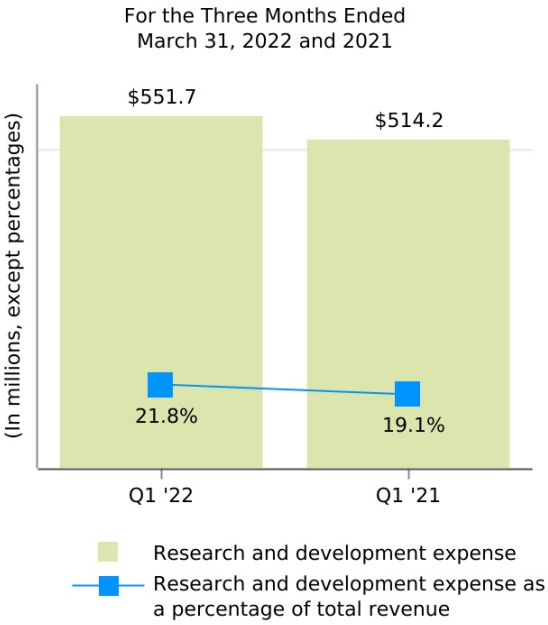
During the first quarter of 2022 we recorded approximately $275.0 million of gross charges associated with inventory and purchase commitments in excess of forecasted demand related to ADUHELM, as well as approximately $45.0 million of gross idle capacity charges, which were recognized in cost of sales within our condensed consolidated statements of income. 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 three months ended March 31, 2022, compared to the same period in 2021, royalty cost of sales remained flat.

Product Cost of Sales

For the three months ended March 31, 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 and idle capacity charges.

Research and Development



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

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

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

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

For the three months ended March 31, 2022, compared to the same period in 2021, the increase in research and development expense was primarily due to milestone payments, 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 Therapeutics, Inc. (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 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 months ended March 31, 2022, compared to the same period in 2021, the decrease in spending related to our early stage programs was primarily due to a decrease 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 an increase 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; and
- an increase in spending in the development of BIIB135 for the potential treatment of MS.

Late Stage Programs

For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in spending associated with our late stage programs was primarily due to:

- 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.

These decreases were 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, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas.

Marketed Programs

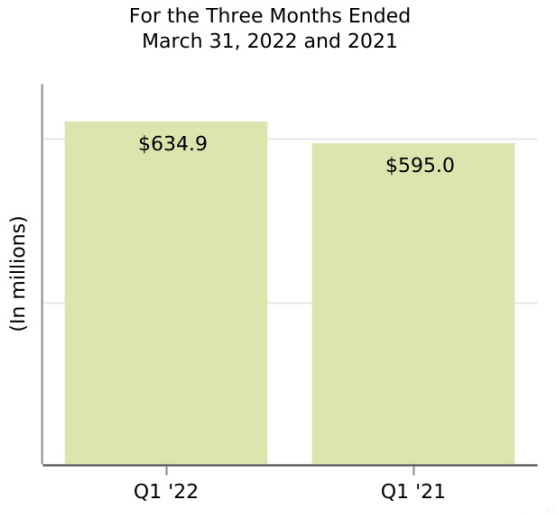
For the three months ended March 31, 2022, compared to the same period in 2021, the increase in spending associated with our marketed programs was primarily due to an increase in costs associated with:

- 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.

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

Selling, General and Administrative

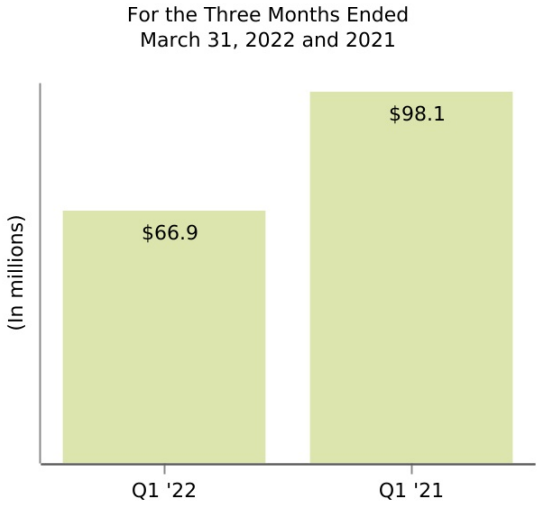


For the three months ended March 31, 2022, compared to the same period in 2021, the 6.7% increase in selling, general and administrative expense was primarily due to gross ADUHELM commercialization expense of approximately $80.0 million, partially offset by cost-reduction measures realized during the first quarter of 2022.

As a result of the final NCD we will substantially eliminate 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.

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 months ended March 31, 2022, compared to the same period in March 31, 2021, the decrease in amortization and impairment of acquired intangible assets was primarily related to a $44.3 million impairment charge recorded during the first quarter of 2021 related to vixotrigine (BIIB074) for the potential treatment of trigeminal neuralgia (TGN). For the three months ended March 31, 2022, we had no impairment charges.

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

IPR&D Related to Business Combinations

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

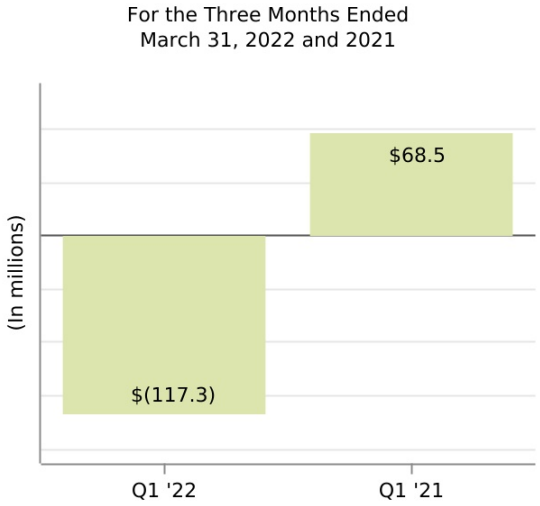
In the periods since we acquired vixotrigine, there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN and for the potential treatment of diabetic painful neuropathy (DPN), another form of neuropathic pain. We have engaged with the FDA regarding the design 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 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 March 31, 2022, the carrying value associated with the remaining IPR&D asset for DPN was $129.1 million and the fair value of this asset was not significantly in excess of its carrying value. Upon the completion of the additional clinical trial we will reevaluate the carrying value of the program.

For additional information on the amortization and impairment of our acquired intangible assets, please read *Note 5, Intangible Assets and Goodwill,* to our condensed consolidated financial statements included in this report.

Collaboration Profit (Loss) Sharing



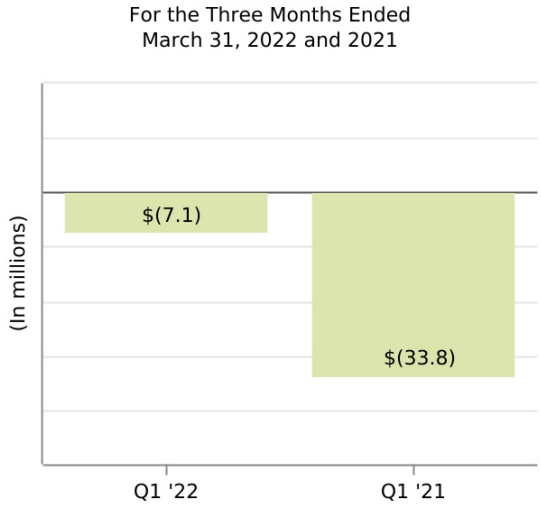
Collaboration profit (loss) sharing primarily includes Samsung Bioepis' 50.0% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis and, beginning in the second quarter of 2021, Eisai's 45.0% share of income and expense in the U.S. related to the ADUHELM Collaboration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

For the three months ended March 31, 2022, we recognized net profit-sharing expense of $64.4 million to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits compared to a net profit-sharing expense of $68.5 million in the prior year comparative period.

For the three months ended March 31, 2022, we recognized a net reduction to our operating expense of $181.7 million to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

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

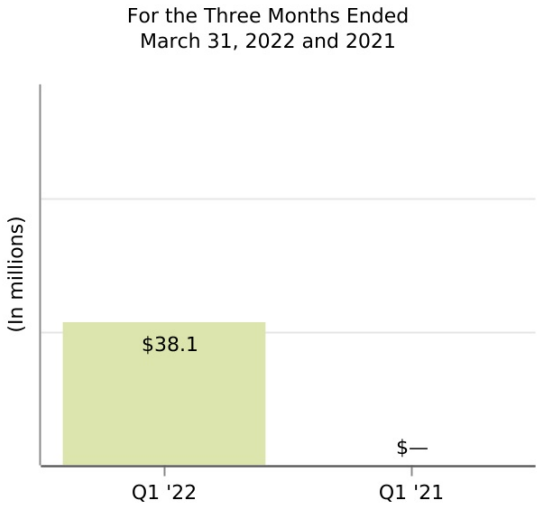
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration



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

For the three months ended March 31, 2022, changes in the fair value of our contingent consideration obligations were primarily due to an increase in 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 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 $100.0 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 months ended March 31, 2022, we recognized $27.7 million of employee related costs, primarily related to severance. 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.

