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, 2023

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 ☒ No ☐

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares of the issuer's Common Stock, $0.0005 par value, outstanding as of April 24, 2023, was 144,742,305 shares.

BIOGEN INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2023

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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, reimbursement 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 or competing products;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- our plans and investments in our portfolio as well as implementation of our corporate strategy;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of, and the anticipated completion of, certain business development transactions and cost-reduction measures;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals, of our products, drug candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- adverse safety events involving our marketed products, generic or biosimilar versions of our marketed products or any other products from the same class as one of our products;
- the direct and indirect impact of the COVID-19 pandemic and other global health outbreaks 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 U.S., including the IRA, and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities, activities in new or existing manufacturing facilities and the expected timeline for the remaining portion of the Solothurn manufacturing facility to begin manufacturing products or product candidates and for the gene therapy manufacturing facility in 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

DEFINED TERMS

2022 Form 10-K	Annual Report on Form 10-K for the year ended December 31, 2022
2020 Share Repurchase Program	Board of Directors authorized program to repurchase up to $5.0 billion of our common stock
300 Binney Street	300 Binney Street, Cambridge, MA
Advisory Committee	Peripheral and Central Nervous System Drugs Advisory Committee
AI	Artificial Intelligence
ALS	Amyotrophic Lateral Sclerosis
AOCI	Accumulated Other Comprehensive Income (Loss)
ASO	Antisense Oligonucleotide
ASU	Accounting Standards Update
ATV	Antibody Transport Vehicle
BLA	Biologics License Application
CCPA	California Consumer Privacy Act
CEO	Chief Executive Officer
cGMP	current Good Manufacturing Practices
CHMP	Committee for Medicinal Products for Human Use
CJEU	Court of Justice of the European Union
CLE	Cutaneous Lupus Erythematosus
CLL	Chronic Lymphocytic Leukemia
CMS	Centers for Medicare & Medicaid Services
Convergence	Convergence Pharmaceuticals Ltd.
CROs	Contract Research Organizations
Denali	Denali Therapeutics Inc.
DPN	Diabetic Painful Neuropathy
EC	European Commission
Eisai	Eisai Co., Ltd.
EMA	European Medicines Agency
EPO	European Patent Office
ERISA	Employee Retirement Income Security Act of 1974
E.U.	European Union
FASB	Financial Accounting Standards Board
FCPA	Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
Genentech	Genentech, Inc.
GILTI	Global Intangible Low Tax Income
GloBE	Global Anti-Base Erosion
GMP	Good Manufacturing Practice
Humana	Humana Inc.
IPR&D	In-process research and development
Ionis	Ionis Pharmaceuticals Inc.
IRA	Inflation Reduction Act of 2022
LRRK2	Leucine-Rich Repeat Kinase 2
MAA	Marketing Authorization Application
MDD	Major Depressive Disorder

DEFINED TERMS (continued)

MS	Multiple Sclerosis
Mylan Ireland	Mylan Ireland Ltd.
NDA	New Drug Application
Neurimmune	Neurimmune SubOne AG
NMPA	National Medicinal Products Administration
OECD	Organization for Economic Co-operation and Development
OIG	Office of Inspector General
PDUFA	Prescription Drug User Fee Act
PMDA	Pharmaceuticals and Medical Devices Agency
Polpharma	Polpharma SA
PPACA	Patient Protection and Affordable Care Act
PPD	Postpartum Depression
PPMS	Primary Progressive MS
RMS	Relapsing MS
RRMS	Relapsing-Remitting MS
RTP	Research Triangle Park
Sage	Sage Therapeutics, Inc.
Samsung Bioepis	Samsung Bioepis Co., Ltd.
Samsung BioLogics	Samsung BioLogics Co., Ltd.
Sangamo	Sangamo Therapeutics, Inc.
SG&A	Selling, General and Administrative
SLE	Systemic Lupus Erythematosus
SMA	Spinal Muscular Atrophy
SOD1	Superoxide Dismutase 1
SVB	Silicon Valley Bank
SWISSMEDIC	Swiss Agency for Therapeutic Products
TBA	Technical Boards of Appeal
TGN	Trigeminal Neuralgia
Transition Toll Tax	A one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings
U.K.	United Kingdom
U.S.	United States
U.S. GAAP	Accounting Principles Generally Accepted in the U.S.
VA	Veterans Administration

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,	
	2023	2022
Revenue:		
Product, net	$ 1,763.3	$ 2,066.3
Revenue from LEQEMBI Collaboration	(18.9)	—
Revenue from anti-CD20 therapeutic programs	399.5	399.4
Contract manufacturing, royalty and other revenue	319.1	66.1
Total revenue	2,463.0	2,531.8
Cost and expense:		
Cost of sales, excluding amortization and impairment of acquired intangible assets	662.8	753.9
Research and development	570.6	551.7
Selling, general and administrative	605.0	634.9
Amortization and impairment of acquired intangible assets	50.2	66.9
Collaboration profit sharing/(loss reimbursement)	57.1	(117.3)
(Gain) loss on fair value remeasurement of contingent consideration	—	(7.1)
Restructuring charges	9.6	38.1
Other (income) expense, net	69.4	263.3
Total cost and expense	2,024.7	2,184.4
Income before income tax expense and equity in loss of investee, net of tax	438.3	347.4
Income tax (benefit) expense	50.7	125.6
Equity in (income) loss of investee, net of tax	—	3.3
Net income	387.6	218.5
Net income (loss) attributable to noncontrolling interests, net of tax	(0.3)	(85.3)
Net income attributable to Biogen Inc.	$ 387.9	$ 303.8
Net income per share:		
Basic earnings per share attributable to Biogen Inc.	$ 2.69	$ 2.06
Diluted earnings per share attributable to Biogen Inc.	$ 2.67	$ 2.06
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	144.4	147.1
Diluted earnings per share attributable to Biogen Inc.	145.2	147.6

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,	
	2023	2022
Net income attributable to Biogen Inc.	$ 387.9	$ 303.8
Other comprehensive income:		
Unrealized gains (losses) on securities available for sale, net of tax	5.7	(9.7)
Unrealized gains (losses) on cash flow hedges, net of tax	(35.4)	15.9
Gains (losses) on net investment hedges, net of tax	—	6.2
Unrealized gains (losses) on pension benefit obligation, net of tax	0.5	0.9
Currency translation adjustment	22.1	(21.8)
Total other comprehensive income (loss), net of tax	(7.1)	(8.5)
Comprehensive income (loss) attributable to Biogen Inc.	380.8	295.3
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	(0.3)	(85.3)
Comprehensive income (loss)	$ 380.5	$ 210.0

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, 2023	As of December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,898.2	$ 3,419.3
Marketable securities	2,143.1	1,473.5
Accounts receivable, net	1,634.4	1,705.0
Due from anti-CD20 therapeutic programs	393.8	431.4
Inventory	1,281.0	1,344.4
Other current assets	1,412.0	1,417.6
Total current assets	9,762.5	9,791.2
Marketable securities	978.2	705.7
Property, plant and equipment, net	3,300.9	3,298.6
Operating lease assets	399.1	403.9
Intangible assets, net	1,813.3	1,850.1
Goodwill	5,751.8	5,749.0
Deferred tax asset	1,211.8	1,226.4
Investments and other assets	1,380.8	1,529.2
Total assets	$ 24,598.4	$ 24,554.1
LIABILITIES AND EQUITY		
Current liabilities:		
Taxes payable	$ 235.5	$ 259.9
Accounts payable	491.2	491.5
Accrued expense and other	2,288.2	2,521.4
Total current liabilities	3,014.9	3,272.8
Notes payable	6,282.7	6,281.0
Deferred tax liability	251.3	334.7
Long-term operating lease liabilities	327.0	333.0
Other long-term liabilities	935.5	944.2
Total liabilities	10,811.4	11,165.7
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	91.2	73.3
Accumulated other comprehensive income (loss)	(172.0)	(164.9)
Retained earnings	16,854.4	16,466.5
Treasury stock, at cost	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	13,796.6	13,397.9
Noncontrolling interests	(9.6)	(9.5)
Total equity	13,787.0	13,388.4
Total liabilities and equity	$ 24,598.4	$ 24,554.1

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,	
	2023	2022
Cash flow from operating activities:		
Net income	$ 387.6	$ 218.5
Adjustments to reconcile net income to net cash flow from operating activities:		
Depreciation and amortization	112.3	143.1
Excess and obsolescence charges related to inventory	17.4	281.5
Share-based compensation	75.6	67.6
Contingent consideration	—	(7.1)
Deferred income taxes	(64.5)	1.0
(Gain) loss on strategic investments	79.6	191.1
(Gain) loss on equity method investments	—	3.3
Other	31.4	43.3
Changes in operating assets and liabilities, net:		
Accounts receivable	77.2	(87.5)
Due from anti-CD20 therapeutic programs	37.6	22.9
Inventory	27.9	(142.6)
Accrued expense and other current liabilities	(295.0)	(461.6)
Income tax assets and liabilities	65.0	101.9
Other changes in operating assets and liabilities, net	(96.8)	(213.6)
Net cash flow provided by (used in) operating activities	455.3	161.8
Cash flow from investing activities:		
Purchases of property, plant and equipment	(66.6)	(57.9)
Proceeds from sales and maturities of marketable securities	406.7	543.6
Purchases of marketable securities	(1,321.2)	(1,133.5)
Acquisitions of intangible assets	(5.0)	—
Proceeds from sales of strategic investments	33.8	—
Other	(0.7)	(0.2)
Net cash flow provided by (used in) investing activities	(953.0)	(648.0)
Cash flow from financing activities:		
Payments related to issuance of stock for share-based compensation arrangements, net	(60.1)	(20.8)
Net (distribution) contribution to noncontrolling interest	0.2	0.2
Other	16.5	4.1
Net cash flow provided by (used in) financing activities	(43.4)	(16.5)
Net increase (decrease) in cash and cash equivalents	(541.1)	(502.7)
Effect of exchange rate changes on cash and cash equivalents	20.0	(9.4)
Cash and cash equivalents, beginning of the period	3,419.3	2,261.4
Cash and cash equivalents, end of the period	$ 2,898.2	$ 1,749.3

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, 2022	—	$ —	167.9	$ 0.1	$ 73.3	$ (164.9)	$ 16,466.5	(23.8)	$(2,977.1)	$ 13,397.9	$ (9.5)	$13,388.4
Net income	—	—	—	—	—	—	387.9	—	—	387.9	(0.3)	387.6
Other comprehensive income (loss), net of tax	—	—	—	—	—	(7.1)	—	—	—	(7.1)	—	(7.1)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	0.2	0.2
Issuance of common stock under stock option and stock purchase plans	—	—	0.1	—	20.1	—	—	—	—	20.1	—	20.1
Issuance of common stock under stock award plan	—	—	0.6	—	(80.2)	—	—	—	—	(80.2)	—	(80.2)
Compensation related to share-based payments	—	—	—	—	78.9	—	—	—	—	78.9	—	78.9
Other	—	—	—	—	(0.9)	—	—	—	—	(0.9)	—	(0.9)
Balance, March 31, 2023	—	$ —	168.6	$ 0.1	$ 91.2	$ (172.0)	$ 16,854.4	(23.8)	$(2,977.1)	$ 13,796.6	$ (9.6)	$13,787.0

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2021	—	$ —	170.8	$ 0.1	$ 68.2	$ (106.7)	$ 13,911.7	(23.8)	$ (2,977.1)	$ 10,896.2	$ 63.5	$ 10,959.7
Net income	—	—	—	—	—	—	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.

1: mary 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 innovative therapies for people living with serious and complex diseases worldwide. We have a broad portfolio of medicines to treat MS, have introduced the first approved treatment for SMA and co-developed two treatments to address a defining pathology of Alzheimer's disease. We are focused on advancing our pipeline in neurology, neuropsychiatry, specialized immunology and rare diseases. We support our drug discovery and development efforts through internal research and development programs and external collaborations.

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 also collaborate with Eisai on the commercialization of LEQEMBI for the treatment of Alzheimer's disease, which was granted accelerated approval by the FDA in January 2023. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, 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 PPMS and RMS; LUNSUMIO, which was granted accelerated approval in the U.S. during the fourth quarter of 2022 for the treatment of relapsed or refractory follicular lymphoma; glofitamab, an investigational bispecific antibody for the potential treatment of non-Hodgkin's lymphoma; and have the option to add other potential anti-CD20 therapies, pursuant to our collaboration arrangements with Genentech, a wholly-owned member of the Roche Group.

In addition to continuing to invest in new potential innovation in MS and SMA we are advancing our mid-to-late stage programs including zuranolone for MDD and PPD, BIIB080 for Alzheimer's disease, QALSODY (tofersen) for ALS and both litifilimab and dapirolizumab pegol for certain forms of lupus.

We also commercialize biosimilars of advanced biologics including BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe, as well as BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in the U.S. We continue to develop potential biosimilar products including BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, and SB15, a proposed aflibercept biosimilar referencing EYLEA.

For additional information on our collaboration arrangements, please read *Note 16, Collaborative and Other Relationships,* to these unaudited condensed consolidated financial statements (condensed consolidated financial statements). For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships,* to our audited consolidated financial statements included in our 2022 Form 10-K.

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 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 2022 Form 10-K. Our accounting policies are described in the *Notes to Consolidated Financial Statements* in our 2022 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, 2023, 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 certain variable interest entities where we are the primary beneficiary. For consolidated entities where we own or are exposed to less than 100.0% of the economics, we record net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. Intercompany balances and transactions are eliminated in consolidation.

