Biogen

ANNUAL REPORT 2022

Safe harbor

This letter contains forward-looking statements relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings and approvals; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, cost-saving initiatives, actions to improve risk profile and productivity of R&D pipeline, collaborations and business development activities; and our future financial and operating results. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later-stage or larger-scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing and reimbursement for our products; our dependence on collaborators, joint venture partners and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; the potential impact of the conflict in Ukraine; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early-stage clinical trials may not be predictive of results in later-stage or large-scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, the risk that regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use of our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; results of operations and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this letter. We do not undertake any obligation to publicly update any forward-looking statements.

CEO Letter

For more than 40 years, Biogen has been driven by its heritage of innovation. As we write the next chapter in our story, I see substantial opportunity to build on that strong legacy as we execute on clear priorities to put the company back on a sustainable growth trajectory.

Christopher A. Viehbacher
President and Chief Executive Officer

My fellow stockholders,

I am honored to write you as Biogen's new President and Chief Executive Officer and to have joined a team that is pioneering important new medicines to address some of the most difficult and challenging conditions in healthcare. For more than 40 years, Biogen has been driven by its heritage of innovation. As we write the next chapter in our story, I see substantial opportunity to build on that strong legacy as we execute on clear priorities to put the company back on a sustainable growth trajectory.

In 2022, Biogen continued to advance therapeutic breakthroughs for patients and achieved financial performance in line with expectations, while adversely affected by increased competition in our multiple sclerosis (MS) portfolio. I step into this role with the clear understanding that we are operating in a much more competitive environment, with a cost base higher than industry benchmarks, and therefore need to transform the business to build an even stronger company for the benefit of patients, investors and other stakeholders.

We are starting that journey with some clear advantages, including being in the remarkable position of having developed two potentially transformative medicines that we believe would give us significant potential future opportunity. The first would treat Alzheimer's disease (AD), and a second, pending U.S. Food and Drug Administration (FDA) approval, would treat depression in a new way. In 2023, we are focused on executing on these and other opportunities, while also reducing our cost base, as we build on our 2022 results.

We maintained a strong financial position last year, giving us the opportunity to invest prudently in our business. We generated more than $10.1 billion in revenue, while reducing overall expenses through our cost reduction measures.

We ended the year with approximately $5.6 billion in total cash, cash equivalents and marketable securities. Allocating that capital will be a primary focus for Biogen in 2023 as we look to rationalize our cost base and achieve a meaningful return on investment where we do invest.

I would like to thank you for your continued support of and investment in Biogen. I outline below how in 2023 we intend to execute against several priorities.

Bringing two breakthrough medicines to market
In January 2023, the FDA granted accelerated approval to LEQEMBI (lecanemab-irmb), a treatment for early AD developed in collaboration with Eisai Co., Ltd (Eisai). The accelerated approval was based on phase 2 data that demonstrated LEQEMBI reduced the accumulation of amyloid-beta (Aβ) plaque in the brain, a defining feature of AD. The data from the phase 3 CLARITY AD study provide clear evidence that reducing plaque burden slows cognitive decline. After decades of research, we can now see the promise of potential disease modification.

With potential traditional approval – the Prescription Drug User Fee Act (PDUFA) date is planned for July 6, 2023 – broader access could be within reach of more patients. The Centers for Medicare

& Medicaid Services (CMS) announced its intent to provide broader coverage on the same day within the Coverage with Evidence Development framework.

We believe LEQEMBI represents a catalyst for further innovation and is an incredible opportunity to build upon as we invest in advancing the care of patients suffering with AD. We continue to see progress in the development of blood-based and digital biomarkers. We imagine a world where early detection, before the onset of symptoms, will have the potential to allow treatment much earlier in the disease course to potentially delay or even prevent AD. Biogen is committed to continuing research in AD, including investigation into a promising molecule in our pipeline which could reduce tau, another defining pathology of AD.

In collaboration with Sage Therapeutics Inc. (Sage), we have advanced zuranolone, a potential treatment for major depressive disorder (MDD) and postpartum depression (PPD). If approved, zuranolone could be an important new treatment option in an area with high unmet need.

We have all seen the surge in mental illness the last few years, and we know the current standard-of-care antidepressants may not work for everyone or may take up to six to eight weeks to reach maximal efficacy when they do.

Zuranolone is currently under priority review at the FDA as a potential 14-day, rapid-acting, once-daily, oral medication to treat MDD and PPD following promising phase 3 clinical trial results. Its novel mechanism of action targets brain networks responsible for functions such as mood, arousal, behavior and cognition and could provide benefit as early as day three. With a PDUFA date set for August 5, 2023, we are anticipating a potential launch toward the end of the year in the United States, and we are building our commercial infrastructure and capabilities to enter this market.

Strengthening our portfolio and our pipeline, and improving operational efficiency

We believe our return to a sustainable growth trajectory will also require thoughtful portfolio and pipeline optimization, external growth initiatives and diligent cost management across the enterprise.

In our core business, we are working to deliver on further growth opportunities in spinal muscular atrophy (SMA) and improving our profitability in MS. We have started a review of our strategic options for our biosimilars business.

Our research and development pipeline and balance sheet are strong, and we believe our pipeline will be able to deliver significant growth over the medium and long term. But there is still more we must do to optimize our existing portfolio and diversify into new therapeutic areas such as neuropsychiatry, specialized immunology and rare diseases. We are closely examining new paths to balancing and de-risking our pipeline in a systemic and data-driven way, while sharpening our focus on value generation in the areas in which we have the most confidence, as compared to the achievement of operational milestones alone.

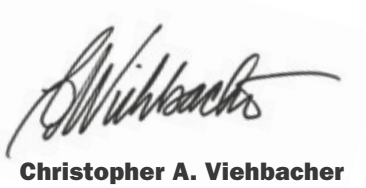
Through internal research and development, thoughtful business development, and disciplined capital allocation, I believe we will create new opportunities for growth.

We also have the goal of bringing our cost base in line with our revenue expectations while, at the same time, investing in upcoming launches and potential future growth drivers. We remain on track to achieve our previously announced $1.0 billion in cost-saving initiatives, and we will continue to seek new ways to create shareholder value and achieve greater operational efficiency.

Building on our heritage of innovation

As we approach the 45th anniversary of Biogen, it is a privilege to lead such an established, purpose-driven and diverse organization. I was drawn to join Biogen not only for its reputation as a biotechnology pioneer, but also by its dynamic team, which is as committed to advancing health equity as it is to pioneering patient breakthroughs. I have had the pleasure of getting to know many talented employees over the past several months and have witnessed firsthand their incredible expertise, tenacity and passion for our mission. I look forward to executing against our key milestones in 2023, with the support of the accomplished team at Biogen, our strong partnerships with collaborators like Eisai and Sage, and the continued support of our shareholders.

Sincerely,



Christopher A. Viehbacher
President and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 0-19311

BIOGEN INC.

(Exact name of registrant as specified in its charter)

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

225 Binney Street, Cambridge, MA 02142

(617) 679-2000

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.0005 par value	BIIB	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $29,397,964,818.

As of February 14, 2023, the registrant had 144,485,646 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

BIOGEN INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022
TABLE OF CONTENTS

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the anticipated amount, timing and accounting of revenue; contingent, milestone, royalty and other payments under licensing, collaboration, acquisition or divestiture agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expense; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth, 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 United States (U.S.), including the Inflation Reduction Act of 2022 (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 Research Triangle Park (RTP), NC 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

PART I

ITEM 1. 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 multiple sclerosis (MS), have introduced the first approved treatment for spinal muscular atrophy (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 Co., Ltd. (Eisai) on the commercialization of LEQEMBI for the treatment of Alzheimer's disease, which was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in January 2023. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions; RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL; GAZYVA for the treatment of CLL and follicular lymphoma; OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS); 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, Inc. (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 major depressive disorder (MDD) and postpartum depression (PPD), BIIB080 for Alzheimer's disease, tofersen for amyotrophic lateral sclerosis (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 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Key Business Developments

The following is a summary of key developments affecting our business since the beginning of 2022.

For additional information on our collaborative and other relationships discussed below, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Developments in Key Collaborative Relationships

Eisai Collaboration Agreements

LEQEMBI (lecanemab) Collaboration Agreement

In January 2023 we and Eisai announced that 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 Biologics License Application (BLA) to the FDA for traditional approval of LEQEMBI.

In January 2023 the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for lecanemab.

In January 2023 Eisai completed the submission of a MAA to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for lecanemab, and was granted Priority Review by the Japanese Ministry of Health, Labor and Welfare.

In December 2022 Eisai initiated a rolling submission of a BLA to the National Medicinal Products Administration (NMPA) of China for the approval of lecanemab.

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.

ADUHELM Collaboration Agreement

On March 14, 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.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Zuranolone (BIIB125)

In June 2022 we and our collaboration partner Sage Therapeutics, Inc. (Sage) announced that the Phase 3 SKYLARK study of zuranolone, for the potential treatment of MDD and PPD, met its primary and all key secondary endpoints.

In December 2022 we and Sage completed the rolling submission of a New Drug Application (NDA) to the FDA for the approval of zuranolone for the potential treatment of MDD and PPD. This submission completes the NDA filing initiated earlier in 2022.

In February 2023 the FDA accepted the NDA and granted Priority Review for zuranolone, with a Prescription Drug User Fee Act (PDUFA) action date of August 5, 2023.

For additional information on our collaboration arrangement with Sage, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Genentech

LUNSUMIO (mosunetuzumab)

In January 2022 we exercised our option with Genentech to participate in the joint development and commercialization of LUNSUMIO (mosunetuzumab), a bispecific antibody for the treatment of relapsed or refractory follicular lymphoma. In connection with this exercise, we recorded a $30.0 million option exercise fee payable to Genentech in December 2021.

In December 2022 Genentech announced that the FDA granted accelerated approval of LUNSUMIO, which was also approved by the European Commission (EC) in June 2022.

Glofitamab

In December 2022 we reached an agreement with Genentech related to the commercialization and sharing of economics for glofitamab, an investigational T-cell engaging bispecific antibody targeting CD20 and CD3 for the potential treatment of B-cell non-Hodgkin's lymphoma.

For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Other Collaborative Relationships

Alcyone Therapeutics

In December 2022 we entered into a license and collaboration agreement with Alcyone Therapeutics (Alcyone) to jointly develop the ThecaFlex DRx™ System, an implantable medical device intended for subcutaneous delivery of antisense oligonucleotide (ASO) therapies with a goal of improving the patient treatment experience and accessibility for people suffering from neurological disorders, such as SMA and ALS. Under the terms of this collaboration, we and Alcyone will jointly develop the ThecaFlex DRx™ System and Alcyone will be solely responsible for its manufacture and commercialization. In connection with this transaction, we made an upfront payment of $10.0 million to Alcyone.

Corporate Matters

Samsung Bioepis - Biogen's Joint Venture with Samsung BioLogics

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

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.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions,* to our consolidated financial statements included in this report.

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 $131.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of December 31, 2022, approximately $35.9 million remained in our restructuring reserve and payments are expected to be made through 2026.

For additional information on our 2022 cost saving initiatives, please read *Note 4, Restructuring*, to our consolidated financial statements included in this report.

125 Broadway Sale and Leaseback Transaction

In September 2022 we completed the sale of our building and land parcel located at 125 Broadway, Cambridge, MA (125 Broadway) for an aggregate sales price of approximately $603.0 million, which is inclusive of a $10.8 million tenant allowance. Simultaneously, with the close of this transaction we leased back the building for a term of approximately 5.5 years.

For additional information on our 125 Broadway sale and leaseback transaction, please read *Note 11, Property, Plant and Equipment* and *Note 12, Leases*, to our consolidated financial statements included in this report.

Management Changes

- In November 2022 we announced the appointment of Christopher A. Viehbacher as President and Chief Executive Officer.
- In February 2022 we announced the appointment of Nicole Murphy as Executive Vice President, Pharmaceutical Operations and Technology.
- In January 2023 we announced the appointment of Priya Singhal as Executive Vice President, Head of Development.

Board of Directors Update

- In June 2022 Nancy Leaming and Brian Posner retired from our Board of Directors.
- In November 2022 Christopher A. Viehbacher joined our Board of Directors.

For additional information on our executive officers, please read the subsection entitled "Information about our Executive Officers" included in this report.

Product and Pipeline Developments

Multiple Sclerosis and Neuroimmunology

TECFIDERA (dimethyl fumerate)

- In June 2022 the European Patent Office (EPO) granted a patent that expires in February 2028 related to TECFIDERA.
- In October 2022 the Advocate General of the Court of Justice of the European Union (CJEU) issued a nonbinding advisory opinion in Biogen's favor relating to regulatory data protection for TECFIDERA. This opinion recommends that the CJEU set aside the earlier judgement of the European General Court annulling the EMA's decision not to validate an application to market a generic version of TECFIDERA.

Alzheimer's Disease and Dementia

LEQEMBI (lecanemab)

- In January 2023 we and Eisai announced that 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 September 2022 we and Eisai announced positive topline results from the confirmatory Phase 3 CLARITY Alzheimer's disease study of LEQEMBI. LEQEMBI met the primary endpoint and all key secondary endpoints with highly statistically significant results.
- In November 2022 Eisai presented full results from the confirmatory Phase 3 CLARITY Alzheimer's disease study of LEQEMBI at the 2022 Clinical Trials on Alzheimer's Disease conference.
- In November 2022 *The New England Journal of Medicine* published full results from the confirmatory Phase 3 CLARITY Alzheimer's disease study of LEQEMBI.

ADUHELM (aducanumab)

- In March 2022 we announced new data showing that after nearly two and a half years of treatment (128 weeks) with ADUHELM injection 100 mg/mL for intravenous use, patients in the long-term extension phase of the Phase 3 trials continued to experience significant reductions in two key Alzheimer's disease pathologies, amyloid beta plaques and plasma p-tau181.
- In March 2022 *The Journal of Prevention of Alzheimer's Disease* published a peer-reviewed manuscript detailing data from the pivotal Phase 3 EMERGE and ENGAGE studies of ADUHELM 100 mg/mL injection for intravenous use in early Alzheimer's disease. The publication includes results from the primary, secondary and tertiary endpoints in the trials, as well as safety data and biomarker sub-studies.
- In March 2022 we submitted the final study protocol for the confirmatory Phase 4 ENVISION study of ADUHELM to the FDA for review and approval.
- In April 2022 the Centers for Medicare and Medicaid Services (CMS) released a final NCD for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. This decision effectively resulted in denying all Medicare beneficiaries access to ADUHELM.
- In April 2022 we announced our plans to offer a continuity of care plan for U.S. patients currently treated with ADUHELM, as a result of the CMS decision.

Neuropsychiatry

Zuranolone (BIIB125)

- In February 2022 we and Sage announced the Phase 3 CORAL study of zuranolone in people with MDD met the trial objectives, demonstrating a rapid and statistically significant reduction in depressive symptoms at Day 3 and over the 2-week treatment period, achieving the primary and key secondary endpoints.
- In June 2022 we and Sage announced that the Phase 3 SKYLARK study of zuranalone in women with PPD met its primary and all key secondary endpoints.
- In October 2022 we and Sage presented additional data from the Phase 3 SKYLARK study of zuranalone in women with PPD. This data was presented at the European College of Neuropsychopharmacology (ECNP) Congress.
- In December 2022 we and Sage completed the rolling submission of a NDA to the FDA for the approval of zuranolone for the potential treatment of MDD and PPD. This submission completes the NDA filing initiated earlier in 2022.
- In February 2023 the FDA accepted the NDA and granted Priority Review for zuranolone, with a PDUFA action date of August 5, 2023.

Neuromuscular Disorders

SPINRAZA (nusinersen)

- In March 2022 we announced the first patient was treated in the global Phase 3b ASCEND study, which is designed to evaluate the clinical outcomes and assess the safety of a higher dose of SPINRAZA in children, teens and adults with later-onset SMA who were previously treated with Evrysdi.

BIIB115

- In October 2022 the first patient in the Phase 1 study of BIIB115, an investigational ASO in development for SMA, was dosed.

Tofersen (BIIB067)

- In June 2022 we announced new 12-month data for tofersen demonstrating that earlier initiation of tofersen compared to delayed initiation (six months later in the open-label extension study) slowed declines in clinical function, respiratory function, muscle strength and quality of life.
- In July 2022 the FDA accepted the NDA and granted Priority Review for tofersen, an investigational antisense drug being evaluated for people with superoxide dismutase 1 (SOD1) ALS, which currently has a PDUFA action date of April 25, 2023.
- In September 2022 *The New England Journal of Medicine* published detailed results from the Phase 3 VALOR study of tofersen, including the combined analysis of the Phase 3 VALOR study and its open-label extension study evaluating tofersen for the potential treatment of SOD1 ALS.
- In December 2022 the EMA accepted for review the MAA for tofersen.

Movement Disorders

BIIB122 (DNL151)

- In May 2022 dosing commenced in the Phase 2b LUMA study of BIIB122, a small molecule inhibitor of leucine-rich repeat kinase 2 (LRRK2), evaluating the efficacy and safety of BIIB122 compared to placebo in approximately 640 patients with early stage Parkinson's disease.
- In October 2022 we and our collaboration partner Denali Therapeutics Inc. (Denali) announced the initiation of the Phase 3 LIGHTHOUSE study of BIIB122 in patients with Parkinson's disease and a confirmed pathogenic mutation in the LRRK2 gene.