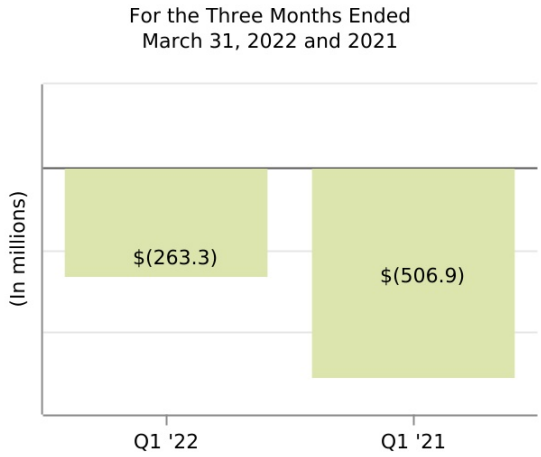
Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, North Carolina. We are marketing the space for sublease. Our decision to cease using the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility, which we do not believe can be adequately recovered in a sublease. As a result, for the three months ended March 31, 2022, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in

restructuring charges in our condensed consolidated statements of income.

The following table summarizes the charges and spending related to our 2022 cost saving initiatives for the three months ended March 31, 2022:

(In millions)	Workforce Reduction	Total
Restructuring reserve as of December 31, 2021	$ —	$ —
Expense	27.7	27.7
Payment	(6.2)	(6.2)
Restructuring reserve as of March 31, 2022	$ 21.5	$ 21.5

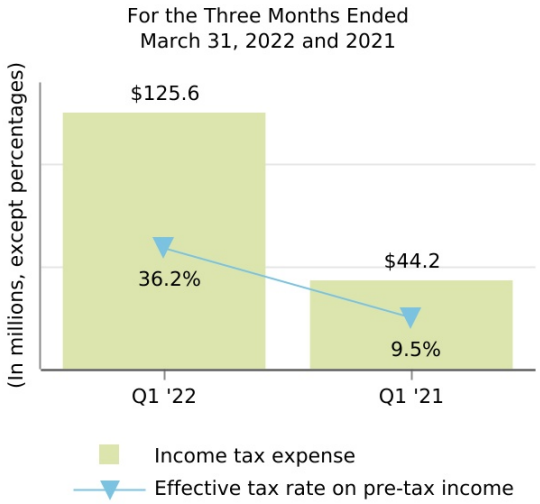
Other Income (Expense), Net



For the three months ended March 31, 2022, compared to the same period in 2021, the change in other income (expense), net primarily reflects net unrealized losses on our holdings in equity securities.

For the three months ended March 31, 2022, net unrealized losses and realized gains on our holdings in equity securities were approximately $190.9 million and $0.2 million, respectively, compared to net unrealized losses and realized gains of approximately $442.3 million and $6.2 million, respectively, in the prior year comparative period. The net unrealized losses recognized during the three months ended March 31, 2022, primarily reflect decreases in the aggregate fair value of our investments in Denali, Sage and Sangamo Therapeutics, Inc. (Sangamo) common stock of approximately $205.5 million.

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.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune SubOne AG's (Neurimmune) 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.

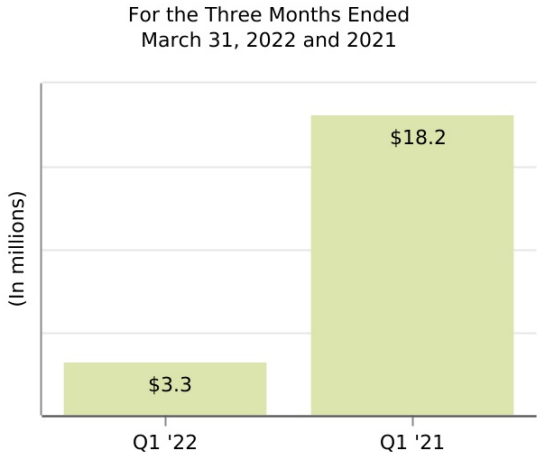
For the three months ended March 31, 2022, compared to the same period in 2021, the increase in our effective tax rate was primarily due to a deferred tax expense related to a valuation allowance, as discussed above, and the non-cash tax effects of changes in the value of our equity investments. The tax effects of this change in value of our equity

investments were recorded discretely, since changes in value of equity investments cannot be forecasted.

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

For additional information on our income taxes please read *Note 14, Income Taxes,* to our condensed consolidated financial statements included in this report.

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



In February 2012 we entered into a joint venture agreement with Samsung BioLogics establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products. As of March 31, 2022, our ownership percentage was approximately 49.9%.

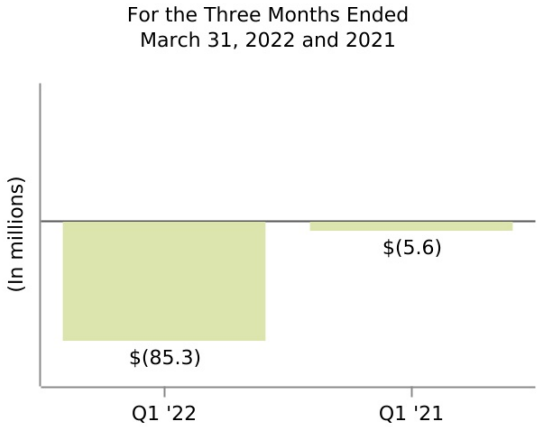
We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in (income) loss of investee, net of tax in our condensed consolidated statements of income. We recognize amortization on certain basis differences resulting from our November 2018 investment.

For the three months ended March 31, 2022, we recognized net losses on our investment of $3.3 million, reflecting our share of Samsung Bioepis' operating profits, net of tax totaling $4.0 million offset by amortization of basis differences totaling $7.3 million.

For the three months ended March 31, 2021, we recognized net losses on our investment of $18.2 million, reflecting our share of Samsung Bioepis' operating losses, net of tax totaling $11.0 million and amortization of basis differences totaling $7.2 million.

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

Noncontrolling Interests, 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 months ended March 31, 2022, compared to the same period in 2021, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily due to a valuation allowance related to a prior year deferred tax benefit associated with the accelerated approval of ADUHELM by the FDA in the U.S.

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

FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

Our financial condition is summarized as follows:

(In millions, except percentages)	As of March 31, 2022	As of December 31, 2021	Change %
Financial assets:			
Cash and cash equivalents	$ 1,749.3	$ 2,261.4	(22.6)%
Marketable securities — current	2,002.4	1,541.1	29.9
Marketable securities — non-current	1,001.6	892.0	12.3
Total cash, cash equivalents and marketable securities	$ 4,753.3	$ 4,694.5	1.3 %
Borrowings:			
Current portion of notes payable	$ 999.5	$ 999.1	— %
Notes payable	6,275.7	6,274.0	—
Total borrowings	$ 7,275.2	$ 7,273.1	— %
Working capital:			
Current assets	$ 7,915.9	$ 7,856.5	0.8 %
Current liabilities	(3,946.6)	(4,298.2)	(8.2)
Total working capital	$ 3,969.3	$ 3,558.3	11.6 %

For the three months ended March 31, 2022, certain significant cash flows were as follows:

- $161.8 million in net cash flow provided by operating activities; and
- $57.9 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. 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. Additionally, in 2022 we will repay or refinance $1.0 billion related to our 3.625% Senior Notes due September 15, 2022.

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.

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

For additional information on certain risks that could negatively impact our financial position or future results of operations, please read *Item 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 March 31, 2022, we had cash, cash equivalents and marketable securities totaling approximately $4.8 billion compared to approximately $4.7 billion as of December 31, 2021. The change in cash, cash equivalents and marketable securities at March 31, 2022, from December 31, 2021, was primarily due to net cash flow provided by operating activities, partially offset by cash used for capital expenditures.

Investments and other assets in our condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021, include the carrying value of our investment in Samsung Bioepis of $586.4 million

and $599.9 million, respectively. In January 2022 we entered into an agreement to sell to Samsung BioLogics our equity in Samsung Bioepis, which was completed on April 20, 2022. Under the terms of the transaction, we received approximately $1.0 billion in cash at closing and will receive approximately $1.3 billion to be deferred over two payments of $812.5 million due at the first anniversary and $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.

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

(In millions)	March 31, 2022	December 31, 2021
Sangamo	$ 138.6	$ 173.7
Denali	428.2	550.7
Sage	184.0	231.9
Ionis	106.5	87.5
	$ 857.3	$ 1,043.8

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

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

Borrowings

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

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

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

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

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

- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022;
- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025; and
- $1.12 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045.

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

For a summary of the fair and carrying values of our outstanding borrowings as of March 31, 2022 and December 31, 2021, please read *Note 6, Fair Value Measurements,* to our condensed consolidated financial statements included in this report.

Credit Facility

In January 2020 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. As of March 31, 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 $4.0 billion and $3.6 billion as of March 31, 2022 and December 31, 2021, respectively. The change in working capital reflects an increase in total current assets of approximately $59.4 million and a decrease in total current liabilities of approximately $351.6 million.

The increase in total current assets was primarily driven by an increase in our product accounts receivable and other receivable balances, partially offset by the write-off of inventory related to ADUHELM.

The decrease in current liabilities was primarily due to a reduction in accounts payable and accrued expense and other, which was primarily related to a decrease in the accrual for employee compensation, as well as approximately $66.0 million of upfront and milestone payments made in 2022, which were

accrued as of December 31, 2021, partially offset by an increase in income taxes payable.

Share Repurchase Programs

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 2.2 million shares of our common stock at a cost of approximately $600.0 million during the three months ended March 31, 2021. There were no share repurchases of our common stock during the three months ended March 31, 2022. Approximately $2.8 billion remained available under our 2020 Share Repurchase Program as of March 31, 2022.