In determining whether we are the primary beneficiary of a variable interest entity, we apply a qualitative approach that determines whether we have both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. We continuously assess whether we are the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in us consolidating or deconsolidating one or more of our collaborators or partners.

Use of Estimates

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

The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts our business, results of operations and financial condition, including sales, expense, reserves and allowances, the supply chain, manufacturing, clinical trials, research and development costs and employee-related costs, depends on future developments that are highly uncertain, subject to change and are difficult to predict, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19 as well as the economic impact on local, regional, national and international customers and markets. Additionally, the ongoing geopolitical tensions related to the conflict in Ukraine, and the related sanctions and other penalties imposed, are creating substantial uncertainty in the global economy. The extent and duration of the conflict, sanctions and resulting market disruptions are highly unpredictable. We have made estimates of the impact of the COVID-19 pandemic and the ongoing geopolitical conflict within our condensed consolidated financial statements and there may be changes to those estimates in future periods.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed below, we do not believe that the adoption of recently issued standards have had or may have a material impact on our condensed consolidated financial statements or disclosures.

Fair Value Measurements

In June 2022 the FASB issued ASU No. 2022-03, *Fair Value Measurement* (Topic 820): *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. This standard clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This standard becomes effective for us on January 1, 2024. We elected to early adopt this standard on a prospective basis during the third quarter of 2022. Upon adoption, we recorded an immaterial amount in other (income) expense, net in our condensed consolidated statements of income, as a result of removing the impact of the remaining contractual sale restrictions from the fair value measurement of certain shares in Sage.

2: positions

Sale of Joint Venture Equity Interest in Samsung Bioepis

In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics. Under the terms of this transaction, we received approximately $1.0 billion in cash at closing and expect to receive approximately $1.3 billion in cash to be deferred over two payments. The first payment of approximately $812.5 million was received in April 2023 and the second payment of approximately $437.5 million is due at the second anniversary of the closing of this transaction.

Prior to the sale, the carrying value of our investment in Samsung Bioepis totaled $581.6 million. During the second quarter of 2022 we recognized a pre-tax gain of approximately $1.5 billion related to this transaction, which was recorded in other (income) expense, net in our condensed consolidated statements of income. This pre-tax gain included reclassifications from AOCI to net income of approximately $58.9 million in cumulative translation losses, partially offset by approximately $57.0 million in gains resulting from the termination of our net investment hedge.

We elected the fair value option and measured the payments due to us from Samsung BioLogics at fair value. As of March 31, 2023, the estimated fair values of the first and second payments using risk-adjusted discount rates of 5.9% and 5.8%, respectively, were approximately $809.9 million and $411.6 million, respectively. These payments have been classified as Level 3 measurements and are reflected in other current assets and investments and other assets, respectively, in our condensed consolidated balance sheets.

For the three months ended March 31, 2023, we recognized a gain of approximately $11.1 million and $6.2 million to reflect the changes in fair value related to the first and second payments due to us, respectively. These changes were recorded in other (income) expense, net in our condensed consolidated statements of income.

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

3: ructuring

2022 Cost Saving Initiatives

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

Under these initiatives, we estimate we will incur total restructuring charges of approximately $135.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of March 31, 2023, $28.0 million remained in our restructuring reserve and payments are expected to be made through 2026.

For the three months ended March 31, 2023 and 2022, we recognized $9.6 million and $38.1 million, respectively, of net pre-tax restructuring charges, of which approximately $7.1 million and $27.7 million, respectively, consisted of employee severance costs. These costs were recorded in restructuring charges in our condensed consolidated statements of income. Our restructuring reserve is included in accrued expense and other in our condensed consolidated balance sheets.

In September 2022 we entered into an agreement to partially terminate a portion of our lease located at 300 Binney Street, as well as to reduce the lease term for the majority of the remaining space. This resulted in a gain of approximately $5.3 million, which was recorded within restructuring charges in our condensed consolidated statements of income during the third quarter of 2022. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to our consolidated financial statements included in our 2022 Form 10-K.

Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, North Carolina. Our decision to cease use of the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility. As a result, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in restructuring charges in our condensed consolidated statements of income for the three months ended March 31, 2022. In May 2022 we entered into a lease assignment agreement whereby we assigned our remaining lease obligations to an external third party. As a result of the lease assignment, we derecognized the related operating lease obligation and right-of-use asset during the second quarter of 2022.

For the three months ended March 31, 2023, we recognized other restructuring costs of approximately $2.5 million, which were recorded in restructuring charges in our condensed consolidated statements of income. Other restructuring costs include items such as facility closure costs, employee non-severance expense, asset write-offs and other costs.

Charges and spending related to our workforce reductions is summarized as follows:

	For the Three Months Ended March 31,	
(In millions)	**2023**	**2022**
Restructuring reserve as of December 31	$ 35.9	$ —
Expense	7.1	27.7
Payment	(15.6)	(6.2)
Foreign currency and other adjustments	0.6	—
Restructuring reserve as of March 31	$ 28.0	$ 21.5

4: enue

Product Revenue

Revenue by product is summarized as follows:

	For the Three Months Ended March 31,					
	2023			2022		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 74.7	$ 199.8	$ 274.5	$ 117.1	$ 292.8	$ 409.9
VUMERITY	93.5	14.7	108.2	125.2	2.8	128.0
Total Fumarate	168.2	214.5	382.7	242.3	295.6	537.9
AVONEX	102.6	69.8	172.4	148.0	81.6	229.6
PLEGRIDY	29.9	43.3	73.2	34.3	45.7	80.0
Total Interferon	132.5	113.1	245.6	182.3	127.3	309.6
TYSABRI	245.4	227.4	472.8	284.5	236.3	520.8
FAMPYRA	—	24.1	24.1	—	26.2	26.2
Subtotal: MS	546.1	579.1	1,125.2	709.1	685.4	1,394.5
Spinal Muscular Atrophy:						
SPINRAZA	146.7	296.6	443.3	163.3	309.2	472.5
Biosimilars:						
BENEPALI	—	109.0	109.0	—	114.7	114.7
IMRALDI	—	54.4	54.4	—	57.1	57.1
FLIXABI	—	20.4	20.4	—	22.5	22.5
BYOOVIZ	8.2	0.4	8.6	—	—	—
Subtotal: Biosimilars	8.2	184.2	192.4	—	194.3	194.3
Other[1]	0.4	2.0	2.4	2.8	2.2	5.0
Total product revenue	$ 701.4	$ 1,061.9	$ 1,763.3	$ 875.2	$ 1,191.1	$ 2,066.3

[1] Other includes FUMADERM and ADUHELM.

We recognized revenue from two wholesalers accounting for 27.3% and 7.4% of gross product revenue for the three months ended March 31, 2023, and 26.3% and 10.5% of gross product revenue for the three months ended March 31, 2022.

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, 2022	$ 153.8	$ 857.7	$ 23.5	$ 1,035.0
Current provisions relating to sales in current year	182.3	638.0	3.5	823.8
Adjustments relating to prior years	(1.1)	(8.1)	1.0	(8.2)
Payments/credits relating to sales in current year	(94.0)	(261.8)	(1.0)	(356.8)
Payments/credits relating to sales in prior years	(73.3)	(368.1)	(7.4)	(448.8)
Balance, March 31, 2023	$ 167.7	$ 857.7	$ 19.6	$ 1,045.0

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

(In millions)	As of March 31, 2023	As of December 31, 2022
Reduction of accounts receivable	$ 137.8	$ 143.4
Component of accrued expense and other	907.2	891.6
Total revenue-related reserves	$ 1,045.0	$ 1,035.0

Revenue from LEQEMBI Collaboration

In January 2023 the FDA granted accelerated approval of LEQEMBI, which became commercially available in the U.S. during the first quarter of 2023. Upon commercialization, we began recognizing commercial profits and losses related to the LEQEMBI Collaboration Agreement on a net basis as a separate component of total revenue within our condensed consolidated income statements, as we are not the principal.

For the three months ended March 31, 2023, we recognized a reduction to revenue of approximately $18.9 million, reflecting our net profit-share of the LEQEMBI Collaboration results in the U.S.

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

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)	2023	2022
Royalty revenue on sales of OCREVUS	$ 283.6	$ 252.3
Biogen's share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO	112.5	143.2
Other revenue from anti-CD20 therapeutic programs	3.4	3.9
Total revenue from anti-CD20 therapeutic programs	$ 399.5	$ 399.4

For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2022 Form 10-K.

Contract Manufacturing, Royalty and Other Revenue

Contract manufacturing, royalty and other revenue is summarized in the table below.

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Contract manufacturing revenue	$ 306.9	$ 47.5
Royalty and other revenue	12.2	18.6
Total contract manufacturing, royalty and other revenue	$ 319.1	$ 66.1

Contract Manufacturing Revenue

Contract manufacturing revenue primarily reflects amounts earned under contract manufacturing agreements with our strategic customers. During the first quarter of 2023 we began recognizing contract manufacturing revenue for LEQEMBI, upon accelerated approval of LEQEMBI in the U.S. Prior to accelerated approval, contract manufacturing amounts related to LEQEMBI were recognized in research and development within our condensed consolidated income statements.

Royalty and Other Revenue

Royalty and other revenue primarily reflects the royalties we receive from net sales on products related to patents that we have out-licensed, as well as royalty revenue on biosimilar products from our license arrangements with Samsung Bioepis.

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

5: ntory

The components of inventory are summarized as follows:

(In millions)	As of March 31, 2023	As of December 31, 2022
Raw materials	$ 432.4	$ 413.2
Work in process	684.9	751.9
Finished goods	205.9	200.4
Total inventory	$ 1,323.2	$ 1,365.5
Balance Sheet Classification:		
Inventory	$ 1,281.0	$ 1,344.4
Investments and other assets	42.2	21.1
Total inventory	$ 1,323.2	$ 1,365.5

During the first quarter of 2022 we wrote-off approximately $275.0 million of inventory related to ADUHELM, as a result of the final NCD, which was recognized in cost of sales within our condensed consolidated statements of income for the three months ended March 31, 2022. We recognized approximately $136.0 million related to Eisai's 45.0% share of these charges in collaboration profit sharing/(loss reimbursement) within our condensed consolidated statements of income for the three months ended March 31, 2022. As of March 31, 2023 and December 31, 2022, the carrying value of our ADUHELM inventory was immaterial.

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

6: ngible Assets and Goodwill

Intangible Assets

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

		As of March 31, 2023			As of December 31, 2022		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,428.7	$ (5,679.4)	$ 1,749.3	$ 7,415.3	$ (5,629.2)	$ 1,786.1
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 7,492.7	$ (5,679.4)	$ 1,813.3	$ 7,479.3	$ (5,629.2)	$ 1,850.1

Amortization and Impairments

For the three months ended March 31, 2023, amortization and impairment of acquired intangible assets totaled $50.2 million, compared to $66.9 million in the prior year comparative period. The decrease was primarily due to a lower rate of amortization for acquired intangible assets. For the three months ended March 31, 2023 and 2022, we had no impairment charges.

Completed Technology

Completed technology primarily relates to our other marketed products and programs acquired through asset acquisitions, licenses and business combinations.

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, 2023
2023 (remaining nine months)	$ 165.0
2024	195.0
2025	190.0
2026	175.0
2027	170.0
2028	165.0

Goodwill

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

(In millions)	As of March 31, 2023
Goodwill, December 31, 2022	$ 5,749.0
Other	2.8
Goodwill, March 31, 2023	$ 5,751.8

As of March 31, 2023, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

7: Value Measurements

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

	Fair Value Measurements on a Recurring Basis			
	As of March 31, 2023			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 2,406.6	$ —	$ 2,406.6	$ —
Marketable debt securities:				
Corporate debt securities	1,704.2	—	1,704.2	—
Government securities	1,285.0	—	1,285.0	—
Mortgage and other asset backed securities	132.1	—	132.1	—
Marketable equity securities	678.1	678.1	—	—
Other current assets:				
Receivable from Samsung BioLogics[1]	809.9	—	—	809.9
Derivative contracts	35.1	—	35.1	—
Other assets:				
Plan assets for deferred compensation	34.1	—	34.1	—
Receivable from Samsung BioLogics[1]	411.6	—	—	411.6
Total	$ 7,496.7	$ 678.1	$ 5,597.1	$ 1,221.5
Liabilities:				
Derivative contracts	$ 39.8	$ —	$ 39.8	$ —
Total	$ 39.8	$ —	$ 39.8	$ —

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

	Fair Value Measurements on a Recurring Basis			
	As of December 31, 2022			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 2,847.6	$ —	$ 2,847.6	$ —
Marketable debt securities:				
Corporate debt securities	1,231.6	—	1,231.6	—
Government securities	810.3	—	810.3	—
Mortgage and other asset backed securities	137.3	—	137.3	—
Marketable equity securities	791.1	791.1	—	—
Other current assets:				
Receivable from Samsung BioLogics[1]	798.8	—	—	798.8
Other assets:				
Derivative contracts	63.0	—	63.0	—
Plan assets for deferred compensation	32.8	—	32.8	—
Receivable from Samsung BioLogics[1]	405.4	—	—	405.4
Total	$ 7,117.9	$ 791.1	$ 5,122.6	$ 1,204.2
Liabilities:				
Derivative contracts	$ 26.0	$ —	$ 26.0	$ —
Total	$ 26.0	$ —	$ 26.0	$ —

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

The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities was determined through third-party pricing services. During the third quarter of 2022 we elected to early adopt ASU 2022-03 on a prospective basis, which resulted in removing the impact of contractual sale restrictions from the fair value measurement of our remaining Sage common stock subject to certain holding period restrictions. As of December 31, 2022, our entire investment in the common stock of Sage was classified as a Level 1 measurement. Prior to the adoption of this standard, the fair value of Level 2 instruments classified as marketable equity securities represented a portion of our investment in the common stock of Sage and was valued using an option pricing valuation model.