ALO1811

- In June 2022 we entered into a collaboration and license agreement with Alectos Therapeutics Inc. (Alectos) to develop and commercialize ALO1811, a novel preclinical selective GBA2 inhibitor, for the potential oral disease modifying treatment for patients with Parkinson's disease.

Immunology

Litifilimab (BIIB059)

- In July 2022 *The New England Journal of Medicine* published positive results from the cutaneous lupus erythematosus (CLE) portion of the two-part Phase 2 LILAC study (Part B) evaluating litifilimab, an investigational drug for the treatment of lupus. The study met its primary endpoint by demonstrating the enhanced efficacy of litifilimab compared to placebo in reducing skin disease activity.
- In September 2022 *The New England Journal of Medicine* published a second manuscript detailing positive results from the systemic lupus erythematosus (SLE) portion of the two-part Phase 2 LILAC study (Part A) evaluating litifilimab. The study met its primary endpoint by demonstrating that litifilimab was associated with a statistically significant reduction in total active joint count compared to placebo.
- In October 2022 the first patient was dosed in the Phase 2/3 AMETHYST study of litifilimab, evaluating the efficacy and safety of litifilimab compared to placebo in patients with CLE.

Biosimilars

BIIB801 (referencing CIMZIA)

- In February 2022 we entered into a commercialization and license agreement with Xbrane Biopharma AB (Xbrane) to develop, manufacture and commercialize BIIB801, a proposed certolizumab pegol biosimilar referencing CIMZIA.

BYOOVIZ (referencing LUCENTIS)

- In June 2022 we and Samsung Bioepis announced that BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, launched in the U.S.

BIIB800 (referencing ACTEMRA)

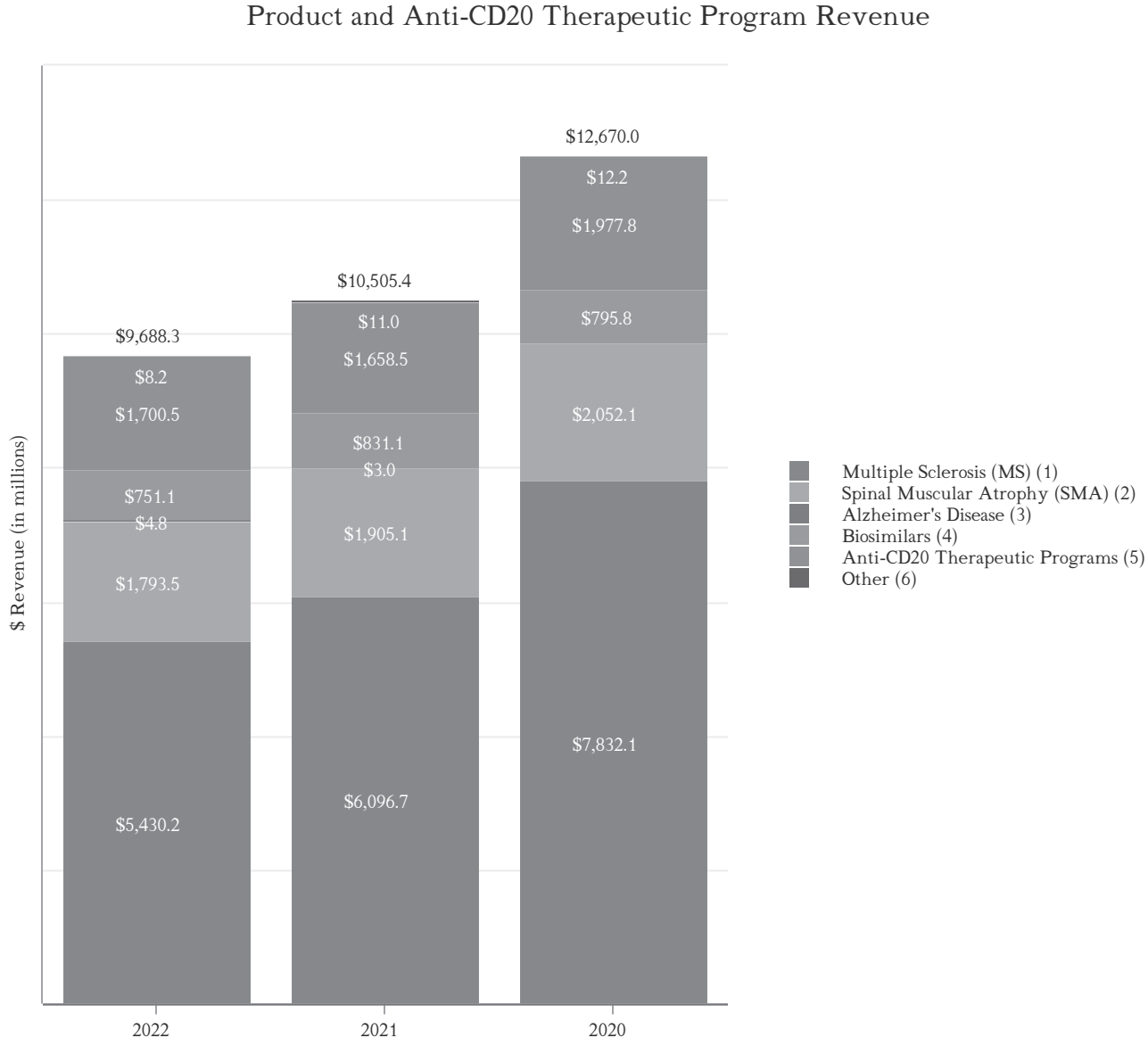
- In June 2022 we and our collaboration partner Bio-Thera Solutions, Ltd. (Bio-Thera) presented positive results from the Phase 3 study of BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, an anti-interleukin-6 receptor monoclonal antibody, for the treatment of severe, active and progressive rheumatoid arthritis. The data was presented at the 2022 Annual European Congress of Rheumatology.
- In September 2022 the EMA accepted for review the MAA for BIIB800.
- In December 2022 the FDA accepted for review the abbreviated BLA for BIIB800.

Discontinued Programs

- In March 2022 we and Ionis Pharmaceuticals Inc. (Ionis) announced that the Phase 1 study of BIIB078 in ALS did not meet any secondary efficacy endpoints and it did not demonstrate clinical benefit. Based on these results, we discontinued development of BIIB078.
- In June 2022 we discontinued further development of BIIB100 for the potential treatment of certain neurological and neurodegenerative diseases, primarily in ALS, based on the decision by management as part of its strategic review process.
- In July 2022 we announced that the Phase 2 TALLY study of BIIB104 in cognitive impairment associated with schizophrenia did not meet its primary or secondary efficacy endpoints. Given the consistent lack of efficacy observed across the primary and secondary measures of cognition and functioning, we decided to discontinue the BIIB104 program.
- In 2022 we discontinued further development of BIIB118 (CK1 inhibitor) for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases, based on the decision by management as part of its strategic review process.
- In December 2022 we discontinued further development of vixotrigine (BIIB074) for the potential treatment of trigeminal neuralgia (TGN) and diabetic painful neuropathy (DPN), based on regulatory, development and commercialization challenges.
- In February 2023 we terminated our license and collaboration agreement with InnoCare Pharma Limited (InnoCare) for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor for the potential treatment of MS.

Marketed Products

The following graph shows our revenue by product and revenue from anti-CD20 therapeutic programs for the years ended December 31, 2022, 2021 and 2020.



(1) MS includes TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA. VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.

(2) SMA includes SPINRAZA.

(3) Alzheimer's disease includes ADUHELM.

(4) Biosimilars includes BENEPALI, IMRALDI, FLIXABI and BYOOVIZ. BYOOVIZ launched in the U.S. in June 2022 and became commercially available during the third quarter of 2022.

(5) Anti-CD20 therapeutic programs include RITUXAN, RITUXAN HYCELA, GAZYVA and OCREVUS.

(6) Other includes FUMADERM.

Product sales for TECFIDERA, TYSABRI and SPINRAZA each accounted for more than 10.0% of our total revenue for the years ended December 31, 2022, 2021 and 2020. For additional financial information about our product and other revenue and geographic areas where we operate, please read *Note 5, Revenue* and *Note 25, Segment Information,* to our consolidated financial statements included in this report and *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this report. A discussion of the risks attendant to our operations is set forth in *Item 1A. Risk Factors* included in this report.

Multiple Sclerosis

We develop, manufacture and market a number of products designed to treat patients with MS. MS is a progressive disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis and, in some cases, death. Patients with active RMS experience an uneven pattern of disease progression characterized by periods of stability that are interrupted by flare-ups of the disease after which the patient may return to a lower baseline of functioning.

The MS products we market and our major markets are as follows:

Product	Indication	Collaborator	Major Markets
Tecfidera (dimethyl fumarate) delayed-release capsules	RMS in the U.S. Relapsing-remitting MS (RRMS) in the E.U.	None	U.S. France Germany Italy Japan Spain U.K.
VUMERITY (diroximel fumarate)	RMS in the U.S. RRMS in the E.U.	Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes)	U.S. Germany Israel Switzerland U.K.
AVONEX (interferon beta-1a)	RMS	None	U.S. France Germany Italy Japan Spain
plegridy (peginterferon beta-1a)	RMS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Spain U.K.
TYSABRI (natalizumab)	RMS RRMS in the E.U. Crohn's disease in the U.S.	None	U.S. France Germany Italy Spain U.K.
fampyra 10 mg prolonged-release tablets fampridine	Walking ability for patients with MS	Acorda Therapeutics, Inc. (Acorda)	France Germany

For additional information on our collaboration arrangements with Alkermes and Acorda, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Neuromuscular Disorders

SMA is characterized by loss of motor neurons in the spinal cord and lower brain stem, resulting in severe and progressive muscular atrophy and weakness. Ultimately, individuals with the most severe type of SMA can become paralyzed and have difficulty performing the basic functions of life, like breathing and swallowing. Due to a deletion or mutations in the SMN1 gene, people with SMA do not produce enough survival motor neuron (SMN) protein, which is critical to the survival of the neurons that control muscles. The severity of SMA correlates with the amount of SMN protein. People with Type 1 SMA, the most severe life-threatening form, produce very little SMN protein and do not

achieve the ability to sit without support, and typically do not live beyond two years of age without respiratory support and nutritional interventions. People with Type 2 and Type 3 SMA produce greater amounts of SMN protein and have less severe, but still life-altering, forms of SMA.

Our SMA product and major markets are as follows:

Product	Indication	Collaborator	Major Markets
SPINRAZA (nusinersen) injection 12 mg/5 mL	SMA	Ionis	U.S. Brazil Canada China France Germany Italy Japan Spain Turkey

For additional information on our collaboration arrangements with Ionis, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Alzheimer's Disease

Alzheimer's disease is characterized by two abnormalities in the brain: amyloid plaques and neurofibrillary tangles. Amyloid plaques, which are found in the tissue between the nerve cells, are unusual clumps of a protein called beta amyloid along with degenerating bits of neurons and other cells.

Our Alzheimer's disease products and major markets are as follows:

Product	Indication	Collaborator	Major Market
LEQEMBI (lecanemab-irmb) 100 mg/mL	Alzheimer's disease	Eisai	U.S.
Aduhelm (aducanumab-avwa)	Alzheimer's disease	Eisai	U.S.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Biosimilars

Biosimilars are a group of biologic medicines that are highly similar to currently available biologic therapies developed by companies known as "originators". Under our agreements with Samsung Bioepis, we commercialize three anti-tumor necrosis factor (TNF) biosimilars in certain countries in Europe: BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE. We have also secured the exclusive rights to commercialize BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, which was approved in the U.S., the E.U. and the United Kingdom (U.K.) during the third quarter of 2021. BYOOVIZ launched in the U.S. in June 2022 and became commercially available during the third quarter of 2022.

Our current biosimilar products and major markets are as follows:

Product	Indication	Major Markets
Benepali™ Etanercept	Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Axial spondyloarthritis Plaque psoriasis Paediatric plaque psoriasis	France Germany Italy Spain U.K.
Imraldi™ Adalimumab	Rheumatoid arthritis Juvenile idiopathic arthritis Axial spondyloarthritis Psoriatic arthritis Psoriasis Paediatric plaque psoriasis Hidradenitis suppurativa Adolescent hidradenitis suppurativa Crohn's disease Paediatric Crohn's disease Ulcerative colitis Uveitis Paediatric Uveitis	France Germany Sweden U.K.
Flixabi™ Infliximab	Rheumatoid arthritis Crohn's disease Paediatric Crohn's disease Ulcerative colitis Paediatric ulcerative colitis Ankylosing spondylitis Psoriatic arthritis Psoriasis	France Germany Italy
Byooviz™ ranibizumab-nuna	Neovascular (wet) age-related macular degeneration Macular edema following retinal vein occlusion Myopic choroidal neovascularization	U.S.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Genentech Relationships

We have agreements with Genentech that entitle us to certain business and financial rights with respect to RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS, LUNSUMIO, which was granted accelerated approval in the U.S. during the fourth quarter of 2022, glofitamab and options to add other potential anti-CD20 therapies.

Our current anti-CD20 therapeutic programs and major markets are as follows:

Product	Indication	Major Markets
Rituxan Rituximab	Non-Hodgkin's lymphoma CLL Rheumatoid arthritis Two forms of ANCA-associated vasculitis Pemphigus vulgaris	U.S. Canada
RituxanHYCELA rituximab/hyaluronidase human subcutaneous injection	Non-Hodgkin's lymphoma CLL	U.S.
GAZYVA obinutuzumab injection	In combination with chlorambucil for previously untreated CLL Follicular lymphoma In combination with chemotherapy followed by GAZYVA alone for previously untreated follicular lymphoma	U.S.
OCREVUS® ocrelizumab	RMS PPMS	U.S.
Lunsumio mosunetuzumab-axgb injection for intravenous use 1 mg | 30 mg	Relapsed or refractory follicular lymphoma	U.S.

For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Other

Product	Indication	Collaborator	Major Markets
Fumaderm	Moderate to severe plaque psoriasis	None	Germany

Patient Support and Access

We interact with patients, advocacy organizations and healthcare societies in order to gain insights into unmet needs. The insights gained from these engagements help us support patients with services, programs and applications that are designed to help patients lead better lives. Among other things, we provide customer service and other related programs for our products, such as disease and product specific websites, insurance research services, financial assistance programs and the facilitation of the procurement of our marketed products.

We are dedicated to helping patients obtain access to our therapies. Our patient representatives have access to a suite of financial assistance tools. With those tools, we help patients understand their insurance coverage and, if needed, help patients compare insurance options and programs. In the U.S., we have established programs that provide co-pay assistance or free product for qualified uninsured or underinsured patients, based on specific eligibility criteria. We also provide charitable contributions to

independent charitable organizations that assist patients with out-of-pocket expenses associated with their therapy.

We believe all healthcare stakeholders have a shared responsibility to ensure patients have equitable access to new, innovative medicines. We regularly review our pricing strategy and prioritize patient access to our therapies. We have a value-based contracting program designed to align the price of our therapies to the value our therapies deliver to patients. We also work with regulators, clinical researchers, ethicists, physicians and patient advocacy organizations and communities, among others, to determine how best to address requests for access to our investigational therapies in a manner that is consistent with our patient-focused values and compliant with regulatory standards and protocols. In appropriate situations, patients may have access to investigational therapies through Early Access Programs, single patient access or emergency use based on humanitarian or compassionate grounds.

Marketing and Distribution

Sales Force and Marketing

We promote our marketed products worldwide, including in the U.S., Europe and Japan, primarily through our own sales forces and marketing groups. In some countries, particularly in areas where we continue to expand into new geographic areas, we partner with third parties.

RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS and LUNSUMIO are marketed by the Roche Group and its sublicensees.

We commercialize BENEPALI, IMRALDI and FLIXABI pursuant to our agreement with Samsung Bioepis in certain countries in Europe, as well as BYOOVIZ in the U.S.

We focus our sales and marketing efforts on specialist physicians in private practice or at major medical centers. We use customary industry practices to market our products and to educate physicians. This includes our sales representatives calling on individual health care providers (in-person and virtually), advertisements, professional symposia, direct mail, digital marketing, point of care marketing, public relations and other methods. We focus on health care provider sales and marketing efforts on specialty providers in both private practice and at major medical centers.

Distribution Arrangements

We distribute our products in the U.S. principally through wholesale and specialty distributors of pharmaceutical products and specialty pharmacies, mail order specialty distributors or shipping service providers. In other countries, the distribution of our products varies from country to country, including through wholesale distributors of pharmaceutical products and third-party distribution partners who are responsible for most marketing and distribution activities.

Eisai distributes AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS and LUNSUMIO are distributed by the Roche Group and its sublicensees.

We distribute BENEPALI, IMRALDI and FLIXABI in certain countries in Europe and have an option to acquire exclusive rights to distribute these products in China, as well as BYOOVIZ in the U.S.

Our product sales to two wholesale distributors each accounted for more than 10.0% of our total revenue for the years ended December 31, 2022, 2021 and 2020, and on a combined basis, accounted for approximately 37.9%, 38.9% and 45.8%, respectively, of our gross product revenue. For additional information, please read *Note 5, Revenue*, to our consolidated financial statements included in this report.