Cash Flow

The following table summarizes our cash flow activity:

	For the Three Months Ended March 31,		
(In millions, except percentages)	**2022**	**2021**	**% Change**
Net cash flow provided by (used in) operating activities	$ 161.8	$ 769.0	(79.0)%
Net cash flow provided by (used in) investing activities	(648.0)	(64.7)	901.5
Net cash flow provided by (used in) financing activities	(16.5)	(785.0)	(97.9)

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 three months ended March 31, 2022, compared to the same period in 2021, the decrease in net cash flow provided by operating activities was primarily due to lower net income as well as timing of payments, which includes approximately $69.0 million of upfront and milestone payments made in 2022.

Investing Activities

For the three months ended March 31, 2022, compared to the same period in 2021, the increase in net cash flow used in investing activities was primarily due to an increase in net purchases of marketable securities in the current period.

Financing Activities

For the three months ended March 31, 2022, compared to the same period in 2021, the decrease in net cash flow used in financing activities was primarily due to no share repurchase activity in 2022 compared to approximately $600.0 million of shares repurchased in the prior year comparative period. Additionally, we executed our Exchange Offer in the first quarter of 2021, which resulted in net cash outflows of $169.3 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 recorded as cost of sales in our condensed consolidated statements of income.

In October 2019 we entered into a new supply agreement and amended our license and collaboration agreement with Alkermes. We have elected to initiate a technology transfer and, following a transition period, to manufacture VUMERITY or have VUMERITY manufactured by a third party we have engaged in exchange for paying an increased royalty rate to Alkermes on any portion of future worldwide net 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 March 31, 2022, we could trigger potential future milestone payments to third parties of up to approximately $9.2 billion, including approximately $1.9 billion in development milestones, approximately $900.0 million in regulatory milestones and approximately $6.4 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of March 31, 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 $49.8 million in milestones in 2022 under our current agreements. Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay additional milestones to Neurimmune, including $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the ADUHELM Collaboration Agreement.

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

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

Other Funding Commitments

As of March 31, 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 $26.9 million in our condensed consolidated balance sheet for expenditures incurred by CROs as of March 31, 2022. We have approximately $881.4 million in cancellable future commitments based on existing CRO contracts as of March 31, 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 March 31, 2022, we have approximately $105.6 million of liabilities associated with uncertain tax positions.

As of March 31, 2022 and December 31, 2021, we have accrued income tax liabilities of approximately $633.0 million under a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). Of the amounts accrued as of March 31, 2022, approximately $72.7 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

Other Off-Balance Sheet Arrangements

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

New Accounting Standards

For a discussion of new accounting standards please read *Note 1, Summary of Significant Accounting Policies,* to our condensed consolidated financial statements included in this report.

Critical Accounting Estimates

The preparation of our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenue and expense and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and assumptions. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenue and expense. Actual results may differ from these estimates.

For a discussion of our critical accounting estimates, please read *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* in our 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 Russia's invasion of 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 March 31, 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 to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 18 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read *Note 8, Derivative Instruments,* to our condensed consolidated financial statements included in this report.

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

Balance Sheet Risk Management Hedging Program

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

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of March 31, 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 $298.5 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 is designed to mitigate currency fluctuations between the U.S. dollar and the South Korean won as a result of our approximately 49.9% ownership interest in Samsung Bioepis. We entered into foreign currency forward contracts to hedge changes in the spot rate over the next seven months. As of March 31, 2022 and December 31, 2021, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $58.0 million and $58.7 million, respectively. The estimated fair value was determined by measuring the impact of the hypothetical spot rate movement on outstanding forward contracts. In conjunction with the closing of our sale of equity in Samsung Bioepis to Samsung BioLogics, which occurred in April 2022, we concurrently closed our foreign currency forward contracts.

Interest Rate Risk

Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of March 31, 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 $19.8 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 Russia's invasion of 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 March 31, 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 March 31, 2022 and December 31, 2021, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $86.0 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 March 31, 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 March 31, 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 March 31, 2022, please read *Note 18, Litigation,* to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We are substantially dependent on revenue from our products.

Our revenue depends upon continued sales of our products as well as the financial rights we have in our anti-CD20 therapeutic programs. A significant portion of our revenue is concentrated on sales of our products in increasingly competitive markets and in markets affected directly and indirectly by the COVID-19 pandemic. Any of the following negative developments relating to any of our products or any of our anti-CD20 therapeutic programs may adversely affect our revenue and results of operations or could cause a decline in our stock price:

- the introduction, 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:

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

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

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

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

Product development is very expensive and involves a high degree of uncertainty and risk and may not be successful. Only a small number of research and development programs result in the commercialization of a product. It is difficult to predict the success and the time and cost of product development of novel approaches for the treatment of diseases. The development of novel approaches for the treatment of diseases, including development efforts in new modalities such as those based on the antisense oligonucleotide platform and gene therapy, may present additional challenges and risks, including obtaining approval from regulatory authorities that have limited experience with the development of such therapies.

Clinical trial data are subject to differing interpretations and even if we view data as sufficient to support the safety, effectiveness and/or approval of an investigational therapy, regulatory authorities may disagree and may require additional data, limit the scope of the approval or deny approval altogether. Furthermore, the approval of a product candidate by one regulatory agency does not mean that other regulatory agencies will also approve such product candidate.

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

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

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

If we fail to compete effectively, our business and market position would suffer.

The biopharmaceutical industry and the markets in which we operate are intensely competitive. We compete in the marketing and sale of our products, the development of new products and processes, the acquisition of rights to new products with commercial potential and the hiring and retention of personnel. We compete with biotechnology and pharmaceutical companies that have a greater number of products on the market and in the product pipeline, substantially greater financial, marketing, research and development and other resources and other technological or competitive advantages.

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

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

- the introduction of other products, including products that may be more efficacious, safer, less expensive or more convenient alternatives to our products, including our own products and products of our collaborators;
- the off-label use by physicians of therapies indicated for other conditions to treat patients;
- patient dynamics, including the size of the patient population and our ability to identify, attract and maintain new and current patients to our therapies;
- the reluctance of physicians to prescribe, and patients to use, our products without additional data on the efficacy and safety of such products;

- damage to physician and patient confidence in any of our products, generic or biosimilars of our products or any other product from the same class as one of our products, or to our sales and reputation as a result of label changes, pricing and reimbursement decisions or adverse experiences or events that may occur with patients treated with our products or generic or biosimilars of our products;
- inability to obtain appropriate pricing and reimbursement for our products compared to our competitors in key international markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our products.

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

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

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

Supporting the further development of our existing products and potential new products in our pipeline will require significant capital expenditures and management resources, including investments in research and development, sales and marketing, manufacturing capabilities and other areas of our business. We have made, and may continue to make, significant operating and capital expenditures for potential new products prior to regulatory approval with no assurance that such investment will be recouped, which may adversely affect our financial condition, business and operations.

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

We may fail to initiate or complete transactions for many reasons, including failure to obtain regulatory or other approvals as well as disputes or litigation. Furthermore, we may not be able to achieve the full strategic and financial benefits expected to result from transactions, or the benefits may be delayed or not occur at all. We may also face additional costs or liabilities in completed transactions that were not contemplated prior to completion.

Any failure in the execution of a transaction, in the integration of an acquired asset or business or in achieving expected synergies could result in slower growth, higher than expected costs, the recording of asset impairment charges and other actions which could adversely affect our business, financial condition and results of operations.

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

Sales of our products depend, to a significant extent, on adequate coverage, pricing and reimbursement from third-party payors. When a new pharmaceutical product is approved, the availability of government and private reimbursement for that product may be uncertain, as is the pricing and amount for which that product will be reimbursed.

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

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs;
- consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value;
- 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, 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 United Kingdom (U.K.), including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- changes in tax laws; and
- the imposition of tariffs or embargoes and other trade restrictions.

In addition, our international operations are subject to regulation under U.S. law. For example, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures or withdrawal of an approved product from the market, disruption in the supply or availability of our products or suspension of export or import privileges, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results. In addition, while we believe that we have appropriate compliance controls, policies and procedures in place to comply with the FCPA, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers might violate the FCPA and we might be held responsible. If our employees, agents, distributors, collaborators or third-party providers are found to have engaged in such practices,

we could suffer severe penalties and may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

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

In order to support our future growth and drug development pipeline, we are expanding our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland with no assurance that the additional capacity will be required or this investment will be recouped.

If we are unable to fully utilize our manufacturing facilities, our business may be harmed. Charges resulting from excess capacity 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 aducanumab, there can be no assurance that the regulatory authorities will approve the Solothurn facility for the manufacturing of other products or product candidates. If we do not receive the necessary regulatory approvals of the Solothurn facility or if our future growth and drug development plans increase, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.

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

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

- *Risks of Reliance on Third-Parties and Single Source Providers.* We rely on third-party suppliers and manufacturers for many aspects of our manufacturing process for our products and product candidates. In some cases, due to the unique manner in which our products are manufactured, we rely on single source providers of raw materials and manufacturing supplies. These third-parties are independent entities subject to their own unique operational and financial risks that are outside of our control. 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 first 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)
January 2022	—	$ —	—	$ 2,800.0
February 2022	—	$ —	—	$ 2,800.0
March 2022	—	$ —	—	$ 2,800.0
Total[1]	—	$ —		

[1] There were no share repurchases during the first quarter of 2022.