Our investments in the common stock of Sangamo and Denali had holding period restrictions that expired during 2022. As of December 31, 2022, the fair values of our investments in Sangamo and Denali common stock were classified as Level 1 measurements.

Although the contractual holding period restrictions on our investments in Denali, Sage and Sangamo have expired, our ability to liquidate these investments may be limited by the size of our interest, the volume of market related activity, our concentrated level of ownership and potential restrictions resulting from our status as a collaborator. Therefore, we may realize significantly less than the current value of such investments.

For additional information on our investments in Denali, Sangamo and Sage common stock, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2022 Form 10-K.

There have been no material impairments of our assets measured and carried at fair value as of March 31, 2023 and December 31, 2022. In addition, there have been no changes to our valuation techniques as of March 31, 2023 and December 31, 2022.

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 2022 Form 10-K.

Level 3 Assets and Liabilities Held at Fair Value

There were no transfers of assets or liabilities into or out of Level 3 as of March 31, 2023 and December 31, 2022.

Contingent Consideration Obligations

In connection with our acquisition of Convergence, we agreed to make additional payments based upon the achievement of certain milestone events. The following table provides a roll forward of the fair value of our contingent consideration obligations, which were classified as Level 3 measurements:

(In millions)	For the three months ended March 31, 2022
Fair value, beginning of period	$ 209.1
Changes in fair value	(7.1)
Fair value, end of period	$ 202.0

Changes in the fair value of our contingent consideration obligations are recorded in (gain) loss on fair value remeasurement of contingent consideration in our condensed consolidated statements of income.

During the fourth quarter of 2022 we discontinued further development efforts related to vixotrigine for the potential treatment of TGN and DPN, resulting in a reduction of our contingent consideration obligations of approximately $195.4 million, reducing the fair value of vixotrigine to zero.

For the three months ended March 31, 2022, the changes in 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.

Financial Instruments Not Carried at Fair Value

Other Financial Instruments

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

Debt Instruments

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

	As of March 31, 2023		As of December 31, 2022	
(In millions)	Fair Value	Carrying Value	Fair Value	Carrying Value
4.050% Senior Notes due September 15, 2025	$ 1,711.6	$ 1,745.2	$ 1,699.9	$ 1,744.7
2.250% Senior Notes due May 1, 2030	1,262.2	1,493.1	1,219.0	1,492.9
5.200% Senior Notes due September 15, 2045	1,130.2	1,100.4	1,033.2	1,100.3
3.150% Senior Notes due May 1, 2050	1,043.7	1,473.9	989.0	1,473.8
3.250% Senior Notes due February 15, 2051	493.2	470.1	469.1	469.3
Total	$ 5,640.9	$ 6,282.7	$ 5,410.2	$ 6,281.0

The fair values of each of our series of Senior Notes were determined through market, observable and corroborated sources. The changes in the fair values of our Senior Notes as of March 31, 2023, compared to December 31, 2022, are primarily related to decreases in U.S. treasury yields used to value our Senior Notes since December 31, 2022. For additional information related to our Senior Notes, please read *Note 13, Indebtedness,* to our consolidated financial statements included in our 2022 Form 10-K.

8: ncial 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, 2023	As of December 31, 2022
Commercial paper	$ 64.0	$ 177.2
Overnight reverse repurchase agreements	300.3	59.0
Money market funds	2,042.3	2,581.5
Short-term debt securities	—	29.9
Total	$ 2,406.6	$ 2,847.6

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, 2023			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 1,287.6	$ 0.1	$ (4.4)	$ 1,283.3
Non-current	423.4	1.0	(3.5)	420.9
Government securities:				
Current	863.5	0.1	(4.2)	859.4
Non-current	426.1	1.0	(1.5)	425.6
Mortgage and other asset backed securities:				
Current	0.4	—	—	0.4
Non-current	132.9	0.1	(1.3)	131.7
Total marketable debt securities	$ 3,133.9	$ 2.3	$ (14.9)	$ 3,121.3
Marketable equity securities				
Marketable equity securities, current	$ 87.7	$ —	$ (19.8)	$ 67.9
Marketable equity securities, non-current	1,001.1	—	(390.9)	610.2
Total marketable equity securities	$ 1,088.8	$ —	$ (410.7)	$ 678.1

(In millions)	As of December 31, 2022 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable debt securities				
Corporate debt securities:				
Current	$ 936.2	$ —	$ (4.9)	$ 931.3
Non-current	305.3	0.1	(5.1)	300.3
Government securities:				
Current	547.1	0.1	(5.0)	542.2
Non-current	271.4	—	(3.3)	268.1
Mortgage and other asset backed securities:				
Current	—	—	—	—
Non-current	139.1	0.1	(1.9)	137.3
Total marketable debt securities	$ 2,199.1	$ 0.3	$ (20.2)	$ 2,179.2
Marketable equity securities				
Marketable equity securities, non-current	$ 1,133.8	$ —	$ (342.7)	$ 791.1
Total marketable equity securities	$ 1,133.8	$ —	$ (342.7)	$ 791.1

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

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

(In millions)	As of March 31, 2023 Estimated Fair Value	Amortized Cost	As of December 31, 2022 Estimated Fair Value	Amortized Cost
Due in one year or less	$ 2,143.1	$ 2,151.5	$ 1,473.5	$ 1,483.3
Due after one year through five years	962.2	965.8	694.4	703.7
Due after five years	16.0	16.6	11.3	12.1
Total marketable debt securities	$ 3,121.3	$ 3,133.9	$ 2,179.2	$ 2,199.1

The average maturity of our marketable debt securities classified as available-for-sale as of March 31, 2023 and December 31, 2022, was approximately 9 months and 8 months, respectively.

Proceeds from Marketable Debt Securities

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

(In millions)	For the Three Months Ended March 31, 2023	2022
Proceeds from maturities and sales	$ 406.7	$ 543.6
Realized gains	0.1	—
Realized losses	0.7	0.6

Realized losses for the three months ended March 31, 2023, primarily relate to sales of U.S. treasuries and corporate bonds. Realized losses for the three months ended March 31, 2022, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities.

Strategic Investments

As of March 31, 2023 and December 31, 2022, our strategic investment portfolio was comprised of investments totaling $733.6 million and $846.0 million, respectively, which are included in investments and other assets in our condensed consolidated balance sheets.

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

The decrease in our strategic investment portfolio as of March 31, 2023, was primarily due to a decrease in the fair value of our investments in Denali, Sangamo and Ionis common stock.

For additional information on our investments in Denali, Sangamo, Sage and Ionis common stock, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2022 Form 10-K.

9: vative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

Due to the global nature of our operations, portions of our revenue and operating expense are recorded in currencies other than the U.S. dollar. The value of revenue and operating expense measured in U.S. dollars is therefore subject to changes in foreign currency exchange rates. We enter into foreign currency forward contracts and foreign currency options with financial institutions with the primary objective to mitigate the impact of foreign currency exchange rate fluctuations on our international revenue and operating expense.

Foreign currency forward contracts and foreign currency options in effect as of March 31, 2023 and December 31, 2022, had durations of 1 to 18 months and 1 to 12 months, respectively. These contracts have been designated as cash flow hedges and unrealized gains and losses on the portion of these foreign currency forward contracts and foreign currency options that are included in the effectiveness test are reported in AOCI. Realized gains and losses of such contracts and options 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 AOCI and fair value changes of excluded portions in the same line item in our condensed consolidated statements of income that have been impacted by the hedged item.

The notional amount of foreign currency forward contracts and foreign currency options that were entered into to hedge forecasted revenue and operating expense is summarized as follows:

	Notional Amount	
(In millions)	**As of March 31, 2023**	**As of December 31, 2022**
Euro	$ 1,854.8	$ 1,495.5
British pound	124.3	162.8
Swiss franc	248.2	—
Canadian dollar	43.3	57.2
Total foreign currency contracts and options	$ 2,270.6	$ 1,715.5

The pre-tax portion of the fair value of these foreign currency forward contracts and foreign currency options that were included in AOCI in total equity is summarized as follows:

(In millions)	**As of March 31, 2023**	**As of December 31, 2022**
Unrealized gains	$ 8.8	$ 29.9
Unrealized (losses)	(39.0)	(21.3)
Net unrealized gains (losses)	$ (30.2)	$ 8.6

We expect the net unrealized losses of approximately $30.2 million to be settled over the next 18 months, of which approximately $30.0 million of these net unrealized losses are expected to be settled over the next 12 months, with any amounts in AOCI 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, 2023 and December 31, 2022, credit risk did not materially change the fair value of our foreign currency forward contracts and forward currency options.

The following table summarizes the effect of foreign currency forward contracts and forward currency options 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	2023	2022	Location	2023	2022
Revenue	$ 17.6	$ 20.9	Revenue	$ 1.6	$ (6.5)
Operating expense	(0.5)	(0.3)	Operating expense	(2.1)	(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%.

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

The following table summarizes the effect of our net investment hedges 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	Location	2022	Location	2022
Gains (losses) on net investment hedges[1]	$ 10.1	Gains (losses) on net investment hedges[1]	$ (3.3)	Other (income) expense[1]	$ (1.1)

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

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 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 $1,436.3 million and $1,238.8 million as of March 31, 2023 and December 31, 2022, respectively. Net gains of $1.8 million and net losses of $12.2 million related to these contracts were recorded as a component of other (income) expense, net for the three months ended March 31, 2023 and 2022, 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, 2023	As of December 31, 2022
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 12.3	$ 37.9
	Investments and other assets	0.1	—
Liability derivative instruments	Accrued expense and other	31.9	18.4
	Other long-term liabilities	0.3	—
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	22.7	25.1
Liability derivative instruments	Accrued expense and other	7.6	7.6

10: erty, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Accumulated depreciation on property, plant and equipment was $2,218.2 million and $2,165.7 million as of March 31, 2023 and December 31, 2022, respectively. For the three months ended March 31, 2023, depreciation expense totaled $62.1 million compared to $76.3 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, 2023 and December 31, 2022, we had approximately $721.2 million and $711.1 million, respectively, capitalized as construction in progress related to this facility. Solothurn has been approved for the manufacture of ADUHELM and LEQEMBI by the FDA. In the second quarter of 2021 a portion of the Solothurn manufacturing facility was placed into service and we estimate the second manufacturing suite will be operational by the end of 2023.

11: ty

Share Repurchases

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. There were no share repurchases of our common stock during the three months ended March 31, 2023 and 2022. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of March 31, 2023.

Accumulated Other Comprehensive Income (Loss)

The following tables summarize the changes in AOCI, net of tax by component:

	March 31, 2023				
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2022	$ (15.7)	$ 15.1	$ (1.1)	$ (163.2)	$ (164.9)
Other comprehensive income (loss) before reclassifications	5.3	(20.3)	0.5	22.1	7.6
Amounts reclassified from AOCI	0.4	(15.1)	—	—	(14.7)
Net current period other comprehensive income (loss)	5.7	(35.4)	0.5	22.1	(7.1)
Balance, March 31, 2023	$ (10.0)	$ (20.3)	$ (0.6)	$ (141.1)	$ (172.0)

	March 31, 2022					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedges, Net of Tax[1]	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2021	$ (2.2)	$ 53.8	$ 25.5	$ (44.8)	$ (139.0)	$ (106.7)
Other comprehensive income (loss) before reclassifications	(10.2)	34.4	5.1	0.9	(21.8)	8.4
Amounts reclassified from AOCI	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)

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

The following table summarizes the amounts reclassified from AOCI:

	Amounts Reclassified from AOCI For the Three Months Ended March 31,		
(In millions)	2023	2022	Income Statement Location
Gains (losses) on securities available for sale	$ (0.5)	$ (0.6)	Other (income) expense
	0.1	0.1	Income tax (benefit) expense
Gains (losses) on cash flow hedges	17.6	20.9	Revenue
	(0.5)	(0.3)	Operating expense
	(0.1)	(0.1)	Other (income) expense
	(1.9)	(2.0)	Income tax (benefit) expense
Gains (losses) on net investment hedges[1]	—	(1.1)	Other (income) expense
Total reclassifications, net of tax	$ 14.7	$ 16.9	

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

12: ings 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)	2023	2022
Numerator:		
Net income attributable to Biogen Inc.	$ 387.9	$ 303.8
Denominator:		
Weighted average number of common shares outstanding	144.4	147.1
Effect of dilutive securities:		
Time-vested restricted stock units	0.6	0.3
Market stock units	0.1	0.1
Performance stock units settled in stock	0.1	0.1
Dilutive potential common shares	0.8	0.5
Shares used in calculating diluted earnings per share	145.2	147.6

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

13: e-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)	2023	2022
Research and development	$ 31.3	$ 25.7
Selling, general and administrative	50.1	46.1
Subtotal	81.4	71.8
Capitalized share-based compensation costs	(3.3)	(2.8)
Share-based compensation expense included in total cost and expense	78.1	69.0
Income tax effect	(14.7)	(12.8)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 63.4	$ 56.2

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)	2023	2022
Market stock units	$ 2.2	$ 5.9
Time-vested restricted stock units	61.7	51.3
Performance stock units settled in stock	9.5	8.3
Performance stock units settled in cash	2.5	1.4
Employee stock purchase plan	4.7	4.9
Stock options[1]	0.8	—
Subtotal	81.4	71.8
Capitalized share-based compensation costs	(3.3)	(2.8)
Share-based compensation expense included in total cost and expense	$ 78.1	$ 69.0

[1] During the fourth quarter of 2022 we granted stock options. For additional information, please read *Note 16, Share-Based Payments*, to our consolidated financial statements included in our 2022 Form 10-K.