Patents and Other Proprietary Rights

Patents are important for obtaining and protecting exclusive rights in our products and product candidates. We regularly seek patent protection in the U.S. and in selected countries outside the U.S. for inventions originating from our research and development efforts and those we license or acquire. In addition, we license rights to various patents and patent applications.

U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest application was filed; however, U.S. patents on applications filed before June 8, 1995, may be effective until 17 years from the issue date, if that is later than the 20-year date. In some cases, the patent term may be extended to recapture a portion of the term lost during regulatory review of the claimed therapeutic or, in the case of the U.S., because of U.S. Patent and Trademark Office (USPTO) delays in prosecuting the application. Specifically, in the U.S., under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, a patent that covers a drug approved by the FDA may be eligible for patent term extension (for up to 5 years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. The duration and extension of the term of foreign patents varies, in accordance with local law. For example, supplementary protection certificates (SPCs) on some of our products have

been granted in a number of European countries, compensating in part for delays in obtaining marketing approval.

Regulatory exclusivity, which may consist of regulatory data protection and market protection, also can provide meaningful protection for our products. Regulatory data protection provides to the holder of a drug or biologic marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it created at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. After the period of exclusive use, third parties are permitted to reference such data in abbreviated applications for approval and to market (subject to any applicable market protection) their generic drugs and biosimilars. Market protection provides the holder of a drug or biologic marketing authorization the exclusive right to commercialize its product for a period of time, thereby preventing the commercialization of another product containing the same active ingredient(s) during that period. Although the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS) requires signatory countries to provide regulatory exclusivity to innovative pharmaceutical products, implementation and enforcement varies widely from country to country.

We also rely upon other forms of unpatented confidential information to remain competitive. We protect such information principally through refraining from public disclosure and confidentiality agreements with our employees, consultants, outside scientific collaborators, scientists whose research we sponsor and other advisers. In the case of our employees, these agreements also provide, in compliance with relevant law, that inventions and other intellectual property conceived by such employees during their employment are our exclusive property.

Our trademarks are important to us and are generally covered by trademark applications or registrations in the USPTO and the patent or trademark offices of other countries. We also use trademarks licensed from third parties, such as the trademark FAMPYRA, which we license from Acorda. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Our Patent Portfolio

The following table describes certain patents in the U.S. and Europe that we currently consider of primary importance to our marketed products, including the territory, patent number, general subject matter and expected expiration dates. Except as otherwise noted, the expected expiration dates include any granted patent term extensions and issued SPCs. In some instances, there are additional later-expiring patents relating to our products directed to, among other things, particular forms or compositions, methods of manufacturing or use of the drug in the treatment of particular diseases or conditions. We also continue to pursue additional patents and patent term extensions in the U.S. and other territories covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table.

Product	Territory	Patent No.	General Subject Matter	Patent Expiration[1]
TECFIDERA	Europe	1,131,065	Formulations of dialkyl fumarates and their use for treating autoimmune diseases	2024[3]
	Europe	2,653,873	Methods of use	2028
PLEGRIDY	U.S.	8,524,660	Methods of treatment	2023
	U.S.	8,017,733	Polymer conjugates of interferon beta-1a	2027
	Europe	1,656,952	Polymer conjugates of interferon-beta-1a and uses thereof	2024[4]
	Europe	1,476,181	Polymer conjugates of interferon-beta-1a and uses thereof	2023[5]
TYSABRI	U.S.	8,124,350	Methods of treatment	2027
	U.S.	8,349,321	Formulation	2024
	U.S.	8,815,236	Formulation	2024
	U.S.	8,871,449	Methods of treatment	2026
	U.S.	8,900,577	Formulation	2024
	U.S.	9,316,641	Safety-related assay	2032
	U.S.	9,493,567	Methods of treatment	2027
	U.S.	9,709,575	Methods of treatment	2026
	U.S.	10,119,976	Methods of evaluating patient risk	2034
	U.S.	10,233,245	Methods of treatment	2027
	U.S.	10,444,234	Safety-related assay	2031
	U.S.	10,677,803	Methods of treatment	2034
	U.S.	10,705,095	Methods of treatment	2026
	U.S.	11,280,794	Methods of treatment	2034
	U.S.	11,287,423	Safety-related assay	2031
	U.S.	11,292,845	Methods of treatment	2027
	Europe	1,485,127	Methods of use	2023[2]
	Europe	2,170,390	Formulation	2028
	Europe	2,236,154	Formulation	2024
	Europe	2,676,967	Methods of use	2027
	Europe	3,339,865	Safety-related assay	2031
	Europe	3,417,875	Formulation	2024
	Europe	3,575,792	Safety-related assay	2032
FAMPYRA	Europe	1,732,548	Sustained-release aminopyridine compositions for increasing walking speed in patients with MS	2025[6]
	Europe	2,377,536	Sustained-release aminopyridine compositions for treating MS	2025[7]
VUMERITY	U.S.	8,669,281	Compounds and pharmaceutical compositions	2033
	U.S.	9,090,558	Methods of treatment	2033
	U.S.	10,080,733	Crystalline forms, pharmaceutical compositions and methods of treatment	2033
	Europe	2,970,101	Crystalline forms, pharmaceutical compositions and methods of treatment Prodrugs of fumarates and their use in treating various diseases	2034
SPINRAZA	U.S.	7,101,993	Oligonucleotides containing 2'-O-modified purines	2023
	U.S.	7,838,657	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2027
	U.S.	8,110,560	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2025
	U.S.	8,361,977	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	8,980,853	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	9,717,750	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	9,926,559	Compositions and methods for modulation of SMN2 splicing	2034

	U.S.	10,266,822	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2025
	U.S.	10,436,802	Methods for Treating Spinal Muscular Atrophy	2035
	Europe	1,910,395	Compositions and methods for modulation of SMN2 splicing	2026[8]
	Europe	2,548,560	Compositions and methods for modulation of SMN2 splicing	2026[9]
	Europe	3,305,302	Compositions and methods for modulation of SMN2 splicing	2030
	Europe	3,308,788	Compositions and methods for modulation of SMN2 splicing	2026
	Europe	3,449,926	Compositions and methods for modulation of SMN2 splicing	2030
ADUHELM	U.S.	8,906,367	Method of providing disease-specific binding molecules and targets	2032[10]
	U.S.	10,131,708	Methods of treating Alzheimer's disease	2028
LEQEMBI	U.S.	8,025,878	Protofibril selective antibodies and the use thereof	2027[1][10]

Footnotes follow on next page.

(1) In addition to patent protection, certain of our products are entitled to regulatory exclusivity in the U.S. and the E.U. expected until the dates set forth below:

Product	Territory	Expected Expiration
TECFIDERA	E.U.	Subject to appeal
PLEGRIDY	U.S.	2026
	E.U.	2024
SPINRAZA	U.S.	2023
	E.U.	2029
ADUHELM	U.S.	2033
LEQEMBI	U.S.	2035

(2) For additional information as to the validity of this patent, please read *Note 21, Litigation*, to our consolidated financial statements included in this report.

(3) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2024.

(4) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2024.

(5) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2028.

(6) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2026.

(7) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2026.

(8) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2031.

(9) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2031.

(10) A patent with this subject matter may be entitled to patent term extension in the U.S.

The existence of patents does not guarantee our right to practice the patented technology or commercialize the patented product. Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes, such as those that cover our existing products, compounds and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Litigation, interferences, oppositions, *inter partes* reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our patents, regulatory exclusivities or other proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We also face challenges to our patents, regulatory exclusivities or other proprietary rights covering our products by third-parties, such as manufacturers of generics, biosimilars, prodrugs and products approved under abbreviated regulatory pathways. A discussion of certain risks and uncertainties that may affect our patent position, regulatory exclusivities or other proprietary rights is set forth in *Item 1A. Risk Factors* included in this report, and the discussion of legal proceedings related to certain patents described above is set forth in *Note 21, Litigation,* to our consolidated financial statements included in this report.

Competition

Competition in the biopharmaceutical industry and the markets in which we operate is intense. There are many companies, including biotechnology and pharmaceutical companies, engaged in developing products for the indications our approved products are approved to treat and the therapeutic areas we are targeting with our research and development activities. Some of our competitors may have substantially greater financial, marketing, research and development and other resources than we do.

We believe that competition and leadership in the industry is based on managerial and technological excellence and innovation as well as establishing patent and other proprietary positions through research and development. The achievement of a leadership position also depends largely upon our ability to maximize the approval, acceptance and use of our product candidates and the availability of adequate financial resources to fund facilities, equipment, personnel, clinical testing, manufacturing and marketing. Another key aspect of remaining competitive in the industry is recruiting and retaining leading scientists and technicians to conduct our research activities and advance our development programs, including with the commercial expertise to effectively market our products.

Competition among products approved for sale may be based, among other things, on patent position, product efficacy, safety, patient convenience, delivery devices, reliability, availability, reimbursement and price. In addition, early entry of a new pharmaceutical product into the market may have important advantages in gaining product acceptance and market share. Accordingly, the relative speed with which we can develop products, complete the testing and approval process and supply commercial quantities of products will have a significant impact on our competitive position.

The introduction of new products or technologies, including the development of new processes or technologies by competitors or new information about existing products or technologies, results in increased competition for our marketed products and pricing pressure on our marketed products. The development of new or improved treatment options or standards of care or cures for the diseases our products treat reduces and could eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

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

We believe our long-term competitive position depends upon our success in discovering and developing innovative, cost-effective products that serve unmet medical needs, along with our ability to manufacture products efficiently and to launch and market them effectively in a highly competitive environment.

Additional information about the competition that our marketed products face is set forth below and in *Item 1A. Risk Factors* included in this report.

Multiple Sclerosis

TECFIDERA, AVONEX, PLEGRIDY, TYSABRI and VUMERITY each compete with one or more of the following branded products as well as generic and biosimilar versions of these products:

Competing Product	Competitor
AUBAGIO (teriflunomide)	Sanofi Genzyme
BETASERON/BETAFERON (interferon-beta-1b)	Bayer Group
BRIUMVI (ublituximab-xiiy)	TG Therapeutics, Inc.
COPAXONE (glatiramer acetate)	Teva Pharmaceuticals Industries Ltd.
EXTAVIA (interferon-beta-1b)	Novartis AG
GILENYA (fingolimod)	Novartis AG
GLATOPA (glatiramer acetate)	Sandoz, a division of Novartis AG
LEMTRADA (alemtuzumab)	Sanofi Genzyme
MAVENCLAD (cladribine)	EMD Serono
MAYZENT (siponimod)	Novartis AG
OCREVUS (ocrelizumab)	Genentech
PONVORY (ponesimod)	Janssen Pharmaceutical Companies of Johnson & Johnson
REBIF (interferon-beta-1)	EMD Serono
ZEPOSIA (ozanimod)	BMS
BAFIERTAM (monomethyl fumarate)	Banner Life Sciences
KESIMPTA (ofatumumab)	Novartis AG

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 the E.U., we are seeking to enforce a patent granted in June 2022 that relates to TECFIDERA and expires in 2028. In addition, we are litigating to affirm that TECFIDERA is entitled to regulatory data and market protection until at least February 2024. Our Company, the EMA and the EC have each appealed the May 2021 decision of the European General Court, which annulled the EMA's decision not to validate an application for approval of a TECFIDERA generic on the basis that the EMA and EC conducted the wrong assessment when determining TECFIDERA's entitlement to regulatory data and marketing protection. Our Company, the EMA and the EC have each appealed the General Court's decision as wrongly decided and the appeal is pending. On October 6, 2022, the Advocate General of the CJEU issued a nonbinding advisory opinion in Biogen's favor. This opinion recommends that the CJEU set aside the judgment of the European General Court. We are awaiting the decision of the CJEU.

FAMPYRA is indicated as a treatment to improve walking in adult patients with MS who have a walking disability and is the first treatment that addresses this unmet medical need with demonstrated efficacy in people with all types of MS. FAMPYRA is currently the only therapy approved to improve walking in patients with MS.

Competition in the MS market is intense. Along with us, a number of companies are working to develop additional treatments for MS that may in the future compete with our MS products. One such product that was approved in the U.S. in 2017 and in the E.U. in 2018 is OCREVUS, a treatment for RMS and PPMS that was developed by Genentech. While we have a financial interest in OCREVUS, future sales of our MS products may be adversely affected if OCREVUS continues to gain market share, or if other MS products that we or our competitors are developing are commercialized.

Spinal Muscular Atrophy

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

Additionally, we are aware of other products now in development that, if launched, may also compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products.

Psoriasis

FUMADERM competes with several different types of therapies in the psoriasis market within Germany, including oral systemics such as methotrexate and cyclosporine.

Biosimilars

BENEPALI, IMRALDI and FLIXABI, the three biosimilar products we currently commercialize in certain countries in Europe pursuant to an agreement with Samsung Bioepis, compete with their reference products, ENBREL, HUMIRA and REMICADE, respectively, as well as other biosimilars of those reference products.

In addition, BYOOVIZ, a biosimilar product we currently commercialize in the U.S. pursuant to an agreement with Samsung Bioepis, competes with its reference product LUCENTIS, as well as other biosimilars of this reference product.

Genentech Relationships in Other Indications

RITUXAN, RITUXAN HYCELA and GAZYVA in Oncology

RITUXAN, RITUXAN HYCELA and GAZYVA compete with a number of therapies in the oncology market, including TREANDA (bendamustine HCL), ARZERRA (ofatumumab), IMBRUVICA (ibrutinib) and ZYDELIG (idelalisib).

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

RITUXAN in Rheumatoid Arthritis

RITUXAN competes with several different types of therapies in the rheumatoid arthritis market, including, among others, traditional disease-modifying anti-rheumatic drugs such as steroids, methotrexate and cyclosporine, TNF inhibitors, ORENCIA (abatacept), ACTEMRA (tocilizumab) and XELJANZ (tofacitinib).

We are also aware of other products, including biosimilars, in development that, if approved, may

compete with RITUXAN in the rheumatoid arthritis market.

Research and Development Programs

A commitment to research is fundamental to our mission. Our research efforts are focused on better understanding the underlying biology of diseases so we can discover and deliver treatments that have the potential to make a real difference in the lives of patients with high unmet medical needs. By applying our expertise in biologics and our growing capabilities in small molecule, antisense, gene therapy, gene editing and other technologies, we target specific medical needs where we believe new or better treatments are needed.

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. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and technologies and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

For additional information on our research and development expense included in our consolidated statements of income, please read *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this report.

The table below highlights our current research and development programs that are in clinical trials and the current phase of such programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in *Item 1A. Risk Factors* included in this report.

Alzheimer's Disease and Dementia	Lecanemab (Aβ mAb)*** - Alzheimer's	Filed in the U.S., E.U. and Japan
	Lecanemab (Aβ mAb)* - Preclinical Alzheimer's	Phase 3
	Aducanumab (Aβ mAb)** - Alzheimer's	Filed in Japan and Other Markets
	BIIB080 (tau ASO)* - Alzheimer's	Phase 2
	BIIB113 (OGA inhibitor) - Alzheimer's	Phase 1
Neuropsychiatry	Zuranolone ($GABA_A$ PAM)* - MDD	Filed in the U.S.
	Zuranolone ($GABA_A$ PAM)* - PPD	Filed in the U.S.
Specialized Immunology	Dapirolizumab pegol (anti-CD40L)* - SLE	Phase 3
	Litifilimab (anti-BDCA2) - SLE	Phase 3
	Litifilimab (anti-BDCA2) - CLE	Phase 2/3
Neuromuscular Disorders	Tofersen (SOD1 ASO)* - SOD1 ALS	Filed in the U.S. and E.U.
	BIIB105 (ataxin-2 ASO)# - ALS	Phase 1/2
	BIIB115 (SMN ASO)* - SMA	Phase 1
Parkinson's Disease and Movement Disorders	BIIB122 (DNL151)* - LRRK2 Parkinson's	Phase 3
	BIIB122 (DNL151)* - Parkinson's	Phase 2
	BIIB124 (SAGE-324)* - Essential Tremor	Phase 2
	BIIB094 (ION859)# - Parkinson's	Phase 1
	BIIB101 (ION464)# - Multiple System Atrophy	Phase 1
	BIIB132 (ATXN-3 ASO)# - SCA3	Phase 1
Multiple Sclerosis	BIIB091 (peripheral BTK inhibitor) - MS	Phase 1
	BIIB107 (anti-VLA4) - MS	Phase 1
Neurovascular	Glibenclamide IV (SUR1-TRPM4 Inhibitor) - LHI^ Stroke	Phase 3
	Glibenclamide IV (SUR1-TRPM4 Inhibitor) - Brain Contusion	Phase 2
	BIIB131 (TMS-007) - Acute Ischemic Stroke	Phase 2
Genetic Neurodevelopmental Disorders	BIIB121 (UBE3A ASO)# - Angelman Syndrome	Phase 1

* Collaboration program
** Granted accelerated approval in the U.S. in June 2021 under the brand name ADUHELM.
*** Granted accelerated approval in the U.S. in January 2023 under the brand name LEQEMBI and filed for traditional approval in the U.S., E.U. and Japan.
# Option agreement
^ Large Hemispheric Infarction (LHI)

For information about certain of our agreements with collaborators and other third parties, please read the subsection entitled *Business Relationships* below and *Note 2, Acquisitions*, *Note 19, Collaborative and Other Relationships,* and *Note 20, Investments in Variable Interest Entities,* to our consolidated financial statements included in this report.