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 2.2 million shares of our common stock at a cost of approximately $600.0 million during the three months ended March 31, 2021. There were no share repurchases of our common stock during the three months ended March 31, 2022. Approximately $2.8 billion remained available under our 2020 Share Repurchase Program as of March 31, 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
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.
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.
10.2*+	Biogen Inc. 2006 Non-Employee Directors Equity Plan, as amended.
101++	The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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 March 31, 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)

May 3, 2022

BIOGEN INC.

2006 NON-EMPLOYEE DIRECTORS EQUITY PLAN

(Approved by stockholders on May 25, 2006; as amended through March 27, 2015 and approved by stockholders on June 10, 2015; and as amended on April 6, 2022)

1. **Purpose; Establishment**.

The Biogen Inc. 2006 Non-Employee Directors Equity Plan is intended to encourage ownership of shares of Common Stock by Non-Employee Directors of the Company and its Affiliates, and to provide an additional incentive to those directors to promote the success of the Company and its Affiliates. The Plan has been adopted and approved by the Board of Directors, and became effective on the Effective Date.

2. **Definitions.**

As used in the Plan, the following definitions apply to the terms indicated below:

(a) "Affiliate" shall have the meaning set forth in Rule 12b-2 under Section 12 of the Exchange Act.

(b) "Agreement" shall mean either the written or electronic agreement between the Company and a Participant or a written or electronic notice from the Company to a Participant evidencing an Award.

(c) "Award" shall mean any Option, Restricted Stock, Restricted Stock Unit, Dividend Equivalent Rights, Stock Appreciation Right or Other Award granted pursuant to the terms of the Plan.

(d) "Beneficial Owner" shall have the meaning set forth in Section 13(d) of the Exchange Act.

(e) "Board of Directors" or "Board" shall mean the Board of Directors of the Company.

(f) "Certificate" shall mean either a physical paper stock certificate or electronic book entry or other electronic form of account entry evidencing the ownership of shares of Restricted Stock or shares of Common Stock acquired upon exercise, vesting or settlement, as the case may be, of Awards other than Restricted Stock.

(g) "Code" shall mean the Internal Revenue Code of 1986, as amended from time to time, and any regulations promulgated thereunder.

(h) "Committee" shall mean the committee appointed to administer the Plan pursuant to Section 3.

(i) "Company" shall mean Biogen Inc., a Delaware corporation.

(j) "Common Stock" shall mean the common stock of the Company, par value $0.0005 per share.

(k) "Continuing Director" shall mean, as of any date of determination, any member of the Board who (a) was a member of the Board on the Effective Date or (b) becomes a member of the Board subsequent to the Effective Date and was appointed, nominated for election or elected to the Board with the approval of a majority of the Continuing Directors who were members of the Board at the time of such appointment, nomination or election, provided that a director whose

initial assumption of office is in connection with an actual or threatened election contest will not be considered a Continuing Director unless and until (i) such director has served on the Board for at least two years and (ii) the most recent reelection of such director has been approved by a majority of the Continuing Directors in office at the time of such approval.

(l) A "Corporate Change in Control" shall be deemed to have occurred upon the first of the following events:

(i) an event in which any Person, is or becomes the Beneficial Owner, together with all Affiliates and associates (as such terms are used in Rule 12b-2 of the General Rules and Regulations under the Exchange Act) of such Person, directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities;

(ii) the consummation of the merger or consolidation of the Company with any other company, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the Company or such surviving entity outstanding immediately after such merger; or

(iii) at any time the Continuing Directors do not constitute a majority of the Board (or, if applicable, the board of directors of a successor to the Company).

Notwithstanding the foregoing, in any case where the occurrence of a Corporate Change in Control could affect the vesting of or payment under an Award subject to the requirements of Section 409A of the Code, to the extent required to comply with Section 409A of the Code, the term "Corporate Change in Control" shall mean an occurrence that both (i) satisfies the requirements set forth above in this definition and (ii) is a "change in control event" as that term is defined in the regulations under Section 409A of the Code.

(m) A "Corporate Transaction" shall be deemed to have occurred upon the first of the following events: (i) a consolidation, merger or similar transaction or series of related transactions, including a sale or other disposition of stock, in which the Company (or an Affiliate) is not the surviving corporation or which results in the acquisition of all or substantially all of the then outstanding Common Stock by a single person or entity or by a group of persons and/or entities acting in concert; (ii) a sale or transfer of all or substantially all of the Company's assets; or (iii) a dissolution or liquidation of the Company. Where a Corporate Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) as determined by the Committee, the Corporate Transaction shall be deemed to have occurred upon consummation of the tender offer.

Notwithstanding the foregoing, in any case where the occurrence of a Corporate Transaction could affect the vesting of or payment under an Award subject to the requirements of Section 409A of the Code, to the extent required to comply with Section 409A of the Code, the term "Corporate Transaction" shall mean an occurrence that both (i) satisfies the requirements set forth above in this definition and (ii) is a "change in control event" as that term is defined in the regulations under Section 409A of the Code.

(n) A “Disability” shall exist for purposes of the Plan if a Participant is entitled to receive benefits under the applicable long-term disability program of the Company or an Affiliate of the Company, or, if no such program is in effect with respect to such Participant, if the Participant has become totally and permanently disabled within the meaning of Section 22(e)(3) of the Code.

(o) “Dividend Equivalent Rights” shall mean a right, granted in connection with an Award, to receive dividends (which may or may not be made subject to restrictions or forfeiture conditions, as determined by the Committee) upon the payment of a dividend with respect to the Common Stock underlying the Award, which dividends will be held in escrow until all restrictions or conditions to the vesting of the Common Stock underlying the Award have lapsed. Any escrowed dividends may, in the Committee’s discretion, be reinvested or deemed reinvested in Common Stock as of the dividend payment date.

(p) “Effective Date” shall mean May 25, 2006, the date that the Company's stockholders approved the Plan.

(q) “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended from time to time.

(r) “Fair Market Value” of the Common Stock shall be calculated as follows: (i) if the Common Stock is listed on a national securities exchange and sale prices are regularly reported for the Common Stock, then the Fair Market Value shall be the closing selling price for the Common Stock reported on the applicable composite tape or other comparable reporting system on the applicable date, or if the applicable date is not a trading day, on the most recent trading day immediately prior to the applicable date; or (ii) if closing selling prices are not regularly reported for the Common Stock as described in clause (i) above, but bid and asked prices for the Common Stock are regularly reported, then the Fair Market Value shall be the arithmetic mean between the closing or last bid and asked prices for the Common Stock on the applicable date or, if the applicable date is not a trading day, on the most recent trading day immediately prior to the applicable date; or (iii) if prices are not regularly reported for the Common Stock as described in clauses (i) or (ii) above, then the Fair Market Value shall be such value as the Committee in good faith determines.

(s) “For Cause” shall mean any act of: (i) fraud or intentional misrepresentation, or (ii) embezzlement, misappropriation or conversion of assets or opportunities of the Company or any Affiliate. The determination of the Committee as to the existence of circumstances warranting a termination For Cause shall be conclusive.

(t) “Non-Employee Director” has the meaning set forth in Section 5.

(u) “Nonqualified Stock Option” shall mean an Option that is not an “incentive stock option” within the meaning of Section 422 of the Code, or any successor provision.

(v) “Option” shall mean an option to purchase shares of Common Stock granted pursuant to Section 7.

(w) “Other Award” shall mean an Award granted pursuant to Section 10.

(x) “Participant” shall mean a Non-Employee Director to whom an Award is granted pursuant to the Plan.

(y) “Person” shall have the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include: (i) the Company or any of its Affiliates, (ii) a trustee or other fiduciary holding securities under an

employee benefits plan of the Company or any of its Affiliates, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities or (iv) a corporation or other business entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company. (z) “Plan” shall mean the Biogen Inc. 2006 Non-Employee Directors Equity Plan (formerly the Biogen Idec Inc. 2006 Non-Employee Directors Equity Plan), as amended from time to time.

(aa) “Restricted Stock” shall mean a share of Common Stock which is granted pursuant to the terms of Section 8 and which may not be in any manner transferred or disposed of (such restrictions being known as the “Transfer Restrictions”) prior to the applicable Vesting Date.

(bb) “Restricted Stock Unit” means a unit granted pursuant to Section 8 that represents the right to receive the Fair Market Value of one share of Common Stock, which is payable in cash or Common Stock, as specified in the applicable Agreement, and which may or may not be subject to forfeiture restrictions.

(cc) “Retirement” as to any Participant shall mean such person's leaving the Board under the following circumstances: (i) as of the annual stockholders meeting that occurs in the year in which the Participant reaches age 75, or (ii) upon the completion of such person's current term provided he or she has provided the Board with at least six months prior written notice of retirement, but not including a Participant's termination For Cause, as determined by the Committee. Notwithstanding the foregoing, a Participant elected to the Board other than at an annual stockholders meeting shall not be eligible for Retirement pursuant to clause (ii) of this Section 2(cc) until the completion of a term for which such Participant is elected to serve by the stockholders at an annual stockholders meeting.

(dd) “Rule 16b-3” shall mean Rule 16b-3 promulgated under the Exchange Act, as amended from time to time.