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: me Taxes

Inflation Reduction Act

In August 2022 the IRA was signed into law in the U.S. The IRA introduced new tax provisions, including a 15.0% corporate alternative minimum tax and a 1.0% excise tax on stock repurchases. The provisions of the IRA are effective for periods after December 31, 2022. The IRA did not result in any material adjustments to our income tax provision or net deferred tax assets as of March 31, 2023 and December 31, 2022. We expect additional guidance and regulations to be issued in future periods and will continue to assess its potential impact on our business and results of operations as further information becomes available.

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,	
	2023	2022
Statutory rate	21.0%	21.0%
State taxes	1.3	(0.4)
Taxes on foreign earnings	(5.6)	(10.8)
Tax credits	(6.6)	(2.5)
Purchased intangible assets	0.4	0.6
GILTI	0.5	0.3
Neurimmune tax impacts	—	24.2
Other	0.6	3.8
Effective tax rate	11.6%	36.2%

Changes in Tax Rate

For the three months ended March 31, 2023, compared to the same period in 2022, the decrease in our effective tax rate, excluding the impact of the net Neurimmune deferred tax asset, as discussed below, includes the resolution of an uncertain tax matter in the current quarter related to tax credits 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 are recorded discretely since changes in value of equity investments cannot be forecasted.

Neurimmune Deferred Tax Asset

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an increase in a valuation allowance of approximately $85.0 million to reduce the net value of a previously recorded deferred tax asset to zero.

This adjustment to our net deferred tax asset is recorded with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

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

Accounting for Uncertainty in Income Taxes

We and our subsidiaries are routinely examined by various taxing authorities. We file income tax returns in various U.S. states and in U.S. federal and other foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal tax examination for years before 2017 or state, local or non-U.S. income tax examinations for years before 2013.

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 $450.0 million related to the unrecognized tax benefits related to Neurimmune's tax basis in ADUHELM, as discussed above, in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations. Any changes to our gross unrecognized tax benefits related to Neurimmune's tax basis in ADUHELM would result in a zero net impact to net income attributable to Biogen, Inc., as we have recorded a full valuation allowance against the relevant deferred tax assets.

15: r 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)	2023	2022
Interest income	$ (80.9)	$ (2.9)
Interest expense	62.5	66.1
(Gains) losses on investments, net	77.7	191.1
Foreign exchange (gains) losses, net	10.7	8.3
Other, net	(0.6)	0.7
Total other (income) expense, net	$ 69.4	$ 263.3

The (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 relate to our equity securities held during the following periods:

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Net (gains) losses recognized on equity securities	$ 78.1	$ 190.7
Less: Net (gains) losses realized on equity securities	1.6	(0.2)
Net unrealized (gains) losses recognized on equity securities	$ 76.5	$ 190.9

The net unrealized losses recognized during the three months ended March 31, 2023, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sangamo and Ionis common stock of approximately $100.0 million, partially offset by an increase in the fair value of Sage common stock of approximately $23.8 million.

The net unrealized losses recognized during the three months ended March 31, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sage and Sangamo common stock of approximately $205.5 million, partially offset by an increase in the fair value of Ionis common stock of approximately $19.0 million.

Accrued Expense and Other

Accrued expense and other consists of the following:

(In millions)	As of March 31, 2023	As of December 31, 2022
Revenue-related reserves for discounts and allowances	$ 907.2	$ 891.6
Employee compensation and benefits	187.2	395.6
Collaboration expense	265.5	277.9
Royalties and licensing fees	183.9	209.4
Other	744.4	746.9
Total accrued expense and other	$ 2,288.2	$ 2,521.4

Other Long-term Liabilities

Other long-term liabilities were $935.5 million and $944.2 million as of March 31, 2023 and December 31, 2022, respectively, and included accrued income taxes totaling $552.5 million and $541.7 million, respectively.

16: borative and Other Relationships

Genentech, Inc. (Roche Group)

We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, 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 PPMS and RMS; LUNSUMIO (mosunetuzumab), which was granted accelerated approval in the U.S. during the fourth quarter of 2022 for the treatment of relapsed or refractory follicular lymphoma; glofitamab, an investigational bispecific antibody for the potential treatment of non-Hodgkin's lymphoma; and have the option to add other potential anti-CD20 therapies, pursuant to our collaboration arrangements with Genentech, a wholly-owned member of the Roche Group. For purposes of this footnote, we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

RITUXAN

Genentech and its affiliates are responsible for the worldwide manufacture of RITUXAN as well as all development and commercialization activities as follows:

- *U.S.:* We have co-exclusively licensed our rights to develop, commercialize and market RITUXAN in the U.S.
- *Canada:* We have co-exclusively licensed our rights to develop, commercialize and market RITUXAN in Canada.

GAZYVA

The Roche Group and its sub-licensees maintain sole responsibility for the development, manufacture and commercialization of GAZYVA in the U.S. The level of gross sales of GAZYVA in the U.S. has impacted our percentage of the co-promotion profits for RITUXAN and LUNSUMIO, as summarized in the table below.

OCREVUS

Pursuant to the terms of our collaboration arrangements with Genentech, we receive a tiered royalty on U.S. net sales from 13.5% and increasing up to 24.0% if annual net sales exceed $900.0 million. There will be a 50.0% reduction to these royalties if a biosimilar to OCREVUS is approved in the U.S.

In addition, we receive a gross 3.0% royalty on net sales of OCREVUS outside the U.S., with the royalty period lasting 11 years from the first commercial sale of OCREVUS on a country-by-country basis.

The commercialization of OCREVUS does not impact the percentage of the co-promotion profits we receive for RITUXAN, LUNSUMIO or GAZYVA. Genentech is solely responsible for development and commercialization of OCREVUS and funding future costs. Genentech cannot develop OCREVUS in CLL, non-Hodgkin's lymphoma or rheumatoid arthritis.

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.

LUNSUMIO (mosunetuzumab)

In January 2022 we exercised our option with Genentech to participate in the joint development and commercialization of LUNSUMIO. Under our collaboration with Genentech, we were responsible for 30.0% of development costs for LUNSUMIO prior to FDA approval and will be entitled to a tiered share of co-promotion operating profits and losses in the U.S., as summarized in the table below. In addition, we receive low single-digit royalties on sales of LUNSUMIO outside the U.S.

In December 2022 LUNSUMIO was granted accelerated approval by the FDA for the treatment of relapsed or refractory follicular lymphoma. Prior to regulatory approval, we record our share of the expense incurred by the collaboration for the development of anti-CD20 products in research and development expense and pre-commercialization costs within selling, general and administrative expense in our condensed consolidated statements of income. After an anti-CD20 product is approved, we record our share of the development and sales and marketing expense related to that product as a reduction of our share of pre-tax profits in revenue from anti-CD20 therapeutic programs.

Profit-sharing Formulas

RITUXAN and LUNSUMIO Profit Share

Our current pretax co-promotion profit-sharing formula for RITUXAN and LUNSUMIO in the U.S. provides for a 30.0% share on the first $50.0 million of combined co-promotion operating profits earned each calendar year. As a result of the FDA approval of LUNSUMIO our share of the combined annual co-promotion profits for RITUXAN and LUNSUMIO in excess of $50.0 million varies upon the following events, as summarized in the table below:

After LUNSUMIO Approval until the First Threshold Date	37.5 %
After First Threshold Date until the Second Threshold Date	35.0 %
After Second Threshold Date	30.0 %

First Threshold Date means the earlier of (i) the first day of the calendar quarter following the date U.S. gross sales of GAZYVA within any consecutive 12-month period have reached $500.0 million or (ii) the first date in any calendar year in which U.S. gross sales of LUNSUMIO have reached $150.0 million.

Second Threshold Date means the later of (i) the first date the gross sales in any calendar year in which U.S. gross sales of LUNSUMIO reach $350.0 million and (ii) January 1 of the calendar year following the calendar year in which the First Threshold Date occurs.

In March 2023 the First Threshold Date was achieved. As a result, beginning in April 2023 the pre-tax profit share for RITUXAN and LUNSUMIO will be 35.0%.

GAZYVA Profit Share

Our current pretax profit-sharing formula for GAZYVA provides for a 35.0% share on the first $50.0 million of operating profits earned each calendar year. Our share of annual co-promotion profits in excess of $50.0 million varies upon the following events, as summarized in the table below:

Until Second GAZYVA Threshold Date	37.5 %
After Second GAZYVA Threshold Date	35.0 %

Second GAZYVA Threshold Date means the first day of the calendar quarter following the date U.S. gross sales of GAZYVA within any consecutive 12-month period have reached $500.0 million. The second GAZYVA threshold date can be achieved regardless of whether GAZYVA has been approved in a non-CLL indication.

In March 2023 the Second GAZYVA Threshold Date was achieved. As a result, beginning in April 2023 the pre-tax profit share for GAZYVA will be 35.0%.

Eisai Co., Ltd.

As of March 31, 2023, we accrued a $31.0 million payable to Eisai related to the termination of an agreement whereby Eisai co-promoted or distributed our MS products in certain Asia-Pacific markets and settings. The termination fee is included in selling, general and administrative expense in our condensed consolidated statements of income for the three months ended March 31, 2023.

LEQEMBI (lecanemab) Collaboration

We have a collaboration agreement with Eisai to jointly develop and commercialize LEQEMBI (lecanemab), an anti-amyloid antibody for the potential treatment of Alzheimer's disease (the LEQEMBI Collaboration).

Eisai serves as the lead of LEQEMBI 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. Upon LEQEMBI marketing approval, we and Eisai will co-promote LEQEMBI and share profits and losses equally. We currently manufacture LEQEMBI drug substance and drug product and in March 2022 we extended our supply agreement with Eisai related to LEQEMBI from five years to ten years for the manufacture of LEQEMBI drug substance.

In January 2023 the FDA granted accelerated approval of LEQEMBI, which became commercially available in the U.S. during the first quarter of 2023. Upon commercialization, we began recognizing commercial profits and losses related to the LEQEMBI Collaboration Agreement on a net basis. As we are not the principal on sales transactions related to LEQEMBI, our 50.0% share of the revenue and operating expense is recorded on a net basis in revenue from LEQEMBI Collaboration, which is a separate component of revenue within our condensed consolidated statements of income.

For the three months ended March 31, 2023, we recognized a reduction to revenue of approximately $18.9 million, reflecting our net profit-share of the LEQEMBI Collaboration results in the U.S. This amount is included in revenue from LEQEMBI Collaboration within our condensed consolidated statements of income.

During the first quarter of 2023, upon commercialization of LEQEMBI, we began recognizing our share of U.S. revenue, cost of sales and selling and marketing expense in revenue from LEQEMBI Collaboration within our condensed consolidated income statements. Our share of LEQEMBI development expense will continue to be recorded within research and development expense and, until commercial approval on a region by region basis, non-U.S. selling and marketing expense will continue to be recorded in selling, general and administrative expense within our condensed consolidated statements of income. A summary of development and sales and marketing expense related to the LEQEMBI Collaboration is as follows:

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Total development expense incurred by the collaboration related to the advancement of LEQEMBI	$ 107.9	$ 77.0
Biogen's share of the LEQEMBI Collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	54.0	38.5
Total sales and marketing expense incurred by the LEQEMBI Collaboration[1]	10.5	15.9
Biogen's share of the LEQEMBI Collaboration sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income[1]	5.3	8.0

[1] Beginning in the first quarter of 2023 reimbursement to Eisai for our share of U.S. LEQEMBI selling, general and administrative expense is recognized in revenue from LEQEMBI Collaboration within our condensed consolidated statements of income.

ADUHELM Collaboration Agreement

The LEQEMBI Collaboration also provided Eisai with an option to jointly develop and commercialize ADUHELM (aducanumab) (ADUHELM Option). In October 2017 Eisai Exercised its ADUHELM Option and we entered into a new collaboration agreement for the joint development and commercialization of ADUHELM (the ADUHELM Collaboration Agreement).

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 in 2019, Eisai was reimbursing us for 45.0% of development and sales and marketing expense incurred by the collaboration for the advancement of ADUHELM.

In March 2022 we amended our ADUHELM Collaboration Agreement with Eisai. As of the amendment date, we have sole decision making and commercialization rights worldwide on ADUHELM, and beginning January 1, 2023, Eisai receives only a tiered royalty based on net sales of ADUHELM, and no longer participates in sharing ADUHELM's global profits and losses. Eisai's share of development, commercialization and manufacturing expense was limited to $335.0 million for the period from January 1, 2022 to December 31, 2022, which was achieved as of December 31, 2022. Once this limit was achieved, we became responsible for all ADUHELM related costs.