Business Relationships

As part of our business strategy, we establish business relationships, including entering into licenses, joint ventures and collaborative arrangements with other companies, universities and medical research institutions, to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies, universities and medical research institutions.

Below is a brief description of certain business relationships and collaborations that expand our pipeline and provide us with certain rights to existing and potential new products and technologies. For additional information on certain of these relationships, including their ongoing financial and accounting impact on our business, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Eisai Co., Ltd.

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

We also have a collaboration agreement with Eisai for ADUHELM. 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. On March 14, 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.

In addition, we and Eisai co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai distributes AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

Sage Therapeutics, Inc.

We have 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 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.

Ionis Pharmaceuticals, Inc.

We have an exclusive, worldwide option and collaboration agreement with Ionis relating to the development and commercialization of antisense therapeutics for up to three gene targets. Under a separate collaboration and license agreement with Ionis, we have an exclusive, worldwide license to develop and commercialize SPINRAZA for the treatment of SMA. We also have a 10-year exclusive collaboration agreement with Ionis to develop novel ASO drug candidates for a broad range of neurological diseases.

In addition, we have research collaboration agreements with Ionis under which both companies perform discovery level research and will develop and commercialize new ASO drug candidates for the potential treatment of SMA and additional antisense or other therapeutics for the potential treatment of neurological diseases.

Genentech, Inc. (Roche Group)

We have agreements with Genentech that entitle us to certain business and financial rights with respect to RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS, LUNSUMIO, which was granted accelerated approval in the U.S. during the fourth quarter of 2022, glofitamab and options to add other potential anti-CD20 therapies.

Denali Therapeutics Inc.

We have a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of LRRK2 for Parkinson's disease. Under this collaboration, both companies share responsibility and costs for global development based on specified percentages as well as profits and losses for commercialization in the U.S. and China. Outside the U.S. and China, we are responsible for commercialization and may pay Denali potential tiered royalties.

In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle (ATV): ATV enabled anti-amyloid beta program and a second program utilizing its Transport Vehicle technology. Further, we have the right of first negotiation on two additional ATV-enabled therapeutics for indications within specific neurodegenerative diseases, should Denali decide to seek a collaboration for such programs.

Samsung Bioepis Co., Ltd.

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. We also have an agreement with Samsung Bioepis to commercialize, over a 10-year term, three anti-TNF biosimilar product candidates in certain countries in Europe and, in the case of BENEPALI, Japan. Under this agreement, we are commercializing BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe.

In December 2019 we completed a transaction with Samsung Bioepis and acquired an option to extend our existing commercial agreement with Samsung Bioepis for BENEPALI, IMRALDI and FLIXABI in certain countries in Europe. We have also secured the exclusive rights to commercialize BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, which was approved in the U.S., the E.U. and the U.K. during the third quarter of 2021. BYOOVIZ launched in the U.S. in June 2022 and became commercially available during the third quarter of 2022. In addition to our commercialization agreements with Samsung Bioepis, we license certain of our proprietary technology to Samsung Bioepis in connection with Samsung Bioepis' development, manufacture and commercialization of its biosimilar products.

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

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.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions,* to our consolidated financial statements included in this report.

UCB

We have a collaboration agreement with UCB to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of SLE and other future agreed indications. Both companies will share equally costs incurred for agreed indications, including research, development, sales and marketing expense. If marketing approval is obtained, both companies will co-promote dapirolizumab pegol and share profits and losses equally.

Sangamo Therapeutics, Inc.

We have a collaboration and license agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. The companies are leveraging Sangamo's proprietary zinc finger protein technology delivered via adeno-associated virus to modulate the expression of key genes involved in neurological diseases. Under this collaboration, we may pay Sangamo tiered royalties on potential net sales of any products developed under this collaboration in the high single digit to sub-teen percentages.

Regulatory

Our current and contemplated activities and the products, technologies and processes that result from such activities are subject to substantial government regulation.

Regulation of Pharmaceuticals

Product Approval and Post-Approval Regulation in the U.S.

APPROVAL PROCESS

Before new pharmaceutical products may be sold in the U.S., preclinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. With limited exceptions, the FDA requires companies to register both pre-approval and post-approval clinical trials and disclose clinical trial results in public databases. Failure to register a trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties. Clinical trial programs must establish efficacy, determine an appropriate dose and dosing regimen and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. The results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a BLA or a NDA. In response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval.

Product development and receipt of regulatory approval takes a number of years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of suitable alternative treatments, potential safety signals observed in preclinical or clinical tests and the risks and benefits of the product as demonstrated in clinical trials. The FDA has substantial discretion in the product approval process, and it is impossible to predict with any certainty whether and when the FDA will grant marketing approval. The agency may require the sponsor of a BLA or NDA to conduct additional clinical studies or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delays or expenses. Furthermore, even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the existing pre-clinical and/or clinical data.

The FDA has developed four distinct approaches intended to facilitate the development and expedite the regulatory review of therapeutically important drugs, especially when the drugs are the first available treatment or have advantages over existing treatments: accelerated approval, fast track, breakthrough therapy and priority review.

- *Accelerated Approval*: The FDA may grant “accelerated approval” to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Under this pathway, the FDA may approve a product based on surrogate endpoints or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to provide the FDA with confirmatory data post-approval to verify and describe clinical benefit. Under the FDA's accelerated approval regulations, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it may require certain post-marketing restrictions to assure safe use. In addition, for products approved under accelerated approval, sponsors may be required to submit all copies of their promotional materials, including advertisements, to the FDA at least 30 days prior to initial dissemination. The FDA may withdraw approval if, for instance, post-marketing studies fail to verify clinical benefit, it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use or if a sponsor fails to comply with the conditions of the accelerated approval.
- *Fast Track*: The FDA may grant "fast track" status to products that treat a serious condition and have data demonstrating the potential to address an unmet medical need or a drug that has been designated as a qualified infectious disease product.
- *Breakthrough Therapy*: The FDA may grant “breakthrough therapy” status to drugs designed to treat, alone or in combination with another drug or drugs, a serious or life-threatening disease or condition and for which preliminary clinical evidence suggests a substantial improvement over existing therapies based on a clinically significant endpoint. Breakthrough therapy status entitles the sponsor to earlier and more frequent meetings with the FDA regarding the development of nonclinical and clinical data and permits the FDA to offer product development or regulatory advice for the purpose of shortening the time to product approval. Breakthrough therapy status does not guarantee that a product will be eligible for priority review and does not ensure FDA approval.

- *Priority Review*: "Priority review" only applies to applications (original or efficacy supplement) for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Priority review may also be granted for any supplement that proposes a labeling change due to studies completed in response to a written request from the FDA for pediatric studies, for an application for a drug that has been designated as a qualified infectious disease product or for any application or supplement for a drug submitted with a priority review voucher.

  In December 2016 the FDA issued a rare pediatric disease priority review voucher to us in connection with the approval of SPINRAZA.

POST-MARKETING STUDIES

Regardless of the approval pathway employed, the FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. If a sponsor fails to conduct the required studies, the FDA may withdraw its approval. In addition, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it can mandate post-marketing restrictions to assure safe use. In such a case, the sponsor may be required to establish rigorous systems to assure use of the product under safe conditions. These systems are usually referred to as Risk Evaluation and Mitigation Strategies (REMS). The FDA can impose financial penalties for failing to comply with certain post-marketing commitments, including REMS. In addition, any changes to an approved REMS must be reviewed and approved by the FDA prior to implementation.

ADVERSE EVENT REPORTING

We monitor information on side effects and adverse events reported during clinical studies and after marketing approval and report such information and events to regulatory agencies. Non-compliance with the FDA's safety reporting requirements may result in civil or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials) or suspend or withdraw approval of the product. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals.

APPROVAL OF CHANGES TO AN APPROVED PRODUCT

If we seek to make certain types of changes to an approved product, such as adding a new indication, making certain manufacturing changes or changing manufacturers or suppliers of certain ingredients or components, the FDA will need to review and approve such changes in advance. In the case of a new indication, we are required to demonstrate with additional clinical data that the product is safe and effective for a use other than what was initially approved. FDA regulatory review may result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

REGULATION OF PRODUCT ADVERTISING AND PROMOTION

The FDA regulates all advertising and promotion activities and communications for products under its jurisdiction both before and after approval. Pursuant to FDA guidance, a company can make safety and efficacy claims either in or consistent with the product label. However, physicians may prescribe legally available drugs for uses that are not described in the drug's labeling. Such off-label prescribing is common across medical specialties, and often reflects a physician's belief that the off-label use is the best treatment for patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising and the full range of civil and criminal penalties available to the government.

Regulation of Combination Products

Combination products are defined by the FDA to include products comprising two or more regulated components (e.g., a biologic and a device). Biologics and devices each have their own regulatory requirements, and combination products may have additional requirements. Some of our marketed products meet this definition and are regulated under this framework and similar regulations outside the U.S., and we expect that some of our pipeline product candidates may be evaluated for regulatory approval under this framework as well.

In May 2017 new regulations governing medical devices (MDR) and in-vitro diagnostic medical devices (IVDR) entered into force in the E.U. The MDR regulations became applicable in May 2021 and the

IVDR regulations became applicable in May 2022. All products covered by these regulations will be required to comply with them at the end of the transitional periods. These regulations introduce new requirements, including for clinical investigation of certain classifications of medical devices, require increased regulatory scrutiny, enhance the requirements for post market surveillance and vigilance and provide for greater transparency. These regulations also change the requirements for assessment of the medical device components of integral drug-device combination products, necessitating assessment of the device components under both the medical device and medicinal product regulatory regimes.

Product Approval and Post-Approval Regulation Outside the U.S.

We market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, for example, where a substantial part of our ex-U.S. efforts are focused, there are several routes for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing authorization application is similar to the NDA or BLA in the U.S. and is evaluated by the CHMP, the expert scientific committee of the EMA responsible for human medicines. If the CHMP determines that the MAA fulfills the requirements for quality, safety and efficacy and that the medicine has a positive benefit risk balance, it will adopt a positive opinion recommending the granting of the marketing authorization by the EC. The CHMP opinion is not binding, but is typically adopted by the EC. A MAA approved by the EC is valid in all member states of the E.U. The centralized procedure is required for all biological products, orphan medicinal products and new treatments for neurodegenerative disorders, and it is available for certain other products, including those which constitute a significant therapeutic, scientific or technical innovation.

In addition to the centralized procedure, the European regulatory framework includes the following options for regulatory review and approval in the E.U. member states:

- a national procedure, where the first application is made to the competent authority in one E.U. member state only;
- a decentralized procedure, where applicants submit identical applications to several E.U. member states and receive simultaneous approval, if the medicine has not yet been authorized in any E.U. member state; and
- a mutual recognition procedure, where applicants that have a medicine authorized in one E.U. member state can apply for mutual recognition of this authorization in other E.U. member states

As in the U.S., the E.U. also has distinct approaches intended to optimize the regulatory pathways for therapeutically important drugs, including the Priority Medicines Evaluation Scheme (PRIME), accelerated assessment and conditional marketing authorization. PRIME is intended to provide additional support to medicine developers throughout the development process. Regulatory review timelines in the E.U. may be truncated under accelerated assessment for products that address an unmet medical need. In addition, conditional marketing authorizations may be granted for products in the interest of public health, where the benefit of immediate availability outweighs the risk of having less comprehensive data than normally required. Conditional marketing authorizations are valid for one year and can be renewed annually. The marketing authorization holder is required to complete specific obligations (ongoing or new studies and, in some cases, additional activities) with a view to providing comprehensive data confirming that the benefit risk balance is positive. Once comprehensive data on the product have been obtained, the marketing authorization may be converted into a standard marketing authorization.

Aside from the U.S. and the E.U., there are countries in other regions where it is possible to receive an "accelerated" review whereby the national regulatory authority will commit to truncated review timelines for products that meet specific medical needs.

In the E.U. there is detailed legislation on pharmacovigilance and extensive guidance on good pharmacovigilance practices. A failure to comply with the E.U. pharmacovigilance obligations may result in significant financial penalties for the marketing authorization holder.

Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection and evaluation of adverse events post-approval, including national competent authorities, the EMA, the EC and the marketing authorization holder. The EMA’s Pharmacovigilance Risk Assessment Committee is responsible for assessing and monitoring the safety of human medicines and makes recommendations on product safety issues. Marketing authorization holders have an obligation to inform regulatory agencies of any new information which may influence the evaluation of benefits and risks of the medicinal product concerned.

In the U.S., the E.U. and other jurisdictions, regulatory agencies, including the FDA, conduct periodic inspections of NDA, BLA and marketing authorization holders to assess their compliance with pharmacovigilance obligations.

Good Manufacturing Practices

Regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing and testing of pharmaceutical and biologic products prior to approving a product. If, after receiving approval from regulatory agencies, a company makes a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required. We also must adhere to current Good Manufacturing Practices (cGMP) and product-specific regulations enforced by regulatory agencies following product approval. The FDA, the EMA and other regulatory agencies also conduct periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions or remedies against us, including significant financial penalties and the suspension of our manufacturing operations.

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected (commonly referred to as current Good Clinical Practices (cGCP)). Regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites, contract research organizations (CROs) and institutional review boards. If our studies fail to comply with applicable cGCP guidelines, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third-parties, including CROs, to carry out many of our clinical trial-related activities. Failure of such third-parties to comply with cGCP can likewise result in rejection of our clinical trial data or other sanctions.

In April 2014 the EC adopted a new Clinical Trial Regulation, which was entered into force in June 2014 but did not apply until January 2022. There are transitional provisions for clinical trials which are ongoing at the date of application. Clinical trial applications may also continue to be made under the Clinical Trial Directive (the existing regulatory framework) until January 2023. All clinical trials must fully comply with the Clinical Trial Regulation by January 2025. The regulation harmonizes the procedures for assessment and governance of clinical trials throughout the E.U. and will require that information on the authorization, conduct and results of each clinical trial conducted in the E.U. be publicly available.

Approval of Biosimilars

In the U.S. the Patient Protection and Affordable Care Act (PPACA) amended the Public Health Service Act (PHSA) to authorize the FDA to approve biological products, referred to as biosimilars or follow-on biologics, that are shown to be "highly similar" to previously approved biological products based upon potentially abbreviated data packages. The biosimilar must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product, and only minor differences in clinically inactive components are allowable in biosimilar products. The approval pathway for biosimilars does, however, grant a biologics manufacturer a 12-year period of exclusivity from the date of approval of its biological product before biosimilar competition can be introduced. There is uncertainty, however, as the approval framework for biosimilars originally was enacted as part of the PPACA. There have been, and there are likely to continue to be, federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. If the PPACA is repealed, substantially modified or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation.

A biosimilars approval pathway has been in place in the E.U. since 2003. The EMA has issued a number of scientific and product specific biosimilar guidelines, including requirements for approving biosimilars containing monoclonal antibodies. In the E.U., biosimilars are generally approved under the centralized procedure. The approval pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on reliance on the clinical trial data of an innovator product to which the biosimilar has been demonstrated, through comprehensive comparability studies, to be “similar.” In many cases, this allows biosimilars to be brought to market without conducting the full complement of clinical trials typically required for novel biologic drugs.

Orphan Drug Act

Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a “rare disease or condition,” which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. If a product

which has an orphan drug designation subsequently receives an initial FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years following marketing approval, except in certain very limited circumstances, such as if the later product is shown to be clinically superior to the orphan product. Legislation similar to the U.S. Orphan Drug Act has been enacted in other countries to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases. In the E.U., medicinal products that receive and maintain an orphan designation are entitled to 10 years of market exclusivity following approval, protocol assistance and access to the centralized procedure for marketing authorization. SPINRAZA has been granted orphan drug designation in the U.S., the E.U. and Japan.

Regulation Pertaining to Pricing and Reimbursement

In both domestic and foreign markets, sales of our products depend, to a significant extent, on the availability and amount of reimbursement by third-party payors, including governments, private health plans and other organizations. Substantial uncertainty exists regarding the pricing and reimbursement of our products, and drug prices continue to receive significant scrutiny. Governments may regulate coverage, reimbursement and pricing of our products to control cost or affect utilization of our products. Challenges to our pricing strategies, by either government or private stakeholders, could harm our business. The U.S. and foreign governments have enacted and regularly consider additional reform measures that affect health care coverage and costs. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. Other payors, including managed care organizations, health insurers, pharmacy benefit managers, government health administration authorities and private health insurers, seek price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, may impose restrictions on access, coverage or pricing of particular drugs based on perceived value.

Within the U.S.

- *Medicaid*: Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate is established by law and is adjusted upward if the average manufacturer price (AMP) increases more than inflation (measured by the Consumer Price Index - Urban). The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the CMS. The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

- *Medicare*: Medicare is a federal program that is administered by the federal government. The program covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners, are provided in connection with certain durable medical equipment or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price (ASP) of the drugs. Manufacturers, including us, are required to provide ASP information to the CMS on a quarterly basis. The manufacturer-submitted information is used to calculate Medicare payment rates. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.

  Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government. Each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers, including us, are required to provide to the CMS a discount of up to 70.0% on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

  On August 16, 2022, President Biden signed into law the IRA, which provides for (i) the government to negotiate prices for select high-cost Medicare Part D drugs (beginning in 2026) and Part B drugs (beginning in 2028), (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices increase faster than inflation

beginning in 2022 for Part D and 2023 for Part B, and (iii) Medicare Part D redesign which replaces the current coverage gap provisions and establishes a $2,000 cap for out-of-pocket costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10.0% of costs up to the $2,000 cap and 20.0% after that cap is reached.

The result of these forthcoming changes for manufacturers, including us, may include: i) a material adverse effect on our revenue on drugs subject to "negotiation"; ii) new rebate liability for drugs subject to the inflation provisions, and iii) potential significant additional costs related to the Part D re-design. However, as the degree of impact from this legislation on our business depends on a number of forthcoming implementation actions by regulatory authorities, the full extent of the IRA's impact on our sales and, in turn, our business, remains unclear.

- *Federal Agency Discounted Pricing*: Our products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration (VA), Department of Defense, Coast Guard and Public Health Service (PHS). Coverage under Medicaid, Medicare and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the VA, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76.0% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties.
- *340B Discounted Pricing*: To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend significant discounts to certain covered entities that purchase products under Section 340B of the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive certain types of grants under the PHSA. For all of our products, we must agree to charge a price that will not exceed the amount determined under statute (the "ceiling price") when we sell outpatient drugs to these covered entities. In addition, we may, but are not required to, offer these covered entities a price lower than the 340B ceiling price. The 340B discount formula is based on AMP and is generally similar to the level of rebates calculated under the Medicaid Drug Rebate Program.

Outside the U.S.

Outside the U.S., our products are paid for by a variety of payors, with governments being the primary source of payment. Governments may determine or influence reimbursement of products and may also set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization 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). Budgetary pressures in many countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates and expanded generic substitution and patient cost-sharing.

Regulation Pertaining to Sales and Marketing

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. There is therefore a possibility that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and exclusion from federal health care programs (including Medicare and Medicaid). In the U.S., federal and state authorities are paying increased attention to enforcement of these laws

within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include federal "sunshine" provisions. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which 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. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

The laws to which we are subject also include the U.K. Bribery Act 2010 (Bribery Act), which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the U.K. generally will be subject to the Bribery Act. Penalties under the Bribery Act include significant fines for companies and criminal sanctions for corporate officers under certain circumstances.

NIH Guidelines

We seek to conduct research at our U.S. facilities in compliance with the current U.S. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). By local ordinance, we are required to, among other things, comply with the NIH Guidelines in relation to our facilities in RTP, NC and are required to operate pursuant to certain permits.

Other Laws

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to data privacy and protection, safe working conditions, laboratory practices, the experimental use of animals and the purchase, storage, movement, import, export and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights may be subject to national or international antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

The European Parliament and the Council of the E.U. adopted a comprehensive general data privacy regulation (GDPR) in 2016 to replace the current E.U. Data Protection Directive and related country-specific legislation. The GDPR took effect in May 2018 and governs the collection and use of personal data in the E.U. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20.0 million or 4.0% of the annual global revenue of the infringer, whichever is greater.

Manufacturing

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. We believe that our manufacturing facilities, together with the third-party contract manufacturing organizations we outsource to, currently provide sufficient capacity for our products and to Samsung Bioepis, our collaboration partner that develops, manufactures and markets biosimilar products, and other strategic contract manufacturing partners.

In March 2021 we announced our plans to build a new gene therapy manufacturing facility in RTP, NC 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. Construction for this new facility began during the fourth quarter of 2021.

Manufacturing Facilities

Our drug substance manufacturing facilities include:

Facility	Drug Substance Manufactured
RTP, North Carolina	AVONEX PLEGRIDY TYSABRI Other*
Solothurn, Switzerland	ADUHELM LEQEMBI

* Other includes products manufactured for contract manufacturing partners.

In addition to our drug substance manufacturing facilities, we have a drug product manufacturing facility and supporting infrastructure in RTP, NC, including a parenteral facility and an oral solid dose products manufacturing facility.

The parenteral facility adds capabilities and capacity for filling biologics into vials and is used for filling product candidates. The oral solid dose products facility can supplement our outsourced small molecule manufacturing capabilities.

We also have an oligonucleotide synthesis manufacturing facility in RTP, NC. This facility gives us the capability to manufacture ASO candidates currently in our clinical pipeline.

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. In the second quarter of 2021 a portion of the facility received a Good Manufacturing Practice (GMP) multi-product license from the Swiss Agency for Therapeutic Products (SWISSMEDIC). Solothurn has been approved for the manufacture of ADUHELM and LEQEMBI by the FDA. We estimate the second manufacturing suite at the Solothurn facility will be operational by the end of 2023.

Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN, RITUXAN HYCELA and GAZYVA and has sourced the manufacture of certain bulk RITUXAN, RITUXAN HYCELA and GAZYVA requirements to a third party. Ionis supplies the active pharmaceutical ingredient (API) for SPINRAZA. Alkermes currently supplies both VUMERITY and FAMPYRA to us pursuant to separate supply agreements. In October 2019 we entered into a new supply agreement and amended our license and collaboration agreement with Alkermes for VUMERITY. We have elected to initiate a technology transfer and, following a transition period, to manufacture VUMERITY or have VUMERITY manufactured by a third party we have engaged in exchange for paying an increased royalty rate to Alkermes on any portion of future worldwide net commercial sales of VUMERITY that is manufactured by us or our designee. In October 2022 we entered into a new supply agreement with Alkermes for FAMPYRA. Acorda previously supplied FAMPYRA to us pursuant to a sublicensing arrangement with Alkermes, which was terminated in October 2022 as a result of an arbitration outcome between Acorda and Alkermes.

Third-Party Suppliers and Manufacturers

We principally use third parties to manufacture the API and the final product for our small molecule products and product candidates, including TECFIDERA and FUMADERM, and the final drug product for our large molecule products and, to a lesser extent, product candidates.

We source the majority of our fill-finish and all of our final product assembly and storage operations for our products, along with a substantial part of our label and packaging operations, to a concentrated group of third-party contract manufacturing organizations. Raw materials, delivery devices, such as syringes and auto-injectors, and other supplies required for the production of our products and product candidates are procured from various third-party suppliers and manufacturers in quantities adequate to meet our needs. Continuity of supply of such raw materials, devices and supplies is assured through inventory management and dual sourcing as appropriate. Our third-party service providers, suppliers and manufacturers may be subject to routine cGMP inspections by the FDA or comparable agencies in other jurisdictions and undergo assessment and certification by our quality management group.

ESG and Climate-Related Matters

Introduction

Our environmental, social and governance (ESG) efforts prioritize climate, health and equity, with a focus on vulnerable populations, as well as ongoing leadership in sustainability, governance, transparency and disclosure.

We remain committed to reducing our environmental footprint by eliminating harmful emissions and by minimizing resources used to manufacture our products. Since 2014 we have taken responsibility for our impact on climate change by matching 100% of our electricity usage with renewable energy, credits and offsets, driving efficiency initiatives internally and working with our suppliers. Green chemistry is embraced throughout our company, continually exploring new ways to make our drug development processes safer, more efficient and more sustainable while also saving resources.

Governance

ESG oversight is formally embedded into our Board of Director's governance principles and includes an annual review of our ESG strategy and short-and long-term goals. We regularly review our environmental commitments within the landscape of our business performance, rising costs and supply chain challenges. We remain committed to engaging employees and suppliers and collaborating with renowned institutions to advance the science and action to improve health outcomes.

As part of our broader commitment to these priorities, we continue to tie a portion of our employees' and executive officers' compensation to advancing our ESG efforts.

We strive to comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our operations or competitive position. Our Executive Committee has responsibility for evaluating the impact of climate change on the business and overseeing actions taken by the company to limit its adverse impact on the environment.

Our Enterprise Risk Management (ERM) framework is designed to ensure climate-related risks and opportunities are integrated into our overall business strategy. Our ERM team monitors strategic climate-related risks across all aspects of our business and utilizes climate scenarios as part of its assessments. On an annual basis, the ERM team evaluates identified risks, including any climate-related physical and transitional risks, by engaging leaders across the company. The ERM team provides annual updates on their findings and activities to our Executive Committee and Board of Directors.

Risk Management

Addressing ESG matters is part of our long-term global strategy and investment in our future and we have seen increased interest from stakeholders and investors on our ESG practices. While we continue to to advance our ESG efforts, there is no certainty that we will manage ESG matters in ways that successfully meet rapidly changing expectations from investors, regulators, third party rankings firms, customers and society as a whole. Our inability to manage ESG matters in accordance with expectations can negatively impact our reputation and business.

Climate Risk Management

We identify climate risk as the risk of loss arising from climate change and is comprised of both physical risk and transition risk. Physical risk considers how the physical impacts of climate change (e.g., increased storms, drought, fires, floods) can directly damage physical assets or otherwise impact their value or productivity. Transition risk considers how changes in policy. regulations, culture, technology, business practices and market preferences to address climate change (e.g., carbon pricing policies, power generation shifts from fossil fuels to renewable energy) can lead to changes in the value of assets and businesses. Disruption in supply chains, changing customer expectations in the biosimilar market and potential shifts in the regulatory environment that disadvantage the use of fossil fuels, may make it difficult for us to fulfill business obligations or cause us to incur substantial expense.

Identified material risks and opportunities are reported to our ERM team, which reports to our Executive Committee and Board of Directors. We consider and address those risks and opportunities that are financially material and may impact our business model, as well as mitigation measures that are in place or need to be adopted.

For additional information on our environment-related risks, please read *Item 1A. Risk Factors* included in this report.

Human Capital

As of December 31, 2022, we had approximately 8,725 employees worldwide. Approximately 4,970 employees were employed in the U.S. and approximately 3,755 employees were employed in foreign countries.

Diversity, Equity and Inclusion

At Biogen, prejudice, racism and intolerance are unacceptable. We are committed to Diversity, Equity and Inclusion (DE&I) across all aspects of our organization, including recruitment, hiring, promotion, retention and development practices. As of December 31, 2022, 30.4% of Biogen's manager-level and above positions were held by ethnic or racial minorities in the U.S. Our policies and practices are global, but the laws in many countries outside the U.S. do not permit us to collect ethnic or racial data on our employees. Globally, 47.4% of Biogen's positions at director-level and above were held by women as of December 31, 2022.

Our DE&I strategy outlines actionable steps to deepen our commitment across the business, building upon a strong foundation. This plan includes the strategy to build our talent and strengthen our leadership, improve health outcomes for underserved communities in the disease areas we treat and contribute to the communities impacting our employees and patients. We plan to create greater awareness and capability in our organization through leadership accountability and transparency. To establish and progress this strategy, we rely on a cross-company governing body of employees known as the Diversity, Equity & Inclusion Strategic Council.

We are honored to be recognized as an employer of choice. For the fifth consecutive year, we scored 100% on the Disability:IN's Disability Equality Index, which measures our policies and practices related to disability inclusion. Additionally, for the third consecutive year, we were awarded the DI-NC Employer Award by Disability:IN North Carolina for our commitment to champion and invest in disability inclusion at the affiliate and national levels. For the ninth consecutive year, we were recognized as a Best Place to Work for LGBTQ+ Equality by the Human Rights Campaign, scoring 100% on their Corporate Equality Index.

Strengthening our Global Competency

We are committed to strengthening the DE&I awareness and capability of our employees. We have focused on ensuring that our employees have the resources and learning they need to contribute to our strategy. Our people managers are trained on inclusive recruiting and hiring and our global employees are trained on DE&I curriculum.

In 2022 we introduced GlobeSmart® , a tool to enhance cross-cultural collaboration, increase cultural agility and further connect our global teams. Our people leaders have used GlobeSmart® , allowing them to explore different working styles, perspectives and approaches that exist around the globe, getting actionable, personalized advice for better collaboration and teamwork across cultures, and exploring new ways for teams to build trust, strengthen collaboration and leverage diversity.

Philosophy on Pay Equity

We are committed to ensuring our employees receive equal pay for equal work. We establish components and ranges of compensation based on market and benchmark data. Within this context, we strive to pay all employees equitably within a reasonable range, taking into consideration factors such as role; market data; internal equity; job location; relevant experience; and individual, business unit and company performance. In addition, we are committed to providing flexible benefits designed to allow our diverse global workforce to have reward opportunities that meet their varied needs so that they are inspired to perform their best on behalf of patients and stockholders each day.

We regularly review our compensation practices and analyze the equity of compensation decisions, for individual employees and our workforce as a whole. In 2022 we shared the results of a global gender pay assessment, analyzing pay at the executive, management and other professional levels.

We institute measures, such as communications and trainings, to recognize, interrupt and prevent bias in hiring, performance management and compensation decisions and we provide resources to further develop managers and leaders to help them make equitable decisions about pay.

Talent and Development

Many factors influence employee success and well-being. We foster a workplace to allow employees to deliver on our shared mission while helping to mitigate their challenges. From career development to wellness to workplace environment, there are many opportunities to meet employee needs, and to build a workplace where people are empowered to learn, grow and build rewarding careers. Our employees are encouraged to take advantage of an array of professional development resources. Managers coach employees for performance, and also engage in employee development discussions to support growth and learning.

Opportunities for ongoing learning can contribute to employee related engagement and success. At Biogen, development occurs through on-the-job learning, challenging new assignments, formal training, online learning, mentoring and more. With many employees continuing to work from home, virtual learning plays a key role. Virtual learnings are available through Biogen University as well as LinkedIn Learning. Through Biogen University we offer more than 1,200 instructor-based courses, of which approximately 300 are available virtually. Through LinkedIn Learning we provided employees with access

to more than 20,000 on-demand learning modules in 11 languages: English, German, French, Spanish, Japanese, Portuguese, Italian, Dutch, Polish, Turkish and Mandarin.

To create and sustain a workplace as diverse and inclusive as the patients we serve, we offer programs that invest in our talent pipeline and in our current leaders, including:

- *Activate, Reflect and Co-Create:* Preparing top talent for the rigors of executive roles.
- *Women's Leadership Program:* Addressing the unique challenges faced by female leaders to increase influence and impact.
- *Executive Leadership Retreat:* Immersing leaders in topics designed to help them shape culture and build resilience.
- *The Partnership, Inc's BioDiversity Fellows Program:* To continue to bolster our talent pipeline with a diverse mix of leaders, high potential, mid-career, underrepresented minorities participate in this program, which we helped create.
- *Women on the Rise:* Addressing the unique challenges faced by mid-level female leaders to increase influence and impact.
- *Emerging Leaders:* Preparing high-potential individual contributors for first-level leadership roles.
- *BetterUp:* Coaching program available to support individuals as they work toward enhancing their impact in the organization.

Our Employee Resource Networks (ERNs) provide invaluable opportunities for employees to share knowledge and build connections. Our current ERNs include:

- *Parenting Network Group:* Biogen's newest ERN provides support, networking and development opportunities to working parents and caregivers, as well as helping employees navigate the challenges of work-life balance.
- *IGNITE:* Brings together early-career professionals and their advocates.
- *AccessAbility:* Supports employees with disabilities and employees who are caretakers of individuals with disabilities.
- *Biogen Veterans Network:* Encourages veterans and allies of veterans to connect and support one another.
- *Mosaic:* Fosters awareness and appreciation of different cultural backgrounds, in addition to promoting networking and development opportunities for members.
- *ReachOUT:* Supports a best-in-class working environment for LGBTQ+ employees and embraces all LGBTQ+ employees and their allies.
- *Women's Innovation Network:* Creates networking, mentoring and learning opportunities for women and allies worldwide.
- *ourIMPACT:* Advances climate, health and equity at work, in employees' personal lives and in the communities where we live and work.

We continue to evolve our programs to meet our employees' health and wellness needs, which we believe is essential to attract and retain employees of the highest caliber. We have refreshed our flexible working arrangement policies to allow for more flexibility around work hours to help employees balance the demands of their work and home lives, shifted many of our on-site wellness services to virtual, including virtual behavior health, nutrition, fitness and overall well-being classes and counseling, rolled out the Headspace meditation app globally at no cost, provided workshops and programming to help employees cope with stress, isolation and building resilience, along with financial planning workshops and counseling sessions, expanded our caregiver services to meet the growing needs of our employees and provided additional holidays and time off for recharging, voting and volunteering.

Employee Surveys

We utilize an employee survey program to pulse employees through email and mobile apps as well as provide an opportunity for commentary and facilitate feedback to questions. The survey is designed to empower managers and leaders with anonymous information on their practices related to building culture, performance and an engaged workforce, allowing them to create plans and measure efficacy for continuous improvement. We care deeply about employee feedback and are building an analytics community across Human Resources to bring more rigor and sophistication to the collection and analysis of employee opinions. We use their perspectives to guide us to take actions that improve engagement and support and help maintain our reputation as a great place to work for all our employees. An example of such an action was our 2022 Wellness Week, a weeklong mid-year shutdown.