(ee) “Stock Appreciation Right” shall mean the right to receive an amount equal to the excess of the Fair Market Value of a share of Common Stock (as determined on the date of exercise) over: (i) if the Stock Appreciation Right is not related to an Option, the Fair Market Value of a share of Common Stock on the date the Stock Appreciation Right was granted, or (ii) if the Stock Appreciation Right is related to an Option, the exercise price of the related Option, subject to such further terms and conditions as are provided under Section 9.

(ff) “Transaction” has the meaning set forth in Section 4(c).

(gg) “Vesting Date” shall mean the date established by the Committee on which an Award shall vest.

3. **Administration of the Plan.**

The Plan shall be administered by the Board of Directors, or by a committee of the Board which shall consist of two or more persons each of whom, unless otherwise determined by the Board, is (a) a “non-employee director” within the meaning of Rule 16b-3 and (b) an “independent director” as defined in Nasdaq Stock Market Rules. References in the Plan to the “Committee” shall mean the Board or any such committee. The Committee shall have the authority in its sole and absolute discretion, subject to and not inconsistent with the express provisions of the Plan, to administer the Plan and to exercise all the powers and authorities either specifically granted to it under the Plan or necessary or advisable in the administration of the Plan, including, without limitation: (1) the authority to grant Awards, (2) to determine the type and number of Awards to be granted, the number of shares of Common Stock to which an Award may relate and the terms, conditions and restrictions relating to any Award, (3) to determine whether, to what extent, and

under what circumstances an Award may be settled, cancelled, forfeited, exchanged, or surrendered, (4) to construe and interpret the Plan and any Award, (5) to prescribe, amend and rescind rules and regulations relating to the Plan, (6) to determine the terms and provisions of Agreements, and (7) to make all other determinations deemed necessary or advisable for the administration of the Plan.

The Committee may, in its sole and absolute discretion, without amendment to the Plan, waive or amend the operation of Plan provisions respecting exercise after termination of Board service and, except as otherwise provided herein, adjust any of the terms of any Award. The Committee may also (a) accelerate the date on which any Award granted under the Plan becomes exercisable or (b) accelerate the Vesting Date or waive or adjust any condition imposed hereunder with respect to the vesting or exercisability of an Award, provided that the Committee determines that such acceleration, waiver or other adjustment is necessary or desirable in light of extraordinary circumstances. Notwithstanding the foregoing, no Award outstanding under the Plan may be repriced, regranted through cancellation or otherwise amended to reduce the exercise price applicable thereto (other than with respect to adjustments made in connection with a Transaction or other change in the Company's capitalization) without the approval of the Company's stockholders. In addition, no Award shall provide a “reload” feature pursuant to which the Participant would receive an automatic grant of additional Awards to replace the shares of Common Stock surrendered to exercise an Award, and no Option shall be exercisable prior to the applicable Vesting Date for shares of Common Stock subject to repurchase by the Company, upon a termination of Board service prior to such Vesting Date, for the exercise price paid by the Participant.

4. **Stock Subject to the Plan.**

(a) *Shares Available for Awards.* Subject to the provisions of Sections 4(b), 4(c) and 4(d) hereof, the maximum number of shares of Common Stock reserved for issuance under the Plan shall be 1,600,000 shares. Such shares may be authorized but unissued Common Stock or authorized and issued Common Stock held in the Company's treasury. The grant of any Award other than an Option or a Stock Appreciation Right shall, for purposes of this Section 4(a), reduce the number of shares of Common Stock available for issuance under the Plan by one and one-half (1.5) shares of Common Stock for each such share actually subject to the Award. The grant of an Option or a Stock Appreciation Right shall be deemed, for purposes of this Section 4(a), as an Award of one share of Common Stock for each such share actually subject to the Award.

(b) *Adjustment for Change in Capitalization.* In the event that any dividend or other distribution is declared (whether in the form of cash, Common Stock, or other property), or there occurs any recapitalization, reclassification, stock split, reverse stock split, reorganization, merger, consolidation, spin-off, combination, repurchase, or share exchange, or other similar corporate transaction or event, then, unless otherwise determined by the Committee in its sole and absolute discretion with respect to dividends or distributions of cash or other non-stock property, (1) the number and kind of shares of stock which may thereafter be issued in connection with Awards, (2) the number and kind of shares of stock or other property issued or issuable in connection with outstanding Awards, (3) the exercise price, grant price or purchase price relating to any outstanding Awards, and (4) the limits on Awards under Section 6(b) shall be equitably adjusted as necessary to prevent the dilution or enlargement of the rights of Participants.

(c) *Adjustment for Change or Exchange of Shares for Other Consideration.* In the event that outstanding shares of Common Stock shall be changed into or exchanged for any other class or series of capital stock or cash, securities or other property pursuant to a recapitalization, reclassification, reorganization, merger, consolidation, spin-off, combination, repurchase, or share exchange, or other similar corporate transaction or event (“Transaction”), then, unless

otherwise determined by the Committee in its sole and absolute discretion, (1) each outstanding Option shall thereafter become exercisable for the number and/or kind of capital stock, and/or the amount of cash, securities or other property so distributed, into which the shares of Common Stock subject to the Option would have been changed or exchanged had the Option been exercised in full prior to such Transaction, provided that, if necessary, the provisions of the Option shall be appropriately adjusted so as to be applicable to any shares of capital stock, cash, securities or other property thereafter issuable or deliverable upon exercise of the Option, and (2) each outstanding Award that is not an Option and that is not automatically changed in connection with the Transaction shall represent the number and/or kind of capital stock, and/or the amount of cash, securities or other property so distributed, into which the shares of Common Stock covered by the outstanding Award would have been changed or exchanged had they been held by a stockholder of the Company.

(d) *Reuse of Shares.* Any shares subject to an Award that remain unissued upon the cancellation, surrender, exchange or termination of such Award for any reason whatsoever shall again become available for Awards in an amount determined in accordance with the share counting formulas set forth in Section 4(a), except that the exercise of a Stock Appreciation Right shall not be deemed to result in unissued shares, even if fewer shares are issued than the number of shares in which the Award was denominated.

5. **Eligibility.**

The persons who shall be eligible to receive Awards pursuant to the Plan shall be limited to: (i) those individuals who are first elected as non-employee Board members after the Effective Date, whether by the Company's stockholders or by the Board, and (ii) those individuals who continue to serve as non-employee Board members after such Effective Date, whether or not they commenced Board service prior to such Effective Date. In no event, however, shall any non-employee Board member be eligible to participate in the Plan unless such individual is an “independent director” as defined in Nasdaq Stock Market Rules. Each non-employee Board member eligible to participate in the Plan pursuant to the foregoing criteria shall be designated an eligible “Non-Employee Director” for purposes of the Plan.

6. **Awards Under the Plan; Agreement.**

(a) *General.* The Committee may grant Options, shares of Restricted Stock, Restricted Stock Units, Stock Appreciation Rights and Other Awards pursuant to Section 6(b), in such amounts and with such terms and conditions as the Committee shall determine, subject to the provisions of the Plan, and may provide for Dividend Equivalent Rights with respect to any Award. Each Award granted under the Plan shall be evidenced by an Agreement which shall contain such provisions as the Committee may in its sole discretion deem necessary or desirable, which are not in conflict with the terms of the Plan. By accepting an Award, a Participant thereby agrees that the Award shall be subject to all of the terms and provisions of the Plan and the applicable Agreement.

(b) *Awards.* Awards shall be granted as specified below.

(i) *Initial Grant*. Each individual who is first elected as a Non-Employee Director, whether by the Company's stockholders or by the Board, on or after the Effective Date, may be granted, on the date of such initial election, one or more Awards (defined as the “Initial Grant”), the amount and type of which shall be determined by the Committee consistent with the provisions of the Plan, provided that the number of shares of Common Stock subject to such Initial Grant shall not exceed 35,000 shares in the aggregate (calculated as described in subsection (iv) below). Initial Grants shall vest ratably in equal annual installments on each of the first three anniversaries of the date of grant.

(ii) *Annual Grant*. On the date of each annual stockholders meeting, commencing with the 2006 annual meeting, each individual who is at the time serving as a Non-Employee Director shall be granted one or more Awards (defined as the "Annual Grant"), the amount and type of which shall be determined by the Committee consistent with the provisions of the Plan, provided that the number of shares of Common Stock subject to such Annual Grant shall not exceed 17,500 shares in the aggregate (calculated as described in subsection (iv) below). An individual elected as a Non-Employee Director other than at an annual meeting of stockholders shall receive, on the date of such election, a pro rata portion of the Annual Grant made at the preceding annual stockholders meeting based on the number of days from the date of election to the next annual meeting of stockholders, divided by 365. Unless otherwise determined by the Committee, all outstanding and future Annual Grants shall fully vest on the earlier of (i) the next annual meeting of stockholders following the date of grant or (ii) first anniversary of the date of grant or over such longer period and in such increments as the Committee may otherwise determine.