A summary of development expense and sales and marketing expense related to our initial ADUHELM Collaboration Agreement is as follows:

(In millions)	For the Three Months Ended March 31, 2022
Total ADUHELM Collaboration development expense	$ 44.2
Biogen's share of ADUHELM Collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	24.3
Total sales and marketing expense incurred by the ADUHELM Collaboration Agreement	95.0
Biogen's share of ADUHELM Collaboration sales and marketing expense reflected in selling, general and administrative expense and collaboration profit sharing/(loss reimbursement) in our condensed consolidated statements of income	50.9

ADUHELM Co-promotion Profits and Losses

Under our initial ADUHELM Collaboration Agreement, we recognized revenue on sales of ADUHELM in the U.S. to third parties as a component of product revenue in our condensed consolidated statements of income. We also recorded the related cost of revenue and sales and marketing expense in our condensed consolidated statements of income as these costs were incurred. Payments made to and received from Eisai for its 45.0% share of the co-promotion profits or losses in the U.S. were recognized in collaboration profit sharing/(loss reimbursement) 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 approximately $181.7 million to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

During the first quarter of 2022, as a result of the final NCD, we recorded approximately $275.0 million of charges associated with the write-off of inventory and purchase commitments in excess of forecasted demand related to ADUHELM. Additionally, for the three months ended March 31, 2022, we recorded approximately $45.0 million of aggregate gross idle capacity charges related to ADUHELM. These charges were recorded in cost of sales within our condensed consolidated statements of income. We recognized approximately $160.0 million related to Eisai's 45.0% share of these charges in collaboration profit sharing/(loss reimbursement) within our condensed consolidated statements of income for the three months ended March 31, 2022.

Amounts receivable from Eisai related to the agreements discussed above were approximately $72.6 million and $88.0 million as of March 31, 2023 and December 31, 2022, respectively. Amounts payable to Eisai related to the agreements discussed above were $137.8 million and $81.2 million as of March 31, 2023 and December 31, 2022, respectively.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2022 Form 10-K.

UCB

We have a collaboration agreement with UCB, effective November 2003, to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of SLE 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. If marketing approval is obtained, both companies will co-promote dapirolizumab pegol and share profits and losses equally.

A summary of development expense related to the UCB collaboration agreement is as follows:

(In millions)	For the Three Months Ended March 31, 2023	2022
Total UCB collaboration development expense	$ 18.3	$ 17.6
Biogen's share of UCB collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	9.2	8.8

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage to jointly develop and commercialize zuranolone for the potential treatment of MDD and PPD 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. We may pay Sage milestones totaling $225.0 million upon the first commercial sale of zuranolone, for the potential treatment of MDD and PPD, in the U.S.

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

(In millions)	For the Three Months Ended March 31, 2023	2022
Total Sage collaboration development expense	$ 34.8	$ 38.7
Biogen's share of Sage collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	17.4	19.4
Total Sage sales and marketing expense incurred by the collaboration	38.2	18.4
Biogen's share of Sage collaboration sales and marketing expense reflected in selling, general and administrative expense in our condensed consolidated statements of income	19.1	9.2

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 LRRK2 for Parkinson's disease. In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its 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. In April 2023 we exercised our option with Denali to license the ATV-enabled anti-amyloid beta program. In connection with this exercise, we will assume responsibility for all development and commercial activities and associated expenses related to the program. In addition, we will make a one-time option exercise payment to Denali and, should certain milestones be achieved, may pay Denali additional development and commercial milestone payments and royalties based on future net sales.

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.

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

(In millions)	For the Three Months Ended March 31, 2023	2022
Total Denali collaboration development expense	$ 16.6	$ 14.9
Biogen's share of Denali collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	10.0	8.9

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.

In March 2023 we terminated our collaboration and license agreement with Sangamo.

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

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Total Sangamo collaboration development expense	$ 5.1	$ 8.3
Biogen's share of Sangamo collaboration development expense reflected in research and development expense in our condensed consolidated statements of income	2.3	5.5

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

In July 2021 we entered into a collaboration and license agreement with InnoCare Pharma Limited for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor for the potential treatment of MS. This license and collaboration agreement was later terminated in February 2023.

For the three months ended March 31, 2023, we recorded $0.2 million as research and development expense in our condensed consolidated statements of income related to other research and discovery related arrangements, compared to $19.5 million in the prior year comparative period.

Samsung Bioepis Co., Ltd.

2019 Development and Commercialization Agreement

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, BYOOVIZ (ranibizumab-nuna), a ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. Samsung Bioepis will be responsible for development and will supply both products to us at a pre-specified gross margin of approximately 45.0%.

In connection with this transaction, we 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 in our condensed consolidated statements of income and record the related cost of revenue and sales and marketing expense in our condensed consolidated statements of income to their respective line items when these costs are incurred.

We share 50.0% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit sharing/(loss reimbursement) in our condensed consolidated statements of income. For the three months ended March 31, 2023, we recognized net profit-sharing expense of $57.1 million to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits, compared to a net profit-sharing expense of $64.4 million in the prior year comparative period.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a license agreement with Samsung Bioepis. Under the license agreement, we granted Samsung Bioepis an exclusive license to use, develop, manufacture and commercialize biosimilar products created by Samsung Bioepis using Biogen product-specific technology. In exchange, we receive single digit royalties on biosimilar products developed and commercialized by

Samsung Bioepis. Royalty revenue under the license agreement is recognized as a component of contract manufacturing, royalty and other revenue in our condensed consolidated statements of income.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were $6.3 million and $2.0 million as of March 31, 2023 and December 31, 2022, respectively. Amounts payable to Samsung Bioepis related to the agreements discussed above were $32.2 million and $40.5 million as of March 31, 2023 and December 31, 2022, respectively.

For additional information on our collaboration arrangements with Samsung Bioepis and our other significant collaboration arrangements, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in our 2022 Form 10-K.

17: stments 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. Our royalty rates payable on products developed under the Neurimmune Agreement, including royalty rates payable on commercial sales of ADUHELM, range from the high single digits to sub-teens.

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an increase in a valuation allowance of approximately $85.0 million to reduce the net value of a previously recorded deferred tax asset to zero. This adjustment to our net deferred tax asset is 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.

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, 2023 and December 31, 2022, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $28.0 million and $27.8 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

We have also entered into research collaboration agreements with certain variable interest entities where we are required to fund certain development activities. These development activities are included in research and development expense in our condensed consolidated statements of income as they are incurred. We have provided no financing to these variable interest entities other than previous contractually required amounts.

For additional information on our investments in Neurimmune and other variable interest entities, please read *Note 20, Investments in Variable Interest Entities,* to our consolidated financial statements included in our 2022 Form 10-K.

18: ation

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 2022 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. If an estimate of the possible loss or range of loss can be made at this time, it is included in the potential loss contingency description below.

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

In March 2023 the United States District Court for the District of Massachusetts (the District Court) dismissed the previously disclosed shareholder action related to ADUHELM that had been filed in February 2022 against us and certain current and former officers. The second previously disclosed shareholder action related to ADUHELM, filed in November 2022 and dismissed by the District Court in September 2021, remains on appeal to the U.S. Court of Appeals for the First Circuit. Both actions alleged violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5.

Derivative Action

We and members of the Board of Directors are named as defendants in derivative actions filed by shareholders in February and July 2022, in the U.S. District Court for the District of Massachusetts. The actions allege violations of federal securities laws under 15 U.S.C. §78n(a) and 17 C.F.R. §240 14.a-9, and breaches of fiduciary duties and waste of corporate assets, and seek declaratory and injunctive relief, monetary relief payable to Biogen, and attorneys' fees and costs payable to the plaintiffs. The District Court has stayed both cases.

IMRALDI Patent Litigation

In June 2022 Fresenius Kabi Deutschland GmbH (Fresenius Kabi) filed a claim for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris, alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis that Biogen commercializes in Europe, infringes the French counterpart of European Patent 3 145 488 (the EP '488 Patent), which expires in May 2035. In August 2022 Fresenius Kabi filed a claim for damages and injunctive relief against Biogen GmbH in the Düsseldorf Regional Court, alleging infringement of the German counterpart of the EP '488 Patent. A hearing in the Düsseldorf Regional Court has been set for December 2023. No hearing has been set in the French action.

In July 2019 Gedeon Richter Nyrt (Gedeon Richter) filed a claim 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 (the EP '667 Patent), which expires in October 2035. The case has been stayed pending review by the TBA of the EPO of the EPO's decision revoking the '667 Patent. The TBA has set a hearing for July 2023.

In November 2020 Gedeon Richter filed a claim for damages and injunctive relief against Biogen GmbH in the Düsseldorf Regional Court, alleging infringement of a German utility model corresponding to the EP '667 Patent, which expires in October 2025. The proceeding has been stayed pending the outcome of proceedings that Biogen has filed in the German Patent and Trademark Office to cancel the utility model, and the utility model was cancelled in March 2023.

Dispute with Former Convergence Shareholders

In 2015 Biogen acquired Convergence, a U.K. company. 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.

Humana Patient Assistance Litigation

In March 2023 the District Court for the District of Massachusetts dismissed the previously disclosed action filed against us by Humana in September 2020. Humana had alleged damages related to our providing MS patients with free medications and making charitable contributions to non-profit organizations that assist MS patients and had alleged violations of the federal RICO Act and state laws.

Distributor Matter

In December 2022 we terminated our distribution agreement with the distributor of products for Biogen in various countries in the Middle East and northern Africa. The former distributor has asserted breach of contract. No suit has been filed.

Genentech Litigation

In February 2023 Genentech, Inc. filed suit against us in the U.S. District Court for the Northern District of California, alleging that it is owed royalties on sales of TYSABRI that occurred after the expiration of a patent licensed by Genentech to Biogen, together with interest and costs. No trial date has been set.

Other Matters

Government Investigation

The Company has received subpoenas from the Securities and Exchange Commission seeking information relating to ADUHELM, including healthcare sites and ADUHELM's approval.

TYSABRI Biosimilar Patent Matter

In September 2022, following Sandoz Inc.'s announcement that the FDA had accepted its biologics license application for a proposed biosimilar referring to TYSABRI, we filed an action in the U.S. District Court for the District of Delaware against Sandoz Inc., other Sandoz entities and Polpharma Biologics S.A. under the Biologics Price Competition and Innovation Act, 42 U.S.C. §262, seeking a declaratory judgment of patent infringement. No trial has been set.

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

Pharmaceutical Works Polpharma and Mylan Ireland each filed actions in the General Court of the European Union (the General Court) (Polpharma in October 2018 and Mylan Ireland in November 2020) to annul the EMA's 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. On March 16, 2023, the European Court of Justice set aside the judgment of the General Court and dismissed Polpharma's action.

Product Liability and Other Legal Proceedings

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements (condensed consolidated financial statements) and the accompanying notes beginning on page 7 of this quarterly report on Form 10-Q and our audited consolidated financial statements and the accompanying notes included in our 2022 Form 10-K.

EXECUTIVE SUMMARY

INTRODUCTION

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering innovative therapies for people living with serious and complex diseases worldwide. We have a broad portfolio of medicines to treat MS, have introduced the first approved treatment for SMA and co-developed two treatments to address a defining pathology of Alzheimer's disease. We are focused on advancing our pipeline in neurology, neuropsychiatry, specialized immunology and rare diseases. We support our drug discovery and development efforts through internal research and development programs and external collaborations.

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 also collaborate with Eisai on the commercialization of LEQEMBI for the treatment of Alzheimer's disease, which was granted accelerated approval by the FDA in January 2023. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, 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 PPMS and RMS; LUNSUMIO, which was granted accelerated approval in the U.S. during the fourth quarter of 2022 for the treatment of relapsed or refractory follicular lymphoma; glofitamab, an investigational bispecific antibody for the potential treatment of non-Hodgkin's lymphoma; and have the option to add other potential anti-CD20 therapies, pursuant to our collaboration arrangements with Genentech, a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships,* to our audited consolidated financial statements included in our 2022 Form 10-K.

In addition to continuing to invest in new potential innovation in MS and SMA we are advancing our mid-to-late stage programs including zuranolone for MDD and PPD, BIIB080 for Alzheimer's disease, QALSODY (tofersen) for ALS and both litifilimab and dapirolizumab pegol for certain forms of lupus.

We also commercialize biosimilars of advanced biologics including BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe, as well as BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in the U.S. We continue to develop potential biosimilar products including BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, and SB15, a proposed aflibercept biosimilar referencing EYLEA. In February 2023 we announced that we are exploring strategic options for our biosimilars business.

For additional information on our collaboration arrangements, 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 GMP multi-product license from the SWISSMEDIC. Solothurn has been approved for the manufacture of ADUHELM and LEQEMBI by the FDA. In the second quarter of 2021 a portion of the Solothurn manufacturing facility was placed into service and we estimate the second manufacturing suite will be operational by the end of 2023. We believe that the Solothurn facility will support our anticipated near-term needs for the manufacturing of biologic assets. If we are unable to fully utilize our manufacturing facilities, due to lower than forecasted demand for our products, we will incur excess capacity charges which will have a negative effect on our financial condition and results of operations.

Our revenue depends upon continued sales of our products as well as the financial rights we have in our anti-CD20 therapeutic programs, and, unless we develop, acquire rights to and/or commercialize new products and

technologies, we will be substantially dependent on sales from our products and our financial rights in our anti-CD20 therapeutic programs for many years.

In the longer term, our revenue growth will depend upon the successful clinical development, regulatory approval and launch of new commercial products as well as additional indications for our existing products, our ability to obtain and maintain patents and other rights related to our marketed products, assets originating from our research and development efforts and/or successful execution of external business development opportunities.

BUSINESS ENVIRONMENT

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. In addition, the commercialization of certain of our own approved products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing products.

Our products and revenue streams continue to face increasing competition in many markets from generic versions, prodrugs and biosimilars of existing products as well as products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products. Accordingly, the introduction of such products as well as other lower-priced competing products may significantly reduce both the price that we are able to charge for our products and the volume of products we sell, which will negatively impact our revenue. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time.

Sales of our products depend, to a significant extent, on the availability and extent of adequate coverage, pricing and reimbursement from government health administration authorities, private health insurers and other organizations. When a new pharmaceutical product is approved, the availability of government and private reimbursement for that product may be uncertain, as is the pricing and amount for which that product will be reimbursed.