Succession Planning

Each year we conduct a talent review across our global enterprise that includes, among other important topics, a review of succession plans for many of our roles. To help ensure the long-term continuity of our business, we actively manage the development of talent to fill the roles that are most critical to the

ongoing success of our company. In addition, each year our Board of Directors reviews the succession plan for our executives.

Workplace Health and Safety

The well-being of our employees is the priority, and we believe every employee plays a role in creating a safe and healthy workplace. Our employees have varied roles and functions, which is why we empower them to promote a safe working environment, regardless of whether work happens in the lab, in an office or in a manufacturing plant. Our policies and practices are intended to protect not only our employees, but also the surrounding communities where we operate.

In 2022 we continued to make significant progress integrating Human Performance into our Environment, Health and Safety programs. We believe that, when it comes to safety, workers are part of the solution. We encourage employees to collaboratively engage in proactive problem solving through practices such as Open Reporting and Work Observation and Risk Conversations. Additionally, our physical safety program focused on detailed evaluations of critical tasks that could expose employees to serious injury or fatality if controls are absent or not used. The actions we implement as a result of these evaluations reduce the risks associated with these essential activities and ensure our operational systems are safer and more resilient for employees. We also use “After Action Reviews” following the completion of a project. These reviews enable us to not only focus on areas for improvement, but also to learn and apply good practices from what goes well. By engaging and empowering our employees through such programs, we believe that we can help change how the entire industry approaches safety performance and risk management.

Information about our Executive Officers (as of February 15, 2023)

Officer	Current Position	Age	Year Joined Biogen
Christopher A. Viehbacher	President, Chief Executive Officer	62	2022
Susan H. Alexander	Executive Vice President, Chief Legal Officer and Secretary	66	2006
Michael R. McDonnell	Executive Vice President and Chief Financial Officer	59	2020
Nicole Murphy	Executive Vice President, Pharmaceutical Operations and Technology	50	2015
Ginger Gregory, Ph.D.	Executive Vice President and Chief Human Resources Officer	55	2017
Rachid Izzar	Executive Vice President, Global Product Strategy and Commercialization	48	2019
Priya Singhal, M.D., M.P.H.	Executive Vice President, Head of Development	55	2020
Robin C. Kramer	Senior Vice President, Chief Accounting Officer	57	2018

Christopher A. Viehbacher

Experience

Mr. Viehbacher has served as our President and Chief Executive Officer and member of our Board of Directors since November 2022. Prior to joining Biogen, Mr. Viehbacher served as Managing Partner of Gurnet Point Capital, a Boston based investment fund from 2015 to 2022. Prior to that, Mr. Viehbacher served as Global CEO of Sanofi, from 2008 to 2014. Prior to joining Sanofi, Mr. Viehbacher spent over 20 years with GlaxoSmithKline in Germany, Canada, France and, latterly, the U.S. as president of its North American pharmaceutical division. Mr. Viehbacher began his career with PricewaterhouseCoopers LLP and qualified as a chartered accountant. Mr. Viehbacher previously served on the board of directors of Vedanta Biosciences, Inc. as chair, BEFORE Brands, Inc., and Crossover Health. He is also a trustee of Northeastern University and a member of the board of fellows at Stanford Medical School.

Public Company Boards

- PureTech Health Plc.

Education

- Queen's University in Kingston, Ontario, Canada, B.A.

Susan H. Alexander

Experience

Ms. Alexander has served as our Executive Vice President, Chief Legal Officer and Secretary since April 2018. Prior to that, Ms. Alexander served as our Executive Vice President, Chief Legal, Corporate Services and Secretary from March 2017 to March 2018, as our Executive Vice President, Chief Legal Officer and Secretary from December 2011 to March 2017 and as our Executive Vice President, General Counsel and Corporate Secretary from 2006 to December 2011. Prior to joining Biogen, Ms. Alexander served as the Senior Vice President, General Counsel and Corporate Secretary of PAREXEL International Corporation, a biopharmaceutical services company, from 2003 to January 2006. From 2001 to 2003 Ms. Alexander served as General Counsel of IONA Technologies, a software company. From 1995 to 2001 Ms. Alexander served as Counsel at Cabot Corporation, a specialty chemicals and performance materials company. Prior to that, Ms. Alexander was a partner at the law firms of Hinckley, Allen & Snyder and Fine & Ambrogne.

Education

- Wellesley College, B.A.
- Boston University School of Law, J.D.

Michael R. McDonnell

Experience

Mr. McDonnell has served as our Executive Vice President and Chief Financial Officer since August 2020. Prior to joining Biogen, Mr. McDonnell served as Executive Vice President and Chief Financial Officer of IQVIA Holdings Inc., a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry, from December 2015 until July 2020. Prior to that, Mr. McDonnell served as the Executive Vice President and Chief Financial Officer of Intelsat, a leading global provider of satellite services, from November 2008 to December 2015, as Executive Vice President and Chief Financial Officer of MCG Capital Corporation, a publicly-held commercial finance company, from September 2004 until October 2008 and as MCG Capital Corporation's Chief Operating Officer from August 2006 until October 2008. Before joining MCG Capital Corporation, Mr. McDonnell served as Executive Vice President and Chief Financial Officer for EchoStar Communications Corporation (f/k/a DISH Network Corporation), a direct-to-home satellite television operator, from July 2004 until August 2004 and as its Senior Vice President and Chief Financial Officer from August 2000 to July 2004. Mr. McDonnell spent 14 years at PricewaterhouseCoopers LLP, including 4 years as a partner. Mr. McDonnell is a licensed certified public accountant (CPA).

Public Company Boards

- Merit Medical Systems, Inc.

Education

- Georgetown University, B.S. Accounting

Nicole Murphy

Experience

Ms. Murphy has served as our Executive Vice President, Pharmaceutical Operations and Technology since February 2022. Prior to that, Ms. Murphy has held senior executive positions at Biogen, including most recently as our Senior Vice President, Head of Global Manufacturing & Technical Operations, from June 2019 to January 2022. In 2017, Ms. Murphy played a critical role during the successful spin-off of Biogen's hemophilia franchise, as the Vice President and Head of Technical Operations of Bioverativ responsible for clinical and commercial development, quality, regulatory, manufacturing and procurement. Prior to the spin-off Ms. Murphy was the General Manager and Head of Cambridge Site Operations at Biogen from May 2015 to December 2016. Prior to joining Biogen, Ms. Murphy was Executive Director, Head of Supply Chain at Amgen, a biopharmaceutical company, where her responsibilities included leadership of commercial manufacturing and technical operations. Ms. Murphy also held numerous technical and operational roles during her time at Amgen from 2001 to 2015 where she contributed significantly to various facility start-ups, business development integrations, strategic transformations and new product introductions. Prior to Amgen, Ms. Murphy held a variety of process development and engineering positions at Immunex Pharmaceuticals and the Monsanto Company.

Education

- University of Massachusetts Amherst, B.S. Engineering
- Rensselaer Polytechnic Institute, M.S. Engineering and a Masters of Business Administration

Ginger Gregory, Ph.D.

Experience

Dr. Gregory has served as our Executive Vice President and Chief Human Resources Officer since July 2017. Prior to joining Biogen, Dr. Gregory served as Executive Vice President and Chief Human Resources Officer at Shire PLC, a global specialty biopharmaceutical company, from February 2014 to April 2017. Prior to that, Dr. Gregory held executive-level human resources positions for several multinational companies across a variety of industries, including Dunkin' Brands Group Inc., a restaurant holding company, where she served as Chief Human Resource Officer, Novartis AG, a pharmaceutical company, where she was the division head of Human Resources for Novartis Vaccines and Diagnostics, Novartis Consumer Health and Novartis Institutes of BioMedical Research and Novo Nordisk A/S, a pharmaceutical company, where she served as Senior Vice President, Corporate People & Organization at the company's headquarters in Copenhagen, Denmark. Earlier in her career, Dr. Gregory held a variety of human resources generalist and specialist positions at BMS, a pharmaceutical company, and served as a consultant with Booz Allen & Hamilton, an information technology consulting company, in the area of organization change and effectiveness.

Education

- University of Massachusetts, B.A. Psychology
- The George Washington University, Ph.D. Psychology

Rachid Izzar

Experience

Mr. Izzar has served as our Executive Vice President, Head of Global Product Strategy and Commercialization since July 2021. Prior to that Mr. Izzar served as our President for the Intercontinental Region, which includes Latin America, Australia, Asia, Japan, the Middle East and Africa, Turkey and Russia, and the Global Biogen Biosimilars Unit. Prior to joining Biogen, Mr. Izzar was a Country President for AstraZeneca in France, where his responsibilities included leadership for commercial and manufacturing operations. He held numerous roles at his time with AstraZeneca, including the position of Global Vice President of the Cardiovascular Franchise where he contributed significantly to the development of the franchise within the North American subsidiary, as well as in Europe and China. Prior to that, Mr. Izzar was Vice President Strategic Transformation, also, China Portfolio for CEO based in Shanghai and Vice President Commercial International covering China, Australia, Brazil, Russia, America Latin, Asia, Turkey, the Middle East and Africa.

Education

- University of Sherbrooke, Masters of Business Administration
- Harvard Business School, Enterprise Executive Transformation Program

Priya Singhal, M.D., M.P.H.

Experience

Dr. Singhal has served as our Executive Vice President and Head of Development since January 2023. Prior to that Dr. Singhal served as our Interim Head of Research and Development since 2021 in addition to serving as Head of Global Safety and Regulatory Sciences, including China and Japan Research and Development, since rejoining Biogen in 2020. Dr. Singhal was initially at Biogen from 2012 to 2018 and served in positions of increasing seniority as Vice President Clinical Trials Benefit-Risk Management, Global Head of Safety and Benefit Risk Management and as the Interim Co-lead and Senior Vice President of Global Development. Prior to her 2020 return to Biogen, Dr. Singhal served as Head of Research and Development and Manufacturing at Zafgen Inc. from 2019 to 2020. From 2008 to 2012 Dr. Singhal held roles at Vertex Pharmaceuticals, including Vice President, Medical Affairs. Dr. Singhal began her drug-development career at Millennium Pharmaceuticals, Inc. in 2005 and led benefit-risk management for Velcade and other compounds.

Education

- Harvard School of Public Health, M.P.H. in International Health
- University of Mumbai, Doctor of Medicine (M.D.)

Robin C. Kramer

Experience

Ms. Kramer has served as our Senior Vice President, Chief Accounting Officer since December 2020. Prior to that, Ms. Kramer served as our Vice President, Chief Accounting Officer from November 2018 to December 2020. Prior to joining Biogen, Ms. Kramer served as the Senior Vice President and Chief Accounting Officer of Hertz Global Holdings, Inc., a car rental company, from May 2014 to November 2018. Prior to that, Ms. Kramer was an audit partner at Deloitte & Touche LLP (Deloitte), a professional services firm, from 2007 to 2014, including serving in Deloitte's National Office Accounting Standards and Communications Group from 2007 to 2010. From 2005 to 2007 Ms. Kramer served as Chief Accounting Officer of Fisher Scientific International, Inc., a laboratory supply and biotechnology company, and from 2004 to 2005 Ms. Kramer served as Director, External Reporting, Accounting and Control for the Gillette Company, a personal care company. Ms. Kramer also held partner positions in the public accounting firms of Ernst & Young LLP and Arthur Andersen LLP. Ms. Kramer is a licensed CPA in Massachusetts. She is a member of the Massachusetts Society of CPAs and the American Institute of CPAs. Ms. Kramer currently serves on the board of directors of the Center for Women and Enterprise. Ms. Kramer previously served as a Board Member for the Massachusetts State Board of Accountancy from September 2011 to December 2015 and Probus Insurance Company Europe DAC from 2016 to 2018.

Public Company Boards

- Armata Pharmaceuticals, Inc., a biotechnology company

Education

- Salem State University, B.B.A. Accounting

Available Information

Our principal executive offices are located at 225 Binney Street, Cambridge, MA 02142 and our telephone number is (617) 679-2000. Our website address is www.biogen.com. We make available free of charge through the *Investors* section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the U.S. Securities and Exchange Commission. We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

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 Patient Protection and Affordable Care Act (PPACA) have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and the expansion of the number of hospitals eligible for discounts under Section 340B of the Public Health Service Act. These changes have had and are expected to continue to have a significant impact on our business.

We may face uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There is increasing public attention on the costs of prescription drugs and we expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. For example, two committees of the U.S. House of Representatives 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, adversely affect our expense associated with such trials and if such CRO does not adequately perform, many of our trials may be affected. We may need to replace our CROs, which may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates.

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

Adverse safety events involving our marketed products, generic or biosimilar versions of our marketed products or products from the same class as one of our products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market and/or the imposition of fines or criminal penalties. Adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any of these could result in adverse impacts on our results of operations.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales to decline or our stock price to experience periods of volatility.

Restrictions on use or safety warnings that may be required to be included in the label of our products may significantly reduce expected revenue for those products and require significant expense and management time.

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 California Consumer Privacy Act (CCPA), and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with the CCPA may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Failure to comply with these current and future laws, policies, industry standards or legal obligations or any security incident resulting in the unauthorized access to, or acquisition, release or transfer of personal information may result in governmental enforcement actions, litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have a material adverse effect on our business and results of operations.

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

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

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

- *Global Bulk Supply Risks.* We rely on our manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor or raw material shortages, public health epidemics, natural disasters, power failures, cyber-attacks and many other factors.
- *Risks Relating to Compliance with current GMP (cGMP).* We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and other regulatory authorities to confirm compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or operations or those of third-parties to receive regulatory approval or pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.
- *Risk of Product Loss.* The manufacturing process for our products is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.

Any adverse developments affecting our manufacturing operations or the operations of our third-party suppliers and manufacturers may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We may also have to take inventory write-offs and incur other charges and expense for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

In addition, although we have business continuity plans to reduce the potential for manufacturing disruptions or delays and reduce the severity of a disruptive event, there is no guarantee that these plans will be adequate, which could adversely affect our business and operations.

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

Changes in management, other personnel and our overall retention rate may disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition or results of operations. New members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new opportunities or reduce or change emphasis on our existing programs.

Our success is dependent upon our ability to attract and retain qualified management and 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 or late stage programs, recruitment by competitors or changes in the overall labor market. In addition, changes in our organizational structure or in our flexible working arrangements could impact employees' productivity and morale as well as our ability to attract, retain and motivate employees. We cannot ensure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any personnel will not have a material impact on our financial condition and results of operations.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight in the U.S. and in foreign jurisdictions, and are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our business practices. The FDA and comparable foreign agencies directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting, product risk management and our compliance with good practice quality guidelines and regulations. Our interactions with physicians and other health

care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of products and place significant restrictions on the marketing practices of health care companies. Health care companies are facing heightened scrutiny of their relationships with health care providers and have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. The U.S. government has challenged some of our donations to third-party charities that provide patient assistance. If we, or our vendors or donation recipients, are found to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

Conditions and regulations governing the health care industry are subject to change, with possible retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or judicial decisions, related to health care availability, pricing or marketing practices, compliance with employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- changes in the FDA and foreign regulatory approval processes or perspectives that may delay or prevent the approval of new products and result in lost market opportunity;
- government shutdowns or relocations may result in delays to the review and approval process, slowing the time necessary for new drug candidates to be reviewed and/or approved, which may adversely affect our business;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action, which could harm our business; and
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or otherwise adversely affect the market for our products.

Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. We could also be required to repay amounts we received from government payors or pay additional rebates and interest if we are found to have miscalculated the pricing information we submitted to the government. In addition, legal proceedings and investigations are inherently unpredictable, and large judgments or settlements sometimes occur. While we believe that we have appropriate compliance controls, policies and procedures in place to comply with the laws or regulations of the jurisdictions in which we operate, there is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers might violate such laws or regulations. Whether or not we have complied with the law, an investigation or litigation related to alleged unlawful conduct could increase our expense, damage our reputation, divert management time and attention and adversely affect our business.

Our sales and operations are subject to the risks of doing business internationally.

We are increasing our presence in international markets, subjecting us to many risks that could adversely affect our business and revenue. There is no guarantee that our efforts and strategies to expand sales in international markets will succeed. Emerging market countries may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability and may have a higher incidence of corruption and fraudulent business practices. Certain countries may require local clinical trial data as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. We may also be required

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

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

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

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

Although the Solothurn facility was approved by the FDA for ADUHELM 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 and other global health outbreaks, 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 and other global health outbreaks. 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 will continue to have on our business, the broad impact of the pandemic on all business activities may materially and adversely affect our business, supply chain and distribution systems, results of operations and financial condition.

The illegal distribution and sale by third-parties of counterfeit or unfit versions of our products or stolen products could have a negative impact on our reputation and business.

Third-parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing, distribution and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our brand name. Inventory that is stolen from warehouses, plants or while in-transit, and that is subsequently improperly stored and sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations

applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on social media. We may also encounter criticism on social media regarding our company, management, product candidates or products. The immediacy of social media precludes us from having real-time control over postings made regarding us via social media, whether matters of fact or opinion. Our reputation could be damaged by negative publicity or if adverse information concerning us is posted on social media platforms or similar mediums, which we may not be able to reverse. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

Risks Related to Holding Our Common Stock

Our operating results are subject to significant fluctuations.