(iii) *Non-Executive Chairman Grants.* Upon election as Non-Executive Chairman of the Board of Directors on or after the Effective Date, a Non-Employee Director may be granted, on the date of such election, one or more Awards (defined as the "Supplemental Initial Grant"), the amount and type of which shall be determined by the Committee consistent with the provisions of the Plan, provided that the number of shares of Common Stock subject to such an individual's Initial Grant and Supplemental Initial Grant shall not exceed 50,000 shares in the aggregate (calculated as described in subsection (iv) below). On the date of each annual stockholders meeting commencing with the 2006 annual meeting, any Non-Employee Director then serving as Non-Executive Chairman of the Board of Directors shall be granted one or more Awards (defined as the "Supplemental Annual Grant"), the amount and type of which shall be determined by the Committee consistent with the provisions of the Plan, provided that the number of shares of Common Stock subject to such an individual's Annual Grant and Supplemental Annual Grant shall not exceed 30,000 shares in the aggregate (calculated as described in subsection (iv) below). A Non-Employee Director elected as Non-Executive Chairman of the Board other than at an annual meeting of stockholders shall receive, on the date of such election, a pro rata portion of the Supplemental Annual Grant. Supplemental Initial Grants shall vest ratably in equal annual installments on each of the first three anniversaries of the date of grant, and Supplemental Annual Grants shall fully vest on the first anniversary of the date of grant.

(iv) *Share Equivalents.* For purposes of applying the limits on the number of shares of Common Stock which may be subject to Awards made pursuant to Initial Grants, Supplemental Initial Grants, Annual Grants and Supplemental Annual Grants under this Section 6(b): (A) the grant of any Award other than an Option or a Stock Appreciation Right shall be treated as an Award of one and one-half (1.5) shares of Common Stock for each such share actually subject to the Award, and (B) the grant of an Option or a Stock Appreciation Right shall be treated as an Award of one share of Common Stock for each such share actually subject to the Award.

7. **Options.**

(a) *Identification of Options.* Each Option shall be a Nonqualified Stock Option and shall state the number of shares of the Common Stock to which it pertains.

(b) *Exercise Price*. Each Agreement with respect to an Option shall set forth the amount (the "option exercise price") payable by the Participant to the Company upon exercise of the Option. The option exercise price per share shall be equal to the Fair Market Value of the Common Stock on the date of grant.

(c) *Term and Exercise of Options*.

(i) Each Option shall become exercisable at the time or times determined by the Committee as set forth in the applicable Agreement, consistent with the provisions of the Plan. The expiration date of each Option shall be ten (10) years from the date of the grant thereof, or at such earlier time as the Committee shall expressly state in the applicable Agreement.

(ii) An Option shall be exercised by delivering notice as specified in the Agreement on the form of notice provided by the Company. The option exercise price shall be payable upon the exercise of the Option. It shall be payable in one of the following forms: (A) in United States dollars in cash or by check, (B) if permitted by the Committee, in shares of Common Stock that have been held by the Participant (or a permitted transferee of such person) for at least six months and having a Fair Market Value as of the date of exercise equal to the aggregate option exercise price, (C) at the discretion of the Committee, in accordance with a cashless exercise program established with a securities brokerage firm, or (D) at the discretion of the Committee, by any combination of (A), (B) and (C) above, or (E) by such other method as the Committee may, in its discretion, permit.

(iii) Certificates for shares of Common Stock purchased upon the exercise of an Option shall be issued in the name of or for the account of the Participant, or other person entitled to receive such shares, and delivered to the Participant or such other person as soon as practicable following the effective date on which the Option is exercised.

(iv) Notwithstanding anything to the contrary in this Plan, on the last day on which an Option is exercisable in accordance with the Plan and the terms of the Award, if the exercise price of the Option is less than the Fair Market Value of the Common Stock on that day, the stock option will be deemed to have been exercised on a net share settlement basis at the close of business on that day. As promptly as practicable thereafter, the Company will deliver to the Participant the number of shares underlying the Option less the number of shares having a Fair Market Value on the date of the deemed exercise equal to the aggregate exercise price for the Option.

(d) *Effect of Termination of Board Service.*

(i) Except as may otherwise be determined by the Committee (A) in the event that the Participant's Board service shall terminate on account of the Retirement, death or Disability of the Participant, each Option granted to such Participant that is outstanding as of the date of such termination shall become fully vested and exercisable, and (B) in the event that the Participant's Board service shall terminate for any reason other than Retirement, death or Disability, each Option that is not exercisable as of the date of such termination shall be cancelled at the time of such termination.

(ii) In the event that the Participant's Board service shall terminate for any reason other than For Cause, each Option granted to such Participant, to the extent that it is or becomes exercisable at the time of such termination, shall remain exercisable by the Participant (or, in the event of the Participant's death while such Option is still outstanding, by the Participant's legal representatives, heirs or legatees) for the three-year period following such termination (or for such other period as may be provided by the Committee), but in no event following the expiration of its term.

(iii) In the event of the termination of the Participant's Board service For Cause, each outstanding Option granted (including any portion of the Option that is then exercisable) to such Participant shall be cancelled as of the commencement of business on the date of such termination.

8. **Restricted Stock; Restricted Stock Units.**

(a) *Price.* At the time of the grant of shares of Restricted Stock, the Committee shall determine the price, if any, to be paid by the Participant for each share of Restricted Stock subject to the Award.

(b) *Vesting Date.* Provided that all conditions to the vesting of a share of Restricted Stock imposed pursuant to Section 6(b) are satisfied, and except as provided in Section 8(g), upon the occurrence of the Vesting Date with respect to a share of Restricted Stock, such share shall vest and the Transfer Restrictions shall lapse. Provided that all conditions to the vesting of a Restricted Stock Unit imposed pursuant to Section 6(b) are satisfied, and except as provided in Section 8(g), upon the occurrence of the Vesting Date with respect to a Restricted Stock Unit, such Restricted Stock Unit shall vest and become non-forfeitable; provided, however, that the payment with respect to such Restricted Stock Unit shall be made in a manner that complies with the requirements of Section 409A of the Code.

(c) *Dividends.* Any dividends paid on shares of Restricted Stock will be held in escrow until all restrictions or conditions to the vesting of such shares have lapsed. Any escrowed dividends may, in the Committee's discretion, be reinvested or deemed reinvested in Common Stock as of the dividend payment date.

(d) *Issuance of Certificates.* Following the date of grant with respect to shares of Restricted Stock, or the settlement of a Restricted Stock Unit payable in Common Stock, the Company shall cause to be issued a Certificate, registered in the name of or for the account of the Participant to whom such shares were granted, evidencing such shares. In the case of an Award of Restricted Stock, each such Certificate shall bear the following legend or substantially similar restrictive account legend: "The transferability of this Certificate and the shares of stock represented hereby are subject to the restrictions, terms and conditions (including forfeiture provisions and restrictions against transfer) contained in or imposed pursuant to the Biogen Inc. 2006 Non-Employee Directors Equity Plan." Such legend shall not be removed until such shares vest pursuant to the terms hereof. Each Certificate issued pursuant to this Section 8(d) in connection with a grant of Restricted Stock shall be held by the Company or its designee prior to the applicable Vesting Date, unless the Committee determines otherwise.

(e) *Consequences of Vesting of Restricted Stock.* Upon the vesting of a share of Restricted Stock pursuant to the terms hereof, the Transfer Restrictions shall lapse with respect to such share. Following the date on which a share of Restricted Stock vests, the Company shall cause to be delivered to the Participant to whom such shares were granted (or a permitted transferee of such person), a Certificate evidencing such share, free of the legend set forth in Section 8(d).

(f) *Settlement of Restricted Stock Units.* The settlement of Restricted Stock Units may occur or commence when all vesting conditions applicable to the Restricted Stock Units have been satisfied, or it may be deferred in accordance with such terms and conditions as the Committee may specify, subject to compliance with Section 409A of the Code.

(g) *Effect of Termination of Board Service.* In the event that the Participant's Board service shall terminate for any reason other than (i) Retirement, (ii) death or (iii) Disability, each unvested grant of Restricted Stock or Restricted Stock Units shall be forfeited at the time of such termination (except as may be otherwise determined by the Committee). In the event that the Participant's Board service shall terminate on account of Retirement, death or Disability of the Participant, each grant of Restricted Stock and Restricted Stock Units that is outstanding as of the date of Retirement, death or Disability shall become fully vested.

9. **Stock Appreciation Rights.**

(a) A Stock Appreciation Right may be granted in connection with an Option, either at the time of grant or at any time thereafter during the term of the Option, or may be granted unrelated to an Option. At the time of grant of a Stock Appreciation Right, the Committee may impose such restrictions or conditions to the exercisability of the Stock Appreciation Right as it, in its absolute discretion, deems appropriate. The term of a Stock Appreciation Right granted without relationship to an Option shall not exceed ten years from the date of grant.

(b) A Stock Appreciation Right related to an Option shall require the holder, upon exercise, to surrender such Option with respect to the number of shares as to which such Stock Appreciation Right is exercised, in order to receive payment of any amount computed pursuant to Section 9(d). Such Option will, to the extent surrendered, then cease to be exercisable.

(c) Subject to Section 9(d)(i), and to such rules and restrictions as the Committee may impose, a Stock Appreciation Right granted in connection with an Option will be exercisable at such time or times, and only to the extent that a related Option is exercisable, and will not be transferable except to the extent that such related Option may be transferable.

(d) Subject to Section 9(f), the exercise of a Stock Appreciation Right related to an Option will entitle the holder to receive payment of an amount determined by multiplying:

(i) the excess of the Fair Market Value of a share of Common Stock on the date of exercise of such Stock Appreciation Right over the exercise price of the related Option, by

(ii) the number of shares as to which such Stock Appreciation Right is exercised.