Drug prices are under significant scrutiny in the markets in which our products are prescribed, for example the IRA has certain provisions related to drug pricing. 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, supply chain disruptions, 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 2022 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.

TECFIDERA

Multiple TECFIDERA generic entrants are now in North America, Brazil and certain E.U. countries and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue and we expect that TECFIDERA revenue will continue to decline in the future.

In March 2023 the CJEU decided in favor of Biogen, the EMA and the EC in their appeal of a European General Court decision that had annulled the EMA's refusal to evaluate a generic version of TECFIDERA because of TECFIDERA's regulatory data and marketing protection. The CJEU set aside the General Court's judgment and dismissed the generic's action. On the basis of this favorable decision, we believe that TECFIDERA is entitled to regulatory marketing protection in the E.U. until at least February 4, 2024, and are seeking to enforce this protection. In addition, we will continue to enforce our EP 2 653 873 patent related to TECFIDERA, which expires in 2028.

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)* below.

BUSINESS UPDATE REGARDING MACROECONOMIC CONDITIONS AND OTHER DISRUPTIONS

Significant portions of our business are conducted in Europe, Asia and other international geographies. Factors such as the COVID-19 pandemic and other global health outbreaks, adverse weather events, geopolitical events, inflation, 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. Additionally, global disputes and interruptions in international relationships, including tariffs, trade protection measures, import or export licensing requirements and the imposition of trade sanctions or similar restrictions by the U.S. or other governments, affect our ability to do business. For example, tensions between the U.S. and China have led to a series of tariffs and sanctions being imposed by the U.S. on imports from China mainland, as well as other business restrictions.

CURRENT ECONOMIC CONDITIONS

Economic conditions remain vulnerable as markets continue to be impacted in part by elevated inflation, rising interest rates, global supply chain constraints and recent bank failures.

Recently, concerns have arisen with respect to the financial condition of a number of banking institutions in the U.S., in particular those with exposure to certain types of depositors and large portfolios of investment securities. Additionally, in March 2023 SVB and Signature Bank were closed and taken over by the FDIC, which created significant market disruption and uncertainty with respect to the financial condition of a number of banking institutions in the U.S., in particular those with exposure to certain types of depositors and large portfolios of investment securities. While we do not have any direct exposure to SVB or Signature Bank, we do maintain our cash at financial institutions, often in balances that exceed the current FDIC insurance limits, and will continue to monitor our cash, cash equivalents and investments and take steps to identify any potential impact and minimize any disruptions on our business.

If other banks and financial institutions enter receivership or become insolvent in the future due to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments, including transferring funds, making payments or receiving funds, may be threatened and could have a material adverse effect on our business and financial condition.

GEOPOLITICAL TENSIONS

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. In addition, new government sanctions on the export of certain manufacturing materials to Russia may delay or limit our ability to get new products approved.

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, 2023 and the year ended December 31, 2022.

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.

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.

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

INFLATION REDUCTION ACT OF 2022

In August 2022 the IRA was signed into law in the U.S. The IRA introduced new tax provisions, including a 15.0% corporate alternative minimum tax and a 1.0% excise tax on stock repurchases. The provisions of the IRA are effective for periods after December 31, 2022. The IRA did not result in any material adjustments to our income tax provision or net deferred tax assets as of March 31, 2023 and December 31, 2022. We expect additional guidance and regulations to be issued in future periods and will continue to assess its potential impact on our business and results of operations as further information becomes available.

The IRA also contains substantial drug pricing reforms that may have a significant impact on the pharmaceutical industry in the U.S. This includes allowing CMS to negotiate a maximum fair price for certain high-priced single source Medicare drugs, as well as redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, potentially resulting in higher contributions from plans and manufacturers. The IRA also establishes drug inflationary rebate requirements to penalize manufacturers from raising the prices of Medicare covered single-source drugs and biologics beyond the inflation-adjusted rate. Further, to incentivize biosimilar development, the IRA provides an 8.0% Medicare Part B add-on payment for qualifying biosimilar products for a five-year period.

The IRA's drug pricing controls and Medicare redesign may have an adverse impact on our sales (particularly for our products that are more substantially reliant on Medicare reimbursement), our business and our results of operations. However, the degree of impact from this legislation on our business depends on a number of implementation decisions. We will continue to assess as further information becomes available.

FINANCIAL HIGHLIGHTS

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, 2023, compared to the three months ended March 31, 2022, reflects the following:

TOTAL REVENUE

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Decreased
$68.8 million or 2.7%

DILUTED EARNINGS PER SHARE

549755815787

Increased
$0.61 or 29.6%

PRODUCT REVENUE

549755813894

Decreased
$303.0 million or 14.7%

- MS revenue decreased $269.3 million, or 19.3%
- SMA revenue decreased $29.2 million, or 6.2%

- The decrease in MS product revenue was primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in North America, Brazil and certain E.U. countries, a decrease in Interferon demand due to competition as patients transition to higher efficacy therapies, pricing pressure and unfavorable channel dynamics in the U.S.
- The decrease in SPINRAZA revenue was primarily due to a decrease in U.S. sales volumes resulting from unfavorable channel dynamics and the impact of loading dose dynamics. Rest of world SPINRAZA revenue also decreased due to the unfavorable impact of foreign currency exchange and a decrease in sales volumes resulting from increased competition in certain established markets. The decrease was partially offset by sales volume growth in certain Asian markets and the timing of shipments.

TOTAL COST AND EXPENSE

549755813894

Decreased
$159.7 million or 7.3%

- Cost of sales decreased $91.1 million, or 12.1%
- SG&A expense decreased $29.9 million, or 4.7%

- The decrease in cost of sales was primarily due to the write-off of approximately $275.0 million during the first quarter of 2022 related to ADUHELM inventory. The decrease was partially offset by higher cost of sales associated with contract manufacturing revenue, in part related to Eisai for LEQEMBI, which we began recognizing in the first quarter of 2023 upon commercialization.
- The decrease in selling, general and administrative expense was primarily due to cost-reduction measures realized in the first quarter of 2023, partially offset by investments to support new product launches and a $31.0 million obligation to Eisai related to the termination of the co-promotion agreement for our MS products in Japan.

FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

- We generated $455.3 million of net cash flow from operations for the three months ended March 31, 2023.
- Cash, cash equivalents and marketable securities totaled approximately $6,019.5 million as of March 31, 2023.
- There were no share repurchases of our common stock during the first quarter of 2023 under our 2020 Share Repurchase Program. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of March 31, 2023.

RECENT DEVELOPMENTS

DEVELOPMENTS IN KEY COLLABORATIVE RELATIONSHIPS

LEQEMBI (lecanemab)

In January 2023 the FDA granted accelerated approval of LEQEMBI, an anti-amyloid antibody for the treatment of Alzheimer's disease. Additionally, in January 2023 we and Eisai announced the completed submission of a supplemental BLA to the FDA for traditional approval of LEQEMBI. In March 2023 the FDA accepted the supplemental BLA and granted Priority Review for LEQEMBI, with an Advisory Committee meeting scheduled for June 9, 2023, and a PDUFA action date of July 6, 2023.

In March 2023 Eisai announced that the U.S. Veteran's Health Administration will be providing coverage of LEQEMBI to veterans living with early stages of Alzheimer's disease.

In January 2023 the EMA accepted for review the MAA for lecanemab. In January 2023 Eisai completed the submission of a MAA to the PMDA in Japan for lecanemab, which was granted Priority Review by the Japanese Ministry of Health, Labor and Welfare. Additionally, in February 2023 the BLA for lecanemab was granted Priority Review by the NMPA of China.

Zuranolone

In February 2023 the FDA accepted the NDA and granted Priority Review for zuranolone, with a PDUFA action date of August 5, 2023.

OTHER KEY DEVELOPMENTS

QALSODY (tofersen)

In April 2023 the FDA approved QALSODY for the treatment of ALS in adults who have a mutation in the SOD1 gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

TECFIDERA

In March 2023 the CJEU decided in favor of Biogen, the EMA and the EC in their appeal of a European General Court decision that had annulled the EMA's refusal to evaluate a generic version of TECFIDERA because of TECFIDERA's regulatory data and marketing protection. The CJEU set aside the General Court's judgment and dismissed the generic's action. On the basis of this favorable decision, we believe that TECFIDERA is entitled to regulatory marketing protection in the E.U. until at least February 4, 2024, and are seeking to enforce this protection.

BIIB093

In April 2023 we announced that we will be terminating our involvement in the development of BIIB093 (glibenclamide IV), currently in a Phase 3 study for large hemispheric infarction and a Phase 2 study for brain contusion, due to operational challenges and other strategic considerations.

BIIB131

In April 2023 we announced that we will be pausing the initiation of a Phase 2b study for BIIB131 (TMS-007) for acute ischemic stroke and will continue to assess whether to initiate this study.

BIIB132

In April 2023 we announced that we will be discontinuing further development of BIIB132 in spinocerebellar ataxia type 3, as part of our ongoing research and development prioritization initiative.

RESULTS OF OPERATIONS

REVENUE

The following revenue discussion should be read in conjunction with *Note 4, Revenue*, to our condensed consolidated financial statements included in this report.

Revenue is summarized as follows:

	For the Three Months Ended March 31,					
(In millions, except percentages)	2023		2022		$ Change	% Change
Product revenue:						
United States	$ 701.4	28.5 %	$ 875.2	34.6 %	$ (173.8)	(19.9)%
Rest of world	1,061.9	43.1	1,191.1	47.0	(129.2)	(10.8)
Total product revenue	1,763.3	71.6	2,066.3	81.6	(303.0)	(14.7)
Revenue from LEQEMBI Collaboration	(18.9)	(0.8)	—	—	(18.9)	nm
Revenue from anti-CD20 therapeutic programs	399.5	16.2	399.4	15.8	0.1	nm
Contract manufacturing, royalty and other revenue	319.1	13.0	66.1	2.6	253.0	382.8
Total revenue	$ 2,463.0	100.0 %	$ 2,531.8	100.0 %	$ (68.8)	(2.7)%

nm Not meaningful

PRODUCT REVENUE

Product revenue is summarized as follows:

	For the Three Months Ended March 31,									
	2023				2022					
(In millions)	United States	Rest of World	Total	% Total	United States	Rest of World	Total	% Total	$ Change	% Change
Multiple Sclerosis	$ 546.1	$ 579.1	$ 1,125.2	63.9 %	$ 709.1	$ 685.4	$ 1,394.5	67.5 %	$ (269.3)	(19.3)%
Spinal Muscular Atrophy	146.7	296.6	443.3	25.1	163.3	309.2	472.5	22.9	(29.2)	(6.2)
Biosimilars	8.2	184.2	192.4	10.9	—	194.3	194.3	9.4	(1.9)	(1.0)
Other[1]	0.4	2.0	2.4	0.1	2.8	2.2	5.0	0.2	(2.6)	(52.0)
Total product revenue	$ 701.4	$ 1,061.9	$ 1,763.3	100.0 %	$ 875.2	$ 1,191.1	$ 2,066.3	100.0 %	$ (303.0)	(14.7)%

(1) Other includes FUMADERM and ADUHELM.

MULTIPLE SCLEROSIS

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- Global TECFIDERA revenue decreased $135.4 million, from $409.9 million in 2022 to $274.5 million in 2023, or 33.0%, driven by a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in North America, Brazil and certain E.U. countries.
- Global Interferon revenue decreased $64.0 million, from $309.6 million in 2022 to $245.6 million in 2023, or 20.7%, driven by a decrease in sales volumes as patients transition to higher efficacy therapies, as well as pricing pressure and the unfavorable impact of channel dynamics in the U.S.
- U.S. VUMERITY revenue decreased $31.7 million, from $125.2 million in 2022 to $93.5 million in 2023, or 25.3%, primarily due to unfavorable channel dynamics and a favorable Medicaid-related sales adjustment in the first quarter of 2022 related to VUMERITY.
- Global TYSABRI revenue decreased $48.0 million, from $520.8 million in 2022 to $472.8 million in 2023, or 9.2%, primarily due to a decrease in U.S. TYSABRI revenue driven by higher discounts and allowances, increased competition and unfavorable channel dynamics.

MS revenue includes sales from TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA.

In 2023 we expect total MS revenue will continue to decline as a result of increasing competition for many of our MS products in both the U.S. and rest of world markets. We are also aware of a potential biosimilar entrant of TYSABRI that may enter the U.S. and European markets in 2023.

We believe that we have resolved previously reported manufacturing issues at our VUMERITY contract manufacturer. In addition, we are in the process of securing regulatory approval for a secondary source of supply. We do not anticipate a supply shortage in 2023 and are currently focused on rebuilding adequate inventory.

SPINAL MUSCULAR ATROPHY

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- U.S. SPINRAZA revenue decreased $16.6 million, from $163.3 million in 2022 to $146.7 million in 2023, or 10.2%, primarily due to a decrease in sales volumes resulting from unfavorable channel dynamics and the impact of loading dose dynamics.
- Rest of world SPINRAZA revenue decreased $12.6 million, from $309.2 million in 2022 to $296.6 million in 2023, or 4.1%, primarily due to the unfavorable impact of foreign currency exchange and a decrease in sales volumes resulting from increased competition in certain established markets, particularly Germany. The decrease was partially offset by sales volume growth in certain Asian markets and the timing of shipments.

SMA revenue includes sales from SPINRAZA.

BIOSIMILARS

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- **Biosimilar revenue decreased 1.0%, due to unfavorable pricing and the unfavorable impact of foreign currency exchange, offset by an increase in sales volumes related to the continued launch of BYOOVIZ in the U.S. and rest of world.**

Biosimilars revenue includes sales from BENEPALI, IMRALDI, FLIXABI and BYOOVIZ. BYOOVIZ launched in the U.S. in June 2022 and became commercially available in July 2022 through major distributors in the U.S. In the first quarter of 2023 BYOOVIZ became commercially available in Canada.