Our quarterly revenue, expense and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the risks described in these *Risk Factors* as well as the timing of charges and expense that we may take. We have recorded, or may be required to record, charges that include:

- the cost of restructurings or other initiatives to streamline our operations and reallocate resources;
- impairments with respect to investments, fixed assets and long-lived assets, including in-process research and development (IPR&D) and other intangible assets;
- inventory write-downs for failed quality specifications, recurring charges for excess or obsolete inventory and charges for inventory write-downs relating to product suspensions, expirations or recalls;
- changes in the fair value of contingent consideration or our equity investments;
- bad debt expense and increased bad debt reserves;
- outcomes of litigation and other legal or administrative proceedings, regulatory matters and tax matters;
- payments in connection with acquisitions, divestitures and other business development activities and under license and collaboration agreements;
- failure to meet certain contractual commitments; and
- the impact of public health epidemics, such as the COVID-19 pandemic, on employees, the global economy and the delivery of healthcare treatments.

Our revenue and certain assets and liabilities are also subject to foreign currency exchange rate fluctuations due to the global nature of our operations. Our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, the U.S. dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways. Our net income may also fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher than expected charges from early termination of a hedge relationship.

Our operating results during any one period do not necessarily suggest the anticipated results of future periods.

Our investments in properties may not be fully realized.

We own or lease real estate primarily consisting of buildings that contain research laboratories, office space and manufacturing operations. We may decide to consolidate or co-locate certain aspects of our business operations or dispose of one or more of our properties, some of which may be located in markets that are experiencing high vacancy rates and decreasing property values. If we determine that the fair value of any of our owned properties is lower than their book value, we may not realize the full investment in these properties and incur significant impairment charges or additional depreciation when the expected useful lives of certain assets have been shortened due to the anticipated closing of facilities. If we decide to fully or partially vacate a property, we may incur significant cost, including facility closing costs, employee separation and retention expense, lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements and accelerated depreciation of assets. Any of these events may have an adverse impact on our results of operations.

Our investment portfolio is subject to market, interest and credit risk that may reduce its value.

We maintain a portfolio of marketable securities for investment of our cash as well as investments in equity securities of certain biotechnology companies. Changes in the value of our investment portfolio could adversely

affect our earnings. The value of our investments may decline due to, among other things, increases in interest rates, downgrades of the bonds and other securities in our portfolio, negative company-specific news, biotechnology market sentiment, instability in the global financial markets that reduces the liquidity of securities in our portfolio, declines in the value of collateral underlying the securities in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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

From time to time our Board of Directors authorizes share repurchase programs. The amount and timing of share repurchases are subject to capital availability and our determination that share repurchases are in the best interest of our shareholders and are in compliance with all respective laws and our applicable agreements. Our ability to repurchase shares will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, our results of operations, our financial condition and other factors beyond our control that we may deem relevant. 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 Organization for Economic Cooperation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities and economic blocs in the countries in which we operate, could unfavorably impact our effective tax rate. These initiatives focus on common international principles for the entitlement to taxation of global corporate profits and minimum global tax rates.

Our business involves environmental risks, which include the cost of compliance and the risk of contamination or injury.

Our business and the business of several of our strategic partners involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with state, federal and foreign standards, there will always be the risk of accidental contamination or injury. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business. Manufacturing of our products and product candidates also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, including permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business. 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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Below is a summary of our owned and leased properties as of December 31, 2022.

U.S.

Massachusetts

In Cambridge, MA we own approximately 263,000 square feet of real estate space, consisting of a building that houses a research laboratory and a cogeneration plant.

In addition, we lease a total of approximately 1,429,000 square feet in Massachusetts, which is summarized as follows:

- 1,072,000 square feet in Cambridge, MA, which is comprised of offices for our corporate headquarters and other administrative and development functions and laboratories, of which 289,000 square feet is subleased by multiple companies for general office space, laboratories and manufacturing facilities; and
- 357,000 square feet of office space in Weston, MA, of which 174,000 square feet is subleased through the remaining term of our lease agreement.

Our Massachusetts lease agreements expire at various dates through the year 2028.

125 Broadway Building Sale and Leaseback

In September 2022 we completed the sale of our building and land parcel located at 125 Broadway. In connection with this sale, we simultaneously leased back the building for a term of approximately 5.5 years, which resulted in the recognition of approximately $168.2 million in new lease liabilities and right-of-use assets recorded within our consolidated balance sheets as of December 31, 2022. The sale and immediate leaseback of this building qualified for sale and leaseback treatment and is classified as an operating lease. For additional information

on our 125 Broadway sale and leaseback transaction, please read *Note 11, Property, Plant and Equipment and Note 12, Leases*, to our consolidated financial statements included in this report.

300 Binney Street Lease Modification

In September 2022 we entered into an agreement to partially terminate a portion of our lease located at 300 Binney Street, Cambridge, MA (300 Binney Street), as well as to reduce the lease term for the majority of the remaining space. The agreement was driven by our 2022 efforts to reduce costs by consolidating real estate locations. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to our consolidated financial statements included in this report.

North Carolina

In RTP, NC we own approximately 1,040,000 square feet of real estate space, which is summarized as follows:

- 357,000 square feet of laboratory and office space;
- 206,000 square foot multi-purpose facility, including an ASO manufacturing suite and administrative space;
- 175,000 square feet related to a large-scale biologics manufacturing facility;
- 105,000 square feet related to a small-scale biologics manufacturing facility;
- 84,000 square feet of warehouse space and utilities;
- 70,000 square feet related to a parenteral fill-finish facility; and
- 43,000 square feet related to a large-scale purification facility.

In addition, we lease approximately 65,000 square feet of warehouse space in Durham, NC. Our North Carolina lease agreements expire at various dates through the year 2025.

In March 2021 we announced our plans to build a new gene therapy manufacturing facility in RTP, NC 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. Construction for this new facility began during the fourth quarter of 2021.

International

Switzerland

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. In the second quarter of 2021 a portion of the facility received a GMP multi-product license from SWISSMEDIC. Solothurn has been approved for the manufacture of ADUHELM and LEQEMBI by the FDA. We estimate the second manufacturing suite at the Solothurn facility will be operational by the end of 2023.

Other International

We lease office space in Baar, Switzerland, our international headquarters; the U.K.; Germany; France; Japan; Canada and numerous other countries. Our international lease agreements expire at various dates through the year 2031.

ITEM 3. LEGAL PROCEEDINGS

For a discussion of legal matters as of December 31, 2022, please read *Note 21, Litigation,* to our consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market and Stockholder Information

Our common stock trades on The Nasdaq Global Select Market under the symbol “BIIB.” As of February 14, 2023, there were approximately 448 shareholders of record of our common stock.

Dividends

We have not paid cash dividends since our inception. While we historically have not paid cash dividends and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, among other things, payment of cash dividends, share repurchases and acquisitions.

Issuer Purchases of Equity Securities

The following table summarizes our common stock repurchase activity during the fourth quarter of 2022:

Period	Total Number of Shares Purchased (#)	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Programs (#)	Approximate Dollar Value of Shares That May Yet Be Purchased Under Our Programs ($ in millions)
October 2022	—	$ —	—	$ 2,050.0
November 2022	—	$ —	—	$ 2,050.0
December 2022	—	$ —	—	$ 2,050.0
Total[(1)]	—	$ —		

[(1)] There were no share repurchases during the fourth quarter of 2022.

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 3.6 million, 6.0 million and 1.6 million shares of our common stock at a cost of approximately $750.0 million, $1.8 billion and $400.0 million during the years ended December 31, 2022, 2021 and 2020, respectively. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2022.

In December 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (December 2019 Share Repurchase Program), which was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 16.7 million shares of our common stock at a cost of approximately $5.0 billion during the year ended December 31, 2020.

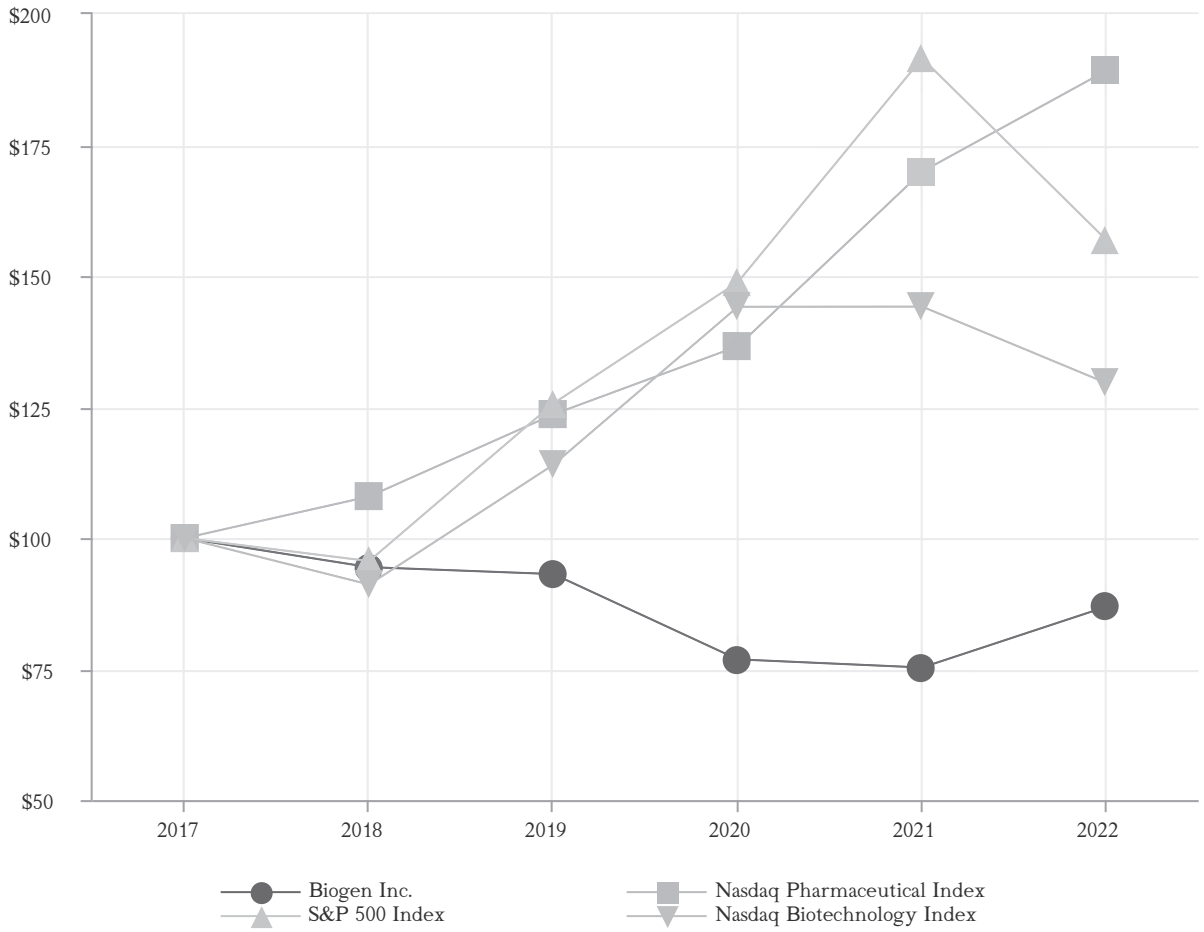
In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program), which was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share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

In August 2022 the IRA was signed into law. Among other things, the IRA levies a 1.0% excise tax on net stock repurchases after December 31, 2022. Historically, we have made discretionary share repurchases.

Performance Graph

The performance graph below compares the five-year cumulative total stockholder return on our common stock, the Nasdaq Pharmaceutical Index, the S&P 500 Index and the Nasdaq Biotechnology Index. The performance graph below assumes the investment of $100.00 on December 31, 2017, in our common stock and each of the three indexes, with dividends being reinvested.

The stock price performance in the graph below is not necessarily indicative of future price performance.



	2017	2018	2019	2020	2021	2022
Biogen Inc.	$100.00	$94.46	$93.14	$76.86	$75.31	$86.92
Nasdaq Pharmaceutical Index	$100.00	$107.95	$123.62	$136.62	$169.94	$189.23
S&P 500 Index	$100.00	$95.62	$125.72	$148.85	$191.58	$156.88
Nasdaq Biotechnology Index	$100.00	$91.14	$114.02	$144.15	$144.18	$129.59

The information included under the heading *Performance Graph* is "furnished" and not "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be "soliciting material" subject to Regulation 14A or incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and the accompanying notes beginning on page F-1 of this report.

For our discussion of the year ended December 31, 2021, compared to the year ended December 31, 2020, please read *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* located in our Annual Report on Form 10-K for the year ended December 31, 2021.

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 (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.

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, 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 19, Collaborative and Other Relationships*, to our 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 SWISSMEDIC. Solothurn has been approved for the manufacture of ADUHELM and LEQEMBI by the FDA. We estimate the second manufacturing suite at the Solothurn facility 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

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

ADUHELM (aducanumab)

U.S.

In June 2021 the FDA granted accelerated approval of ADUHELM, which, until March of 2022, we had been collaborating on with Eisai, based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. As part of the accelerated approval, we are required to conduct a confirmatory trial to verify the clinical benefit of ADUHELM in patients with Alzheimer's disease. The FDA may withdraw approval if, among other things, the confirmatory trial fails to verify clinical benefit of ADUHELM, ADUHELM's benefit-risk is no longer positive or we fail to comply with the conditions of the accelerated approval.

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

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 year ended December 31, 2022, we recorded approximately $111.0 million of aggregate gross idle capacity charges related to ADUHELM. These charges were recorded in cost of sales within our consolidated statements of income for the year ended December 31, 2022.

We have recognized approximately $197.0 million related to Eisai's 45.0% share of inventory, idle capacity charges and contractual commitments in collaboration profit (loss) sharing within our consolidated statements of income for the year ended December 31, 2022.

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

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

On March 14, 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.

Rest of World

In October 2020 the EMA accepted for review the MAA for aducanumab and in December 2020 the Ministry of Health, Labor and Welfare (MHLW) accepted for review the Japanese NDA for aducanumab.

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

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 the E.U., we are seeking to enforce a patent granted in June 2022 that relates to TECFIDERA and expires in 2028. In addition, we are litigating to affirm that TECFIDERA is entitled to regulatory data and

market protection until at least February 2024. Our Company, the EMA and the EC have each appealed the May 2021 decision of the European General Court, which annulled the EMA's decision not to validate an application for approval of a TECFIDERA generic on the basis that the EMA and EC conducted the wrong assessment when determining TECFIDERA's entitlement to regulatory data and marketing protection. Our Company, the EMA and the EC have each appealed the General Court's decision as wrongly decided and the appeal is pending. On October 6, 2022, the Advocate General of the CJEU issued a nonbinding advisory opinion in Biogen's favor. This opinion recommends that the CJEU set aside the judgment of the European General Court. We are awaiting the decision of the CJEU.

For additional information, please read *Note 21, Litigation*, to our consolidated financial statements included in this report and the discussion under *Results of Operations - Product Revenue - Multiple Sclerosis (MS) - Fumarate* below.

Business Update Regarding COVID-19 and Other Disruptions

COVID-19

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

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

While we are currently continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have impacted the timeline for some of our clinical trials and these precautions may, directly or indirectly, have a further impact on timing in the future.

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 and are currently involved in clinical trials with sites in Ukraine and Russia. The timing and costs of these trials may be impacted as a result of the conflict. 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 years ended December 31, 2022 and 2021.

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

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

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

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 will be effective for periods after December 31, 2022. The enactment of the IRA did not result in any material adjustments to our income tax provision or net deferred tax assets as of 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 overall impact that the IRA will have on our business, results of operations and financial condition, and the impact on the pharmaceutical industry as a whole is not yet known. We will continue to assess as further information becomes available.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were $20.87 for 2022, representing an increase of 100.7% as compared to $10.40 in the same period in 2021.

As described below under *Results of Operations*, our net income and diluted earnings per share attributable to Biogen Inc. for the year ended December 31, 2022, compared to the year ended December 31, 2021, reflects the following:

Revenue

- Total revenue was $10,173.4 million for 2022, representing an $808.3 million, or 7.4%, decrease compared to $10,981.7 million in 2021.
- Product revenue, net totaled $7,987.8 million for 2022, representing an $859.1 million, or 9.7%, decrease compared to $8,846.9 million in 2021. This decrease was primarily due to a $666.5 million, or 10.9%, decrease in MS product revenue, a $111.6 million, or 5.9%, decrease in SPINRAZA product revenue and an $80.0 million, or 9.6%, decrease in revenue from our biosimilar business.
    - The decrease in MS product revenue of $666.5 million, or 10.9%, from $6,096.7 million in 2021 to $5,430.2 million in 2022, 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, and a decrease in Interferon demand due to competition as patients transition to higher efficacy and oral MS therapies.
    - The decrease in SPINRAZA revenue of $111.6 million, or 5.9%, from $1,905.1 million in 2021 to $1,793.5 million in 2022, was primarily due to country mix, the unfavorable impact of foreign currency exchange and the timing of shipments, partially offset by an increase in sales volumes. The increase in sales volumes reflects growth in certain Asian markets, partially offset by a decrease in sales volumes from increased competition in certain established markets, particularly Germany and Japan.
    - The decrease in revenue from our biosimilar business of $80.0 million, or 9.6%, from $831.1 million in 2021 to $751.1 million in 2022, was primarily due to unfavorable pricing and the unfavorable impact of foreign currency exchange, partially offset by an increase in sales volumes.
- Revenue from anti-CD20 therapeutic programs totaled $1,700.5 million for 2022, representing a $42.0 million, or 2.5%, increase compared to $1,658.5 million in 2021. This increase was primarily due to a $144.6 million, or 14.6%, increase in royalty revenue on sales of OCREVUS, partially offset by a $103.4 million, or 18.0%, decrease in RITUXAN revenue. Sales of RITUXAN have been adversely affected by biosimilar competition.
- Other revenue totaled $485.1 million for 2022, representing a $8.8 million, or 1.8%, increase from $476.3 million in 2021.