(e) The maximum number of shares underlying a Stock Appreciation Right granted without relationship to an Option shall be set forth in the applicable Award Agreement. A Stock Appreciation Right granted without relationship to an Option will entitle the holder to receive payment, subject to Section 9(f), of an amount determined by multiplying:

(i) the excess of the Fair Market Value of a share of Common Stock on the date of exercise of such Stock Appreciation Right over the Fair Market Value of a share of Common Stock on the date the Stock Appreciation Right was granted or such greater amount as may be set forth in the applicable Agreement, by

(ii) the number of shares as to which such Stock Appreciation Right is exercised.

(f) Notwithstanding subsections (d) and (e) above, the Committee may place a limitation on the amount payable upon exercise of a Stock Appreciation Right. Any such limitation must be determined as of the date of grant and noted in the applicable Award Agreement.

(g) Payment of the amount determined under subsections (d) and (e) above may be made solely in whole shares of Common Stock valued at their Fair Market Value on the date of exercise of the Stock Appreciation Right or alternatively, in the sole discretion of the Committee, solely in cash or a combination of cash and shares of Common Stock. If the Committee decides that payment of the amount determined under subsections (d) and (e) above may be made shares of Common Stock, and the amount payable results in a fractional share, payment for the fractional share will be made in cash. The payment with respect to any Stock Appreciation Right shall be made in a manner that complies with the requirements of Section 409A of the Code.

(h) Other than with respect to an adjustment described in Section 4(b) or 4(c), in no event shall the exercise price with respect to a Stock Appreciation Right be reduced following the grant of such Stock Appreciation Right, nor shall the Stock Appreciation Right be cancelled in exchange for a replacement Stock Appreciation Right with a lower exercise price.

(i) *Effect of Termination of Board Service.*

(i) In the event that the Participant's Board service shall terminate on account of the Retirement of the Participant, each Stock Appreciation Right granted to such Participant that is outstanding as of the date of such termination shall become fully exercisable and shall remain exercisable for the three year period following such termination (or for such other period as may be provided by the Committee), but in no event following the expiration of its term.

(ii) In the event that the Participant's Board service shall terminate on account of the death of the Participant, each Stock Appreciation Right granted to such Participant that is outstanding as of the date of death shall become fully exercisable and shall remain exercisable by the Participant's legal representatives, heirs or legatees for the one year period following the date of death (or for such other period as may be provided by the Committee), but in no event following the expiration of its term.

(iii) In the event that the Participant's Board service shall terminate on account of the Disability of the Participant, each Stock Appreciation Right granted to such Participant that is outstanding as of the date of such termination shall become fully vested and shall remain exercisable by the Participant (or such Participant's legal representatives) for the one year period following such termination (or for such other period as may be provided by the Committee), but in no event following the expiration of its term.

(iv) In the event of the termination of a Participant's Board service For Cause, each outstanding Stock Appreciation Right granted (including any portion of the Stock Appreciation Right that is then exercisable) to such Participant shall be cancelled at the commencement of business on the date of such termination.

(v) In the event that the Participant's Board service shall terminate for any reason other than (A) Retirement, (B) death, (C) Disability or (D) For Cause, each Stock Appreciation Right granted to such Participant, to the extent that it is exercisable at the time of such termination, shall remain exercisable for the six month period following such termination (or for such other period as may be provided by the Committee), but in no event following the expiration of its term. Each Stock Appreciation Right that remains unexercisable as of the date of such a termination shall be cancelled at the time of such termination (except as may be otherwise determined by the Committee).

(vi) In the event of the Participant's death within six months following the Participant's termination of Board service other than For Cause, each Stock Appreciation Right granted to such Participant that is vested and outstanding as of the date of death shall remain exercisable by the Participant's legal representatives, heirs or legatees for the one year period following the date of death (or for such other period as may be provided by the Committee), but in no event following the expiration of its term.

10. **Other Awards.**

(a) *General.* Other Awards valued in whole or in part by reference to, or otherwise based on, Common Stock may be granted either alone or in addition to other Awards under the Plan. Subject to the provisions of Section 6(b), the Committee shall have sole and complete authority to determine the number of shares of Common Stock to be granted pursuant to such Other Awards and all other terms and conditions of such Other Awards.

(b) *Payment of Non-Employee Directors' Fees in Securities.* In addition to the Awards authorized under Section 6(b), and only to the extent permitted by the Committee, a Non-Employee Director may elect to receive his or her annual retainer payments and/or meeting fees

from the Company in the form of Awards under the Plan by completing the procedures prescribed by the Committee. Such Awards shall be issued under the Plan. The terms and the number of Awards to be granted to Non-Employee Directors in lieu of annual retainers and/or meeting fees under this Section 10 shall be determined by the Committee.

11. **Effect of a Corporate Transaction.**

(a) *Options and Stock Appreciation Rights.* In the event of a Corporate Transaction, the Committee shall, prior to the effective date of the Corporate Transaction, as to each outstanding Option and Stock Appreciation Right under the Plan, take one or more of the following actions: (i) make appropriate provisions for the Options and Stock Appreciation Rights to be assumed by the successor corporation or its parent or be replaced with a comparable option or stock appreciation right to purchase shares of the capital stock of the successor corporation or its parent; (ii) upon reasonable prior written notice to the Participants provide that all Options and Stock Appreciation Rights must be exercised prior to a specified date and, to the extent unexercised as of such specified date, such Options and Stock Appreciation Rights will terminate (all Options and Stock Appreciation Rights having been made fully exercisable as set forth below in this Section 11); or (iii) terminate all Options and Stock Appreciation Rights in exchange for, in the case of Options, a cash payment equal to the excess of the then aggregate Fair Market Value of the shares subject to such Options over the aggregate exercise prices thereof, or in the case of Stock Appreciation Rights, the amount otherwise payable on exercise of such Stock Appreciation Rights pursuant to Section 9 (all Options and Stock Appreciation Rights having been made fully exercisable as set forth below in this Section 11). Without limiting the generality of Sections 4(b) and 4(c) hereof, each outstanding Option and Stock Appreciation Right under the Plan which is assumed in connection with a Corporate Transaction, or is otherwise to continue in effect, shall be appropriately adjusted, immediately after such Corporate Transaction, to apply and pertain to the number and class of securities which would have been issued, in consummation of such Corporate Transaction, to an actual holder of the same number of shares of the Common Stock as are subject to such Option or Stock Appreciation Right immediately prior to such Corporate Transaction. Appropriate adjustments shall also be made to the option exercise price payable per share pursuant to the Option, provided the aggregate option exercise price payable for such securities pursuant to the Option shall remain the same, and the basis for calculating the amount payable on exercise of the Stock Appreciation Right pursuant to Section 9.

(b) *Awards other than Options and Stock Appreciation Rights.* In the event of a Corporate Transaction, the Committee shall, prior to the effective date of the Corporate Transaction, as to each outstanding Award (other than an Option or Stock Appreciation Right) under the Plan take one or more of the following actions: (i) make appropriate provisions for the Awards to be assumed by the successor corporation or its parent, or be replaced with a comparable award with respect to the successor corporation or its parent; (ii) provide that such Awards shall be fully vested and settled prior to such Corporate Transaction; or (iii) terminate all such Awards in exchange for a cash payment equal to the then aggregate Fair Market Value of the shares of Common Stock and cash payments subject to such Award (all Awards having been made fully vested as set forth below in this Section 11).

(c) *Involuntary Termination.* If at any time within two years of the effective date of a Corporate Transaction there is an Involuntary Termination with respect to a Participant's continued service as a Non-Employee Director of the successor corporation or its parent, each then outstanding Award assumed or replaced under this Section 11 and held by such Participant (or a permitted transferee of such person) shall, upon the occurrence of such Involuntary Termination, automatically accelerate so that each such Award shall become fully vested or exercisable, as applicable, immediately prior to such Involuntary Termination. Upon the occurrence of an Involuntary Termination with respect to a Participant, any outstanding Option or Stock

Appreciation Right held by such Participant (and a permitted transferee of such person) shall be exercisable within one year of the Involuntary Termination or, if earlier, within the originally prescribed term of the Option or Stock Appreciation Right. An "Involuntary Termination" as to a Participant shall mean the termination of the Participant's Board service other than (1) because of termination For Cause, (2) on account of the Participant's voluntary resignation or (3) on account of the Participant's choosing not to seek reelection; provided, however, that for purposes of the Plan, a termination of Board service, at the request of the Board, where such termination is in connection with a reduction of the number of members of the Board (and not in connection with a replacement of the terminating member) shall be treated as an Involuntary Termination.

(d) *Other Adjustments.* The class and number of securities available for issuance under the Plan on both an aggregate and per Participant or per grant basis shall be appropriately adjusted by the Committee to reflect the effect of the Corporate Transaction upon the Company's capital structure.

(e) *Termination of Plan; Cash Out of Awards.* In the event the Company terminates the Plan or elects to cash out Awards in accordance with clauses (ii) or (iii) of paragraph (a) or clause (iii) of paragraph (b) of this Section 11, then the exercisability and vesting of each affected Award outstanding under the Plan shall be automatically accelerated so that each such Award shall, immediately prior to such Corporate Transaction, become fully vested and may be exercised prior to such Corporate Transaction for all or any portion of such Award. The Committee shall, in its discretion, determine the timing and mechanics required to implement the foregoing Plan provision.

(f) *Special Rule Regarding Determination of Termination for Cause.* Following the occurrence of a Corporate Transaction, the determination of whether circumstances warrant a termination For Cause shall be made in good faith by the Committee, provided that such determination shall not be presumed to be correct or given deference in any subsequent litigation, arbitration or other proceeding with respect to the existence of circumstances warranting a termination For Cause.