In 2023 we anticipate modest growth in revenue from our biosimilars business driven by the continued launch of BYOOVIZ in the U.S. and rest of world, offset in part by continued price reductions in certain markets.

We are currently working with our contract manufacturer for IMRALDI to address facility regulatory inspection deficiencies at two filling locations, which could impact supply and have an adverse impact on 2023 IMRALDI sales, if not resolved. Manufacturing of BENEPALI also utilizes one of these facilities and therefore could have an adverse impact on 2023 BENEPALI sales. We are working with our existing secondary supplier for BENEPALI with the aim to secure additional capacity.

REVENUE FROM LEQEMBI COLLABORATION

In January 2023 the FDA granted accelerated approval of LEQEMBI, which became commercially available in the U.S. during the first quarter of 2023. Upon commercialization, we began recognizing commercial profits and losses related to the LEQEMBI Collaboration Agreement on a net basis as a separate component of total revenue within our condensed consolidated income statements, as we are not the principal.

For the three months ended March 31, 2023, we recognized a reduction to revenue of approximately $18.9 million, reflecting our net profit-share of the LEQEMBI Collaboration results in the U.S.

In 2023 we anticipate we will continue to recognize a reduction to revenue, with commercial expense exceeding initial revenue.

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.

REVENUE FROM ANTI-CD20 THERAPEUTIC PROGRAMS

For purposes of this discussion, we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Royalty revenue on sales of OCREVUS	$ 283.6	$ 252.3
Biogen's share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO	112.5	143.2
Other revenue from anti-CD20 therapeutic programs	3.4	3.9
Total revenue from anti-CD20 therapeutic programs	$ 399.5	$ 399.4

For the three months ended March 31, 2023, compared to the same period in 2022, the increase in royalty revenue on sales of OCREVUS was primarily due to sales growth of OCREVUS in the U.S.

For the three months ended March 31, 2023, compared to the same period in 2022, the decrease in our share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO was primarily due to a decrease in sales volumes of RITUXAN in the U.S. resulting from competition from multiple biosimilar products. Beginning in April 2023 the pre-tax profit share for RITUXAN, GAZYVA and LUNSUMIO will decrease from 37.5% to 35.0%.

Prior to regulatory approval, we record our share of the expense incurred by the collaboration for the development of anti-CD20 products in research and development expense and pre-commercialization costs within selling, general and administrative expense in our condensed consolidated statements of income. After an anti-CD20 product is approved, we record our share of the development and sales and marketing expense related to that product as a reduction of our share of pre-tax profits in revenue from anti-CD20 therapeutic programs.

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 16, Collaborative and Other Relationships,* to our condensed consolidated financial statements included in this report.

CONTRACT MANUFACTURING, ROYALTY AND OTHER REVENUE

Contract manufacturing, royalty and other revenue and is summarized as follows:

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Contract manufacturing revenue	$ 306.9	$ 47.5
Royalty and other revenue	12.2	18.6
Total contract manufacturing, royalty and other revenue	$ 319.1	$ 66.1

For the three months ended March 31, 2023, compared to the same period in 2022, the increase in contract manufacturing revenue was primarily driven by higher volumes due to the timing of batch production, which includes batches related to LEQEMBI that we began recognizing in the first quarter of 2023 upon the accelerated approval of LEQEMBI 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.

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.

Reserves for discounts, contractual adjustments and returns that reduced gross product revenue are summarized as follows:

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Contractual adjustments	$ 629.9	$ 619.3
Discounts	181.2	165.2
Returns	4.5	1.5
Total discounts and allowances	$ 815.6	$ 786.0

For the three months ended March 31, 2023, reserves for discounts and allowances as a percentage of gross product revenue was 31.4% compared to 27.0% in the prior year comparative period.

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, 2023, compared to the same period in 2022, the increase in contractual adjustments was primarily due to higher managed care rebates, due in part to unfavorable changes in estimates and lower Medicaid rebates in the U.S. during the first quarter of 2022 driven by a favorable Medicaid-related sales

adjustment related to VUMERITY. This increase was partially offset by lower government rebates in the U.S. as a result of a contract pharmacy change made during the first quarter of 2023 related to our Interferons.

DISCOUNTS

Discounts include trade term discounts and wholesaler incentives.

For the three months ended March 31, 2023, compared to the same period in 2022, the increase in discounts was primarily driven by higher purchase discounts, partially offset by a decrease in gross sales of TECFIDERA.

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

COST AND EXPENSE

A summary of total cost and expense is as follows:

	For the Three Months Ended March 31,			
(In millions, except percentages)	2023	2022	$ Change	% Change
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 662.8	$ 753.9	$ (91.1)	(12.1)%
Research and development	570.6	551.7	18.9	3.4
Selling, general and administrative	605.0	634.9	(29.9)	(4.7)
Amortization and impairment of acquired intangible assets	50.2	66.9	(16.7)	(25.0)
Collaboration profit sharing/(loss reimbursement)	57.1	(117.3)	174.4	(148.7)
(Gain) loss on fair value remeasurement of contingent consideration	—	(7.1)	7.1	nm
Restructuring charges	9.6	38.1	(28.5)	(74.8)
Other (income) expense, net	69.4	263.3	(193.9)	(73.6)
Total cost and expense	$ 2,024.7	$ 2,184.4	$ (159.7)	(7.3)%

[nm] Not meaningful

COST OF SALES, EXCLUDING AMORTIZATION AND IMPAIRMENT OF ACQUIRED INTANGIBLE ASSETS

	For the Three Months Ended March 31,	
(In millions)	2023	2022
Product	$ 481.4	$ 551.3
Royalty	181.4	202.6
Total cost of sales	$ 662.8	$ 753.9

For the three months ended March 31, 2023, compared to the same period in 2022, product cost of sales decreased primarily due to a write-off of approximately $275.0 million during the first quarter of 2022 of excess inventory and purchase commitments related to ADUHELM. This decrease was partially offset by higher cost of sales associated with contact manufacturing revenue, in part related to Eisai for LEQEMBI, which we began recognizing in the first quarter of 2023 upon the accelerated approval of LEQEMBI in the U.S. Cost of sales as a percentage of revenue was adversely affected by LEQEMBI batches due to minimal margins.

Additionally, for the three months ended March 31, 2023, we recorded approximately $44.8 million of aggregate gross idle capacity charges. For the three months ended March 31, 2022, we recorded approximately $45.0 million of aggregate gross idle capacity charges related to ADUHELM.

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.

RESEARCH AND DEVELOPMENT

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Research and development expense, as a percentage of total revenue, was 23.2% and 21.8% for the three months ended March 31, 2023 and 2022. For the three months ended March 31, 2023, compared to the same period in 2022, the increase in research and development was primarily due to the increase in spending in the development of LEQEMBI for the treatment of Alzheimer's disease, litifilimab for the treatment of CLE and SLE, BIIB122 for the treatment of Parkinson's disease and BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, partially offset by lower milestone payments during the first quarter of 2023.

EARLY STAGE PROGRAMS
Q1 2023 vs. Q1 2022

The increase in early stage programs was driven by an increase in costs associated with:

- development of BIIB131 for the treatment of acute ischemic stroke;
- development of litifilimab for the treatment of CLE; and
- development of BIIB121 for the treatment of Angelman syndrome.

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

- discontinuation of BIIB078 for the treatment of Alzheimer's disease; and
- advancement of BIIB122 for the treatment of Parkinson's disease into late stage.

LATE STAGE PROGRAMS
Q1 2023 vs. Q1 2022

The decrease in late stage programs was driven by a decrease in costs associated with:

- advancement of LEQEMBI from late stage to marketed upon the accelerated approval of LEQEMBI in the U.S.; and
- **advancement of LUNSUMIO from late stage to marketed upon the accelerated approval of LUNSUMIO in the U.S.**

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

- advancement of litifilimab for the treatment of SLE into late stage;
- advancement of BIIB122 for the treatment of Parkinson's disease into late stage; and
- development of BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA.

MARKETED PROGRAMS
Q1 2023 vs. Q1 2022

The increase in marketed programs was driven by an increase in costs associated with:

- advancement of LEQEMBI from late stage to marketed upon the accelerated approval of LEQEMBI in the U.S.; and
- **increased spend in ADUHELM primarily due to change in our cost sharing arrangement with Eisai.**

A significant amount of our research and development costs consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as management costs, as well as depreciation, information technology and facility-based expenses. These costs are considered other research and development costs in the table above and are not allocated to a specific program or stage.

- **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.
- **Development stage:** based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same year.
- **Other research and development costs:** 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.

Excluding upfront payments, we expect our core research and development expense to modestly increase in 2023, 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.

SELLING, GENERAL AND ADMINISTRATIVE

For the three months ended March 31, 2023, compared to the same period in 2022, selling, general and administrative expense decreased approximately 4.7% primarily due to cost-reduction measures realized during 2023, partially offset by investments to support new product launches and a $31.0 million obligation to Eisai related to the termination of the co-promotion agreement for our MS products in Japan. Beginning in the first quarter of 2023 reimbursement to Eisai for our share of U.S. LEQEMBI selling, general and administrative expense is recognized in revenue from LEQEMBI Collaboration within our condensed consolidated statements of income.

We expect selling, general and administrative costs to continue to decline in 2023 due to the implementation of our cost saving initiatives.

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.

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 and VUMERITY products and other programs acquired through business combinations.

For the three months ended March 31, 2023, compared to the same period in 2022, the decrease in amortization and impairment of acquired intangible assets was primarily due to a lower rate of amortization for acquired intangible assets. For the three months ended March 31, 2023 and 2022, we had no impairment charges.

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

COLLABORATION PROFIT SHARING/(LOSS REIMBURSEMENT)

Collaboration profit sharing/(loss reimbursement) primarily includes Samsung Bioepis' 50.0% share of the profit or loss related to our biosimilars 2013 commercial agreement with Samsung Bioepis and Eisai's 45.0% share of income and expense in the U.S. related to the ADUHELM Collaboration Agreement. Beginning January 1, 2023, Eisai receives only a tiered royalty based on net sales of ADUHELM, and will no longer share global profits and losses.

For the three months ended March 31, 2023, we recognized net profit-sharing expense of $57.1 million to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits, compared to a net profit-sharing expense of $64.4 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 approximately $181.7 million to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

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

RESTRUCTURING CHARGES

2022 COST SAVING INITIATIVES

In December 2021 and May 2022 we announced our plans to implement a series of cost-reduction measures that when completed we expect may yield approximately $1.0 billion in expense savings. These savings are being achieved through a number of initiatives, including reductions to our workforce, the substantial elimination of our commercial ADUHELM infrastructure, the consolidation of certain real estate locations and operating efficiency gains across our selling, general and administrative and research and development functions.

Under these initiatives, we estimate we will incur total restructuring charges of approximately $135.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of March 31, 2023, approximately $28.0 million remained in our restructuring reserve and payments are expected to be made through 2026.

For the three months ended March 31, 2023 and 2022, we recognized $9.6 million and $38.1 million, respectively, of net pre-tax restructuring charges, of which approximately $7.1 million and $27.7 million, respectively, consisted of employee severance costs.

For additional information on our cost saving initiatives, please read *Note 3, Restructuring,* to our condensed consolidated financial statements included in this report.

OTHER (INCOME) EXPENSE, NET

For the three months ended March 31, 2023, compared to the same period in 2022, 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, 2023, net unrealized losses and realized losses on our holdings in equity securities were approximately $76.5 million and $1.6 million, respectively, compared to net unrealized losses and realized gains of approximately $190.9 million and $0.2 million, respectively, in the prior year comparative period.

The net unrealized losses recognized during the three months ended March 31, 2023, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sangamo and Ionis common stock of approximately $100.0 million, partially offset by an increase in the fair value of Sage common stock of approximately $23.8 million.

The net unrealized losses recognized during the three months ended March 31, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali, Sage and Sangamo common stock of approximately $205.5 million, partially offset by an increase in the fair value of Ionis common stock of approximately $19.0 million.

INCOME TAX PROVISION

	For the Three Months Ended March 31,	
(In millions, except percentages)	2023	2022
Income before income tax (benefit) expense	$ 438.3	$ 347.4
Income tax (benefit) expense	50.7	125.6
Effective tax rate	11.6 %	36.2 %

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

For the three months ended March 31, 2023, compared to the same period in 2022, the decrease in our effective tax rate includes the impact of recording a valuation allowance on the net Neurimmune deferred tax asset during the first quarter of 2022, the resolution of an uncertain tax matter in the current quarter related to tax credits 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 are recorded discretely since changes in value of equity investments cannot be forecasted.

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

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, 2023, compared to the same period in 2022, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily due to an increase in a valuation allowance of approximately $85.0 million recorded in the first quarter of 2022.

For additional information on the valuation allowance and 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, 2023	As of December 31, 2022	$ Change	% Change
Financial assets:				
Cash and cash equivalents	$ 2,898.2	$ 3,419.3	$ (521.1)	(15.2)%
Marketable securities — current	2,143.1	1,473.5	669.6	45.4
Marketable securities — non-current	978.2	705.7	272.5	38.6
Total cash, cash equivalents and marketable securities	$ 6,019.5	$ 5,598.5	$ 421.0	7.5 %
Borrowings:				
Notes payable	$ 6,282.7	$ 6,281.0	$ 1.7	— %
Total borrowings	$ 6,282.7	$ 6,281.0	$ 1.7	— %
Working capital:				
Current assets	$ 9,762.5	$ 9,791.2	$ (28.7)	(0.3)%
Current liabilities	(3,014.9)	(3,272.8)	257.9	(7.9)
Total working capital	$ 6,747.6	$ 6,518.4	$ 229.2	3.5 %

OVERVIEW

We have historically financed and expect to continue to fund our operating and capital expenditures primarily through cash flow earned through our operations, as well as our existing cash resources. We believe generic competition for TECFIDERA in the U.S. and other key markets, continued decline in the Interferon product class and investments in the development and launch of potential new products will continue to reduce our cash flow from operations in 2023 and will have a significant adverse impact on our future cash flow from operations.

We believe that our existing funds, when combined with cash generated from operations and our access to additional financing resources, if needed, are sufficient to satisfy our operating, working capital, strategic alliance, milestone payment, capital expenditure and debt service requirements for the foreseeable future. In addition, we may choose to opportunistically return cash to shareholders and pursue other business initiatives, including acquisition and licensing activities. We may 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.

LIQUIDITY

WORKING CAPITAL

Working capital is defined as current assets less current liabilities. Our working capital was $6.7 billion and $6.5 billion as of March 31, 2023 and December 31, 2022, respectively. The change in working capital reflects a decrease in total current assets of approximately $28.7 million and a decrease in total current liabilities of approximately $257.9 million. The changes in current assets and current liabilities were primarily driven by the following:

CURRENT ASSETS

- **$148.5 million increase in cash, cash equivalents and current marketable securities;**
- **$70.6 million decrease in accounts receivable; and**
- **$63.4 million decrease in short-term inventory.**

CURRENT LIABILITIES

- **$233.2 million decrease in accrued expense and other primarily reflecting the timing of payment for our annual incentive compensation.**

CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

As of March 31, 2023, we had cash, cash equivalents and marketable securities totaling approximately $6.0 billion compared to approximately $5.6 billion as of December 31, 2022. 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. We have experienced no significant limitations in our liquidity resulting from uncertainties in the banking sector.

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

(In millions)	March 31, 2023	December 31, 2022
Denali	$ 306.7	$ 370.2
Sage	261.9	238.0
Sangamo	41.6	74.3
Ionis	67.9	108.6
Total	$ 678.1	$ 791.1

Although the contractual holding period restrictions on our investments in Denali, Sage, Sangamo and Ionis have expired, our ability to liquidate these investments may be limited by the size of our interest, the volume of market related activity, our concentrated level of ownership and other potential restrictions resulting from our status as a collaborator. Therefore, we may realize significantly less than the current value of such investments.

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

CASH FLOW

The following table summarizes our cash flow activity:

	For the Three Months Ended March 31,		
(In millions, except percentages)	2023	2022	% Change
Net cash flow provided by (used in) operating activities	$ 455.3	$ 161.8	181.4 %
Net cash flow provided by (used in) investing activities	(953.0)	(648.0)	47.1
Net cash flow provided by (used in) financing activities	(43.4)	(16.5)	163.0

OPERATING ACTIVITIES

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 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
- gains (losses) on the disposal of assets, deferred income taxes, changes in the fair value of contingent payments associated with our acquisitions of businesses and acquired IPR&D.

For the three months ended March 31, 2023, compared to the same period in 2022, the increase in net cash flow provided by operating activities was primarily due to higher net income in the current period, the timing of customer payments of accounts receivable and inventory levels, partially offset by a decrease in accounts payable in the first quarter of 2023.

INVESTING ACTIVITIES

For the three months ended March 31, 2023, compared to the same period in 2022, 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, driven by the investment of our increased cash flows from operations.

FINANCING ACTIVITIES

For the three months ended March 31, 2023, compared to the same period in 2022, the increase in net cash flow used in financing activities was primarily due to an increase in payments for payroll tax withholdings related to our equity awards.

CAPITAL RESOURCES

DEBT AND CREDIT FACILITIES

Our long-term obligations primarily consist of long-term debt with final maturity dates ranging between 2025 and 2051. As of March 31, 2023, our outstanding balance related to long-term debt was $6,282.7 million.

We maintain 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, 2023 and December 31, 2022, we had no outstanding borrowings and were in compliance with all covenants under this facility.

For a summary of the fair and carrying values of our outstanding borrowings as of March 31, 2023 and December 31, 2022, please read *Note 7, Fair Value Measurements,* to our condensed consolidated financial statements included in this report.

For additional information on our Senior Notes and credit facility please read, *Note 13, Indebtedness*, to our consolidated financial statements included in our 2022 Form 10-K.

SHARE REPURCHASE PROGRAMS

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. There were no share repurchases of our common stock during the three months ended March 31, 2023 and 2022. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of March 31, 2023.

CAPITAL EXPENDITURES

In the fourth quarter of 2021 we began construction of a new gene therapy manufacturing facility in RTP, North Carolina to support our gene therapy pipeline across multiple therapeutic areas. The new manufacturing facility will be approximately 197,000 square feet and is expected to be operational by the end of 2023, with an estimated total investment of approximately $195.0 million.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

CONTRACTUAL OBLIGATIONS

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases, long-term debt obligations and defined benefit and other purchase obligations, excluding amounts related to uncertain tax positions, funding commitments, contingent development, regulatory and commercial milestone payments and contingent payments, as described below.

In addition, certain of our collaboration and licensing arrangements include royalty payment obligations. For additional information on our royalty payments please read, *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in our 2022 Form 10-K.

There have been no material changes in our contractual obligations since December 31, 2022.

CONTINGENT DEVELOPMENT, REGULATORY AND COMMERCIAL MILESTONE PAYMENTS

Based on our development plans as of March 31, 2023, we could trigger potential future milestone payments to third parties of up to approximately $7.2 billion, including approximately $1.3 billion in development milestones, approximately $0.7 billion in regulatory milestones and approximately $5.2 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, 2023, 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 approximately $314.0 million in milestones in 2023 under our current agreements. This includes milestones totaling $225.0 million due to Sage upon the first commercial sale of zuranolone, for the potential treatment of MDD and PPD, in the U.S.

OTHER FUNDING COMMITMENTS

As of March 31, 2023, we have several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to CROs. The contracts with CROs are generally cancellable, with notice, at our option. We recorded accrued expense of approximately $16.8 million in our condensed consolidated balance sheets for expenditures incurred by CROs as of March 31, 2023. We have approximately $917.5 million in cancellable future commitments based on existing CRO contracts as of March 31, 2023.

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, 2023, we have approximately $137.3 million of liabilities associated with uncertain tax positions.

As of March 31, 2023 and December 31, 2022, we have accrued income tax liabilities of approximately $560.3 million and $558.0 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of March 31, 2023, approximately $138.9 million is expected to be paid within one year. The Transition Toll Tax is being paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

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 2022 Form 10-K. There have been no material changes to our critical accounting estimates since our 2022 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to certain risks that may affect our results of operations, cash flow and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements and equity price exposure as well as changes in economic conditions in the markets in which we operate as a result of the COVID-19 pandemic and the conflict in Ukraine. We manage the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. We do not enter into financial instruments for trading or

speculative purposes. The counterparties to these contracts are major financial institutions, and there is no significant concentration of exposure with any one counterparty.

FOREIGN CURRENCY EXCHANGE RISK

Our results of operations are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. As a result, our consolidated financial position, results of operations and cash flow can be affected by market fluctuations in foreign currency exchange rates, primarily with respect to the Euro, British pound sterling, Canadian dollar, Swiss franc and Japanese yen.

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, 2023, and is not expected to have a material impact on our results of operations or financial position in the future.

REVENUE AND OPERATING EXPENSE HEDGING PROGRAM

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenue and operating expense. We use foreign currency forward contracts and foreign currency options to manage foreign currency risk, with the majority of our forward contracts and options used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 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 9, Derivative Instruments,* to our condensed consolidated financial statements included in this report.

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

BALANCE SHEET RISK MANAGEMENT HEDGING PROGRAM

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

The following quantitative information includes the impact of currency movements on forward contracts used in our revenue, operating expense and balance sheet hedging programs. As of March 31, 2023 and December 31, 2022, 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 $323.1 million and $293.7 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.

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, 2023 and December 31, 2022, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $17.9 million and $11.7 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

CREDIT RISK

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

We operate in certain countries where weakness in economic conditions, including the effects of the COVID-19 pandemic and the conflict in Ukraine, can result in extended collection periods. We continue to monitor these conditions, including the volatility associated with international economies and the relevant financial markets, and assess their possible impact on our business. To date, we have not experienced any significant losses with respect to the collection of our accounts receivable.

We believe that our allowance for doubtful accounts was adequate as of March 31, 2023 and December 31, 2022.

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, 2023 and December 31, 2022, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $67.8 million and $79.1 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) or 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of March 31, 2023. 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, 2023, 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, 2023, 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. 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.

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

- Eisai's ability to obtain and maintain adequate reimbursement for LEQEMBI;
- the effectiveness of Eisai's and Biogen's commercial strategy for marketing LEQEMBI; and
- Eisai's and Biogen's 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 LEQEMBI, which are made by Eisai.

The FDA may withdraw approval if Eisai and Biogen 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, 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 adequate 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. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). Drug prices are under significant scrutiny in the markets in which our products are prescribed; for example the IRA has certain provisions related to drug pricing. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. 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. Additionally, and in part due to the impact of the COVID-19 pandemic, in certain jurisdictions governmental health agencies may adjust, retroactively and/or prospectively, reimbursement rates for our products.

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 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 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 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 or third-parties fail to perform;
- the interests of our collaborators 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 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 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.

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 (including those contained in the IRA) and increasing pressure from social sources could significantly influence the manner in which our products are prescribed, purchased and reimbursed. For example, provisions of the 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 previously investigated the approval and price of ADUHELM. In addition, there have been (including elements of the IRA), 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 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;

- *Ability to Provide Adequate Supply.* Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties we may be unable to meet 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;
- *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; 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 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 exclusivity 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. Legal proceedings may also be necessary to determine the rights, obligations and payments claimed during and after the expiration of intellectual property license agreements we have entered with third parties. 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 could 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, disagree with our trial design or endpoints or not approve adequate reimbursement. 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. 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, including adversely affecting our expenses associated with such trials. 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.

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.

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 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.

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 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.

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.
- *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.

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.

Furthermore, factors such as the COVID-19 pandemic and other global health outbreaks, 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. 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.

Management, personnel and other organizational 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 other 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, pre-clinical or clinical 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 or distributors 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, reimbursement or receive price increases, including those resulting from governmental or regulatory requirements;
- increased cost of goods due to factors such as inflation and supply chain disruptions;
- additional complexity in manufacturing internationally;
- delays in clinical trials relating to geopolitical instability related to Russia's invasion of Ukraine;
- the inability to successfully complete subsequent or confirmatory clinical trials in countries where our experience is limited;
- longer payment and reimbursement cycles and uncertainties regarding the collectability of accounts receivable;
- fluctuations in foreign currency exchange rates that may adversely impact our revenue, net income and value of certain of our investments;
- the imposition of governmental controls;
- diverse data privacy and protection requirements;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- changes in tax laws; and
- the imposition of tariffs or embargoes and other trade restrictions.

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

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

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

If we are unable to fully utilize our manufacturing facilities, our business may be harmed. Charges resulting from excess capacity may continue to occur and would have a negative effect on our financial condition and results of operations.

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

The ongoing COVID-19 pandemic and other global health outbreaks 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 and other global health outbreaks.

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 adopting flexible working arrangements. 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 and other global health outbreaks 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 or other third-parties due to the COVID-19 pandemic and other global health outbreaks 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 and other global health outbreaks. 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 and other global health outbreaks. In addition, the impact of the COVID-19 pandemic and other global health outbreaks on the operations of the FDA and other health authorities may delay potential approvals of our product candidates.

State and federal healthcare reform measures have been adopted in the past, and 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 and other global health outbreaks may have on our business, the broad global health outbreaks on our business activities may materially and adversely affect our business, supply chain and distribution systems, results of operations and financial condition.

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 and artificial intelligence based software 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. Additionally, the use of artificial intelligence (AI) based software is increasingly being used in the biopharmaceutical industry. Use of AI based software may lead to the release of confidential proprietary information which may impact our ability to realize the benefit of our intellectual property.

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 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. Additionally, the recently enacted IRA includes an excise tax on share repurchases, which will increase the cost of share repurchases. 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 (including those related to the IRA).

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 OECD's project on "Base Erosion and Profit Shifting" 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. Many countries have or are in the process of enacting legislation intended to implement the OECD GloBE Model Rules effective starting on January 1, 2024. The impact on the Company will depend on the exact nature of each country's GloBE legislation, guidance and regulations thereon and their application by tax authorities.

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. Additionally, regulators are considering new environmental disclosure rules. For example, the SEC has proposed amendments to its disclosure rules regarding climate-related disclosure requirements. These proposed regulations may impact the manner in which we operate.

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 2023:

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 2023	—	$ —	—	$ 2,050.0
February 2023	—	$ —	—	$ 2,050.0
March 2023	—	$ —	—	$ 2,050.0
Total[1]	—	$ —		

[1] There were no share repurchases during the first quarter of 2023.

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. There were no share repurchases of our common stock during the three months ended March 31, 2023 and 2022. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of March 31, 2023.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1	Fourth Amended and Restated Bylaws of Biogen Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K on April 18, 2023.
10.2*+	Letter regarding employment arrangement of Ginger Gregory dated June 9, 2017.
10.3*+	Letter regarding employment arrangement of Nicole Murphy dated January 28, 2022.
31.1+	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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, 2023, 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)

April 25, 2023