12. **Acceleration Upon Corporate Change in Control.**

Unless otherwise determined by the Committee at the time of grant and set forth in the applicable Award Agreement, in the event of a Corporate Change in Control, the exercisability or vesting of each Award outstanding under the Plan shall be automatically accelerated so that each such Award shall, immediately prior to such Corporate Change in Control, become fully vested and/or exercisable for the full number of shares of the Common Stock purchasable or cash payable under an Award to the extent not previously exercised, and may be exercised for all or any portion of such shares or cash within the originally prescribed term of such Award and in the case of RSUs and other awards shall be immediately settled. The Committee shall, in its discretion, determine the timing and mechanics required to implement the foregoing Plan provision.

13. **Rights as a Stockholder.**

No person shall have any rights as a stockholder with respect to any shares of Common Stock covered by or relating to any Award until the date of issuance of a Certificate with respect to such shares. Except as otherwise expressly provided in Section 4(b) or 4(c), no adjustment to any Award shall be made for dividends or other rights for which the record date occurs prior to the date of issuance of such Certificate.

14. **No Right to Continued Board Service; No Right to Award.**

Nothing contained in the Plan or any Agreement shall confer upon any Participant any right with respect to the continuation of service as a member of the Board or interfere in any way with the right of the Company or its stockholders to remove any individual from the Board at any time in accordance with the provisions of applicable law. No person shall have any claim or right to receive an Award hereunder. The Committee's granting of an Award to a Participant at any time shall neither require the Committee to grant any other Award to such Participant or other person at any time or preclude the Committee from making subsequent grants to such Participant or any other person.

15. **Securities Matters.**

(a) Notwithstanding anything herein to the contrary, the Company shall not be obligated to cause to be issued or delivered any Certificates evidencing shares of Common Stock pursuant to the Plan unless and until the Company is advised by its counsel that the issuance and delivery of such Certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of Certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such Certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable.

(b) The transfer of any shares of Common Stock hereunder shall be effective only at such time as counsel to the Company shall have determined that the issuance and delivery of such shares is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may, in its sole discretion, defer the effectiveness of any transfer of shares of Common Stock hereunder in order to allow the issuance of such shares to be made pursuant to registration or an exemption from registration or other methods for compliance available under federal or state securities laws. The Committee shall inform the Participant (or a permitted transferee of such person) in writing of its decision to defer the effectiveness of a transfer. During the period of such deferral in connection with the exercise of an Option, the Participant (or a permitted transferee of such person) may, by written notice, withdraw such exercise and obtain the refund of any amount paid with respect thereto, subject to compliance with the requirements of Section 409A of the Code.

16. **Notification of Election Under Section 83(b) of the Code.**

If any Participant shall, in connection with the acquisition of shares of Common Stock under the Plan, make the election permitted under Section 83(b) of the Code, such Participant shall notify the Company of such election within 10 days of filing notice of the election with the Internal Revenue Service.

17. **Amendment or Termination of the Plan.**

The Board of Directors may, at any time, suspend or terminate the Plan or revise or amend it in any respect whatsoever; provided, however, that stockholder approval shall be required for any such amendment if and to the extent the Board of Directors determines that such approval is appropriate or necessary for purposes of satisfying any applicable law or the requirements of any securities exchange upon which the securities of the Company trade. Nothing herein shall restrict the Committee's ability to exercise its discretionary authority pursuant to Section 3, which discretion may be exercised without amendment to the Plan. No amendment or termination of the Plan may, without the consent of the affected Participant, reduce the Participant's rights under any outstanding Award.

18. **Transferability.**

The Committee may direct that any Certificate evidencing shares issued pursuant to the Plan shall bear a legend setting forth such restrictions on transferability as may apply to such shares. Awards granted under the Plan shall not be transferable by a Participant other than: (i) by will or by the laws of descent and distribution, (ii) pursuant to a qualified domestic relations order, as defined by the Code or Title 1 of the Employee Retirement Income Security Act or the rules thereunder or (iii) as otherwise determined by the Committee in its sole and absolute discretion. The designation of a beneficiary of an Award by a Participant shall not be deemed a transfer prohibited by this Section 18. Except as provided pursuant to this Section 18, an Award shall be exercisable during a Participant's lifetime only by the Participant (or by his or her legal representative) and shall not be assigned, pledged, or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation, or other disposition of any Award contrary to the provisions of this Section 18, or the levy of any attachment or similar process upon an Award, shall be null and void. Upon the death of a Participant, outstanding Awards granted to such Participant may be exercised only by the designated beneficiary, executor or administrator of the Participant's estate, or by a person who shall have acquired the right to such exercise by will or by the laws of descent and distribution (or by a permitted transferee of such person). No transfer of an Award by will or the laws of descent and distribution, or as otherwise permitted by this Section 18, shall be effective to bind the Company unless the Committee shall have been furnished with: (a) written notice thereof and with such evidence as the Committee may deem necessary to establish the validity of the transfer, and (b) an agreement by the transferee to comply with all the terms and conditions of the Award that are or would have been applicable to the Participant and to be bound by the acknowledgments made by the Participant in connection with the grant of the Award.

19. **Dissolution or Liquidation of the Company.**

Immediately prior to the dissolution or liquidation of the Company, other than in connection with transactions to which Section 11 is applicable, all Awards granted hereunder shall terminate and become null and void; provided, however, that if the rights hereunder of a Participant or one who acquired an Award by will or by the laws of descent and distribution, or as otherwise permitted pursuant to Section 18, have not otherwise terminated and expired, the Participant or such person shall have the right immediately prior to such termination to exercise any Award granted hereunder to the extent that the right to exercise such Award has vested as of the date immediately prior to such dissolution or liquidation. Awards of Restricted Stock and Restricted Stock Units that have not vested as of the date of such dissolution or liquidation shall be forfeited immediately prior to such dissolution or liquidation.

20. **Effective Date and Term of Plan.**

The Plan shall be subject to the requisite approval of the stockholders of the Company. In the absence of such approval, any Awards shall be null and void. Unless the Plan is extended or earlier terminated by the Board of Directors, the right to grant Awards under the Plan shall terminate on the later of (i) the tenth anniversary of the Effective Date (i.e., May 25, 2016) and (ii) if the stockholders approve the amendment to the term of the Plan at the Company’s 2015 annual meeting of stockholders, June 10, 2025. Awards outstanding at Plan termination shall remain in effect according to their terms and the provisions of the Plan and the applicable Award Agreement.

21. **Applicable Law.**

The Plan shall be construed and enforced in accordance with the laws of the State of Delaware, without reference to its principles of conflicts of law.

22. **Participant Rights.**

No Participant shall have any claim to be granted any Award under the Plan, and there is no obligation for uniformity of treatment for Participants.

23. **Unfunded Status of Awards.**

The Plan is intended to constitute an "unfunded" plan for incentive and deferred compensation purposes. With respect to any payments not yet made to a Participant pursuant to an Award, nothing contained in the Plan or any Agreement shall give any such Participant any rights that are greater than those of a general, unsecured creditor of the Company.

24. **No Fractional Shares.**

No fractional shares of Common Stock shall be issued or delivered pursuant to the Plan. The Committee shall determine whether cash, other Awards, or other property shall be issued or paid in lieu of such fractional shares, or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

25. **Beneficiary.**

A Participant may file with the Committee a written designation of a beneficiary on such form as may be prescribed by the Committee and may, from time to time, amend or revoke such designation. If no designated beneficiary survives the Participant, the executor or administrator of the Participant's estate shall be deemed to be the Participant's beneficiary.

26. **Interpretation; Limitation on Liability; Special Rules.**

(a) Awards under the Plan are intended either to be exempt from the rules of Section 409A of the Code or to satisfy those rules, and shall be construed accordingly. Granted Awards may be modified at any time, in the Committee's discretion, so as to increase the likelihood of exemption from or compliance with the rules of Section 409A. In the event that a Participant is prohibited from executing market trades by reason of the application of the federal securities laws or for any other reason determined by the Committee, the Committee may extend the exercise period of an Award to the extent permitted by Section 409A. To the extent required by Section 409A of the Code, references to a termination of Board service shall be construed to require a "separation from service" under Section 409A of the Code.

(b) Notwithstanding anything to the contrary in the Plan, neither the Company nor the Committee, nor any person acting on behalf of the Company or the Committee, will be liable to any Participant or to the estate or beneficiary of any Participant or to any other holder of a Stock Award by reason of any acceleration of income, or any additional tax (including any interest and penalties), by reason of the failure of an Award to satisfy the requirements of Section 409A or by reason of Section 4999 of the Code, or as otherwise asserted with respect to the Award.

(c) Subject to Section 16 of the Exchange Act, to the extent the Committee deems it necessary, appropriate or desirable to comply with foreign law or practices, and to further the purpose of the Plan, the Committee may, without amending the Plan, establish special rules applicable to Awards granted to Participants who are foreign nationals or are employed outside the United States, or both, including rules that differ from those set forth in the Plan, and grant Awards (or amend existing Awards) in accordance with those rules.

27. **Severability.**

If any provision of the Plan is held to be invalid or unenforceable, the other provisions of the Plan shall not be affected but shall be applied as if the invalid or unenforceable provision had not been included in the Plan.

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: May 3, 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: May 3, 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 March 31, 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: May 3, 2022

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

Date: May 3, 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.