Expense

- Total cost and expense was $6,581.6 million for 2022, representing a $2,654.9 million, or 28.7%, decrease compared to $9,236.5 million in 2021.

- Research and development expense decreased $270.1 million, or 10.8%, from $2,501.2 million in 2021 to $2,231.1 million in 2022, primarily due to higher upfront payments in 2021. In 2021 we recorded approximately $285.0 million of upfront payments related to our collaborations with InnoCare, Ionis, Bio-Thera, Genentech, Capsigen Inc., and Ginkgo Bioworks, as compared to $28.5 million in 2022. In addition, $39.1 million of estimated clinical trial closeout costs and manufacturing commitments associated with BIIB111 (timrepigene emparvovec) and BIIB112 (cotoretigene toliparvovec) were recorded in 2021.
- Amortization and impairment of acquired intangible assets decreased $515.4 million, or 58.5%, from $881.3 million in 2021 to $365.9 million in 2022, primarily due to higher impairment charges recorded in 2021. In 2021 we recorded $629.3 million of impairment charges, as compared to $119.6 million in 2022.
- The decrease in cost and expense was also due to a pre-tax gain of $503.7 million recognized in 2022 related to the sale of one of our buildings.
- Other (income) expense, net for 2022 reflected a pre-tax gain of $1.5 billion related to the sale of our 49.9% equity interest in Samsung Bioepis, partially offset by a pre-tax charge of $900.0 million, plus settlement fees and expenses, related to a litigation settlement agreement to resolve a qui tam litigation relating to conduct prior to 2015.

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

- We generated $1,384.3 million of net cash flow from operations for 2022.
- Cash, cash equivalents and marketable securities totaled approximately $5,598.5 million as of December 31, 2022.
- We repurchased and retired approximately 3.6 million shares of our common stock at a cost of approximately $750.0 million during 2022 under our 2020 Share Repurchase Program. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2022.

Developments in Key Collaborative Relationships

For additional information on our collaborative and other relationships discussed below, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Eisai Collaboration Agreements

LEQEMBI (lecanemab) Collaboration Agreement

In January 2023 we and Eisai announced that 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 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, and was granted Priority Review by the Japanese Ministry of Health, Labor and Welfare.

In December 2022 Eisai initiated a rolling submission of a BLA to the NMPA of China for the approval of lecanemab.

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.

ADUHELM Collaboration Agreement

On March 14, 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.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Zuranolone (BIIB125)

In June 2022 we and our collaboration partner Sage announced that the Phase 3 SKYLARK study of zuranolone, for the potential treatment of MDD and PPD, met its primary and all key secondary endpoints.

In December 2022 we and Sage completed the rolling submission of a NDA to the FDA for the approval of zuranolone for the potential treatment of MDD and PPD. This submission completes the NDA filing initiated earlier in 2022.

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

For additional information on our collaboration arrangement with Sage, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Genentech

LUNSUMIO (mosunetuzumab)

In January 2022 we exercised our option with Genentech to participate in the joint development and commercialization of LUNSUMIO (mosunetuzumab), a bispecific antibody for the treatment of relapsed or refractory follicular lymphoma. In connection with this exercise, we recorded a $30.0 million option exercise fee payable to Genentech in December 2021.

In December 2022 Genentech announced that the FDA granted accelerated approval of LUNSUMIO, which was also approved by the EC in June 2022.

Glofitamab

In December 2022 we reached an agreement with Genentech related to the commercialization and sharing of economics for glofitamab, an investigational T-cell engaging bispecific antibody targeting CD20 and CD3 for the potential treatment of B-cell non-Hodgkin's lymphoma.

For additional information on our collaboration arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Other Collaborative Relationships

Alcyone Therapeutics

In December 2022 we entered into a license and collaboration agreement with Alcyone to jointly develop the ThecaFlex DRx™ System, an implantable medical device intended for subcutaneous delivery of ASO therapies with a goal of improving the patient treatment experience and accessibility for people suffering from neurological disorders, such as SMA and ALS. Under the terms of this collaboration, we and Alcyone will jointly develop the ThecaFlex DRx™ System and Alcyone will be solely responsible for its manufacture and commercialization. In connection with this transaction, we made an upfront payment of $10.0 million to Alcyone.

Other Key Developments

Tofersen (BIIB067)

In July 2022 we announced that the FDA accepted the NDA and granted Priority Review for tofersen, an investigational antisense drug being evaluated for people with SOD1 ALS, which currently has a PDUFA action date of April 25, 2023. In December 2022 the EMA accepted for review the MAA for tofersen.

BIIB800 (referencing ACTEMRA)

In September 2022 we and our collaboration partner Bio-Thera announced that the EMA accepted for review the MAA for BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, an anti-interleukin-6 receptor monoclonal antibody, for the treatment of severe, active and progressive rheumatoid arthritis. In December 2022 the FDA accepted for review the abbreviated BLA for BIIB800.

BIIB122 (DNL151)

In October 2022 we and our collaboration partner Denali announced the initiation of the Phase 3 LIGHTHOUSE study of BIIB122 for the potential treatment of Parkinson's disease.

For additional information on our collaboration arrangement with Denali, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Corporate Matters

Samsung Bioepis - Biogen's Joint Venture with Samsung BioLogics

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

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.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions,* to our consolidated financial statements included in this report.

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 $131.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of December 31, 2022, approximately $35.9 million remained in our restructuring reserve and payments are expected to be made through 2026.

For additional information on our 2022 cost saving initiatives, please read *Note 4, Restructuring*, to our consolidated financial statements included in this report.

Senior Note Redemption

In July 2022 we redeemed our 3.625% Senior Notes totaling $1.0 billion in aggregate principal amount prior to their maturity on September 15, 2022.

For additional information on the redemption of our Senior Notes, please read *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

125 Broadway Sale and Leaseback Transaction

In September 2022 we completed the sale of our building and land parcel located at 125 Broadway for an aggregate sales price of approximately $603.0 million, which is inclusive of a $10.8 million tenant allowance. Simultaneously, with the close of this transaction we leased back the building for a term of approximately 5.5 years.

For additional information on our 125 Broadway sale and leaseback transaction, please read *Note 11, Property, Plant and Equipment* and *Note 12, Leases*, to our consolidated financial statements included in this report.

RESULTS OF OPERATIONS

Revenue

Revenue is summarized as follows:

	For the Years Ended December 31,			% Change		$ Change	
(In millions, except percentages)	2022	2021	2020	2022 vs. 2021	2021 vs. 2020	2022 vs. 2021	2021 vs. 2020
Product revenue, net:							
United States	$ 3,469.3	$ 3,805.7	$ 5,900.1	(8.8)%	(35.5)%	$ (336.4)	$ (2,094.4)
Rest of world	4,518.5	5,041.2	4,792.1	(10.4)	5.2	(522.7)	249.1
Total product revenue, net	7,987.8	8,846.9	10,692.2	(9.7)	(17.3)	(859.1)	(1,845.3)
Revenue from anti-CD20 therapeutic programs	1,700.5	1,658.5	1,977.8	2.5	(16.1)	42.0	(319.3)
Other revenue	485.1	476.3	774.6	1.8	(38.5)	8.8	(298.3)
Total revenue	$ 10,173.4	$ 10,981.7	$ 13,444.6	(7.4)%	(18.3)%	$ (808.3)	$ (2,462.9)

Product Revenue

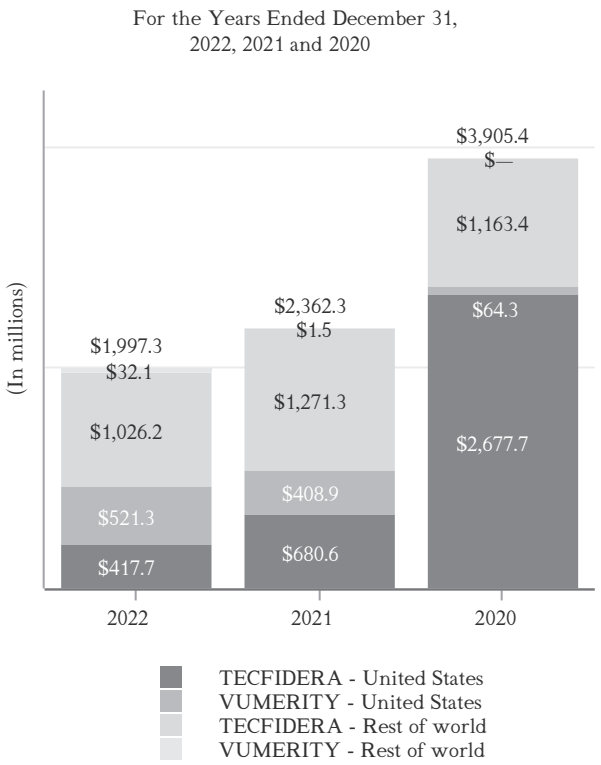
Product revenue is summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020	$ Change 2022 vs. 2021	$ Change 2021 vs. 2020
Multiple Sclerosis (MS):							
TECFIDERA	$ 1,443.9	$ 1,951.9	$ 3,841.1	(26.0)%	(49.2)%	$ (508.0)	$ (1,889.2)
VUMERITY[1]	553.4	410.4	64.3	34.8	538.3	143.0	346.1
Total Fumarate	1,997.3	2,362.3	3,905.4	(15.5)	(39.5)	(365.0)	(1,543.1)
AVONEX	973.5	1,208.7	1,491.9	(19.5)	(19.0)	(235.2)	(283.2)
PLEGRIDY	331.9	357.4	385.6	(7.1)	(7.3)	(25.5)	(28.2)
Total Interferon	1,305.4	1,566.1	1,877.5	(16.6)	(16.6)	(260.7)	(311.4)
TYSABRI	2,030.9	2,063.1	1,946.1	(1.6)	6.0	(32.2)	117.0
FAMPYRA	96.6	105.2	103.1	(8.2)	2.0	(8.6)	2.1
Subtotal: MS	5,430.2	6,096.7	7,832.1	(10.9)	(22.2)	(666.5)	(1,735.4)
Spinal Muscular Atrophy:							
SPINRAZA	1,793.5	1,905.1	2,052.1	(5.9)	(7.2)	(111.6)	(147.0)
Biosimilars:							
BENEPALI	441.0	498.3	481.6	(11.5)	3.5	(57.3)	16.7
IMRALDI	224.5	233.4	216.3	(3.8)	7.9	(8.9)	17.1
FLIXABI	81.3	99.4	97.9	(18.2)	1.5	(18.1)	1.5
BYOOVIZ[2]	4.3	—	—	nm	—	4.3	—
Subtotal: Biosimilars	751.1	831.1	795.8	(9.6)	4.4	(80.0)	35.3
Other:							
FUMADERM	8.2	11.0	12.2	(25.5)	(9.8)	(2.8)	(1.2)
ADUHELM	4.8	3.0	—	60.0	nm	1.8	3.0
Total product revenue, net	$ 7,987.8	$ 8,846.9	$ 10,692.2	(9.7)%	(17.3)%	$ (859.1)	$ (1,845.3)

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

Multiple Sclerosis (MS)

Fumarate



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

For 2022 compared to 2021, the 13.8% decrease in U.S. Fumarate revenue was primarily due to a decrease in TECFIDERA demand as a result of multiple TECFIDERA generic entrants in the U.S. market, partially offset by net price increases in TECFIDERA driven by lower pharmacy rebates, managed care rebates and co-pay assistance as well as an increase in VUMERITY sales volumes.

For 2022 compared to 2021, the 16.9% decrease in rest of world Fumarate revenue was primarily due to TECFIDERA pricing reductions and a decrease in TECFIDERA demand as multiple TECFIDERA generic entrants entered into markets such as Germany and Canada. The decrease was also driven by the unfavorable impact of foreign currency exchange, partially offset by an increase in VUMERITY sales volumes.

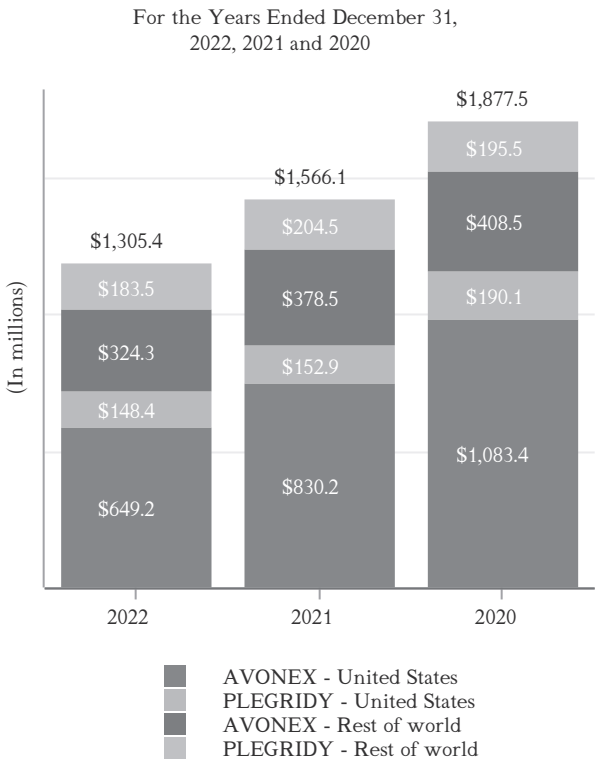
In the E.U., we are seeking to enforce a patent granted in June 2022 that relates to TECFIDERA and expires in 2028. In addition, we are litigating to affirm that TECFIDERA is entitled to regulatory data and market protection until at least February 2024. Our Company, the EMA and the EC have each appealed the May 2021 decision of the European General Court, which annulled the EMA's decision not to validate an application for approval of a TECFIDERA generic on the basis that the EMA and EC conducted the wrong assessment when determining TECFIDERA's entitlement to regulatory data and marketing protection. Our Company, the EMA and the EC have each appealed the General Court's decision as wrongly decided and the appeal is pending. On October 6, 2022, the Advocate General of the CJEU issued a nonbinding advisory opinion in Biogen's favor. This opinion recommends that the CJEU set aside the judgment of the European General Court. We are awaiting the decision of the CJEU.

For additional information, please read *Note 21, Litigation,* to our consolidated financial statements included in this report.

We expect that TECFIDERA revenue will continue to decline in 2023, compared to 2022, as a result of generic competition in the North America, Latin America and certain E.U. countries.

We expect an increase in VUMERITY sales volumes in 2023, compared to 2022, mostly due to demand growth in the U.S. and select European markets. We believe that we have resolved previously reported manufacturing issues at our 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.

Interferon

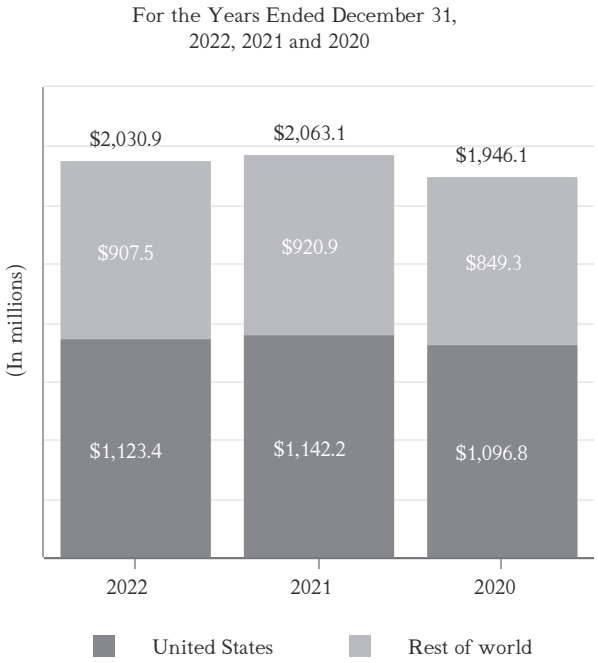


For 2022 compared to 2021, the 18.9% decrease in U.S. Interferon revenue was primarily due to a decrease in Interferon sales volumes of 15.5%. The net decline in sales volumes reflects the continued decline of the Interferon market as patients transition to higher efficacy and oral MS therapies.

For 2022 compared to 2021, the 12.9% decrease in rest of world Interferon revenue was primarily due to a decrease in Interferon sales volumes of 6.0% resulting from the continued decline of the Interferon market as patients transition to higher efficacy and oral MS therapies, as well as the unfavorable impact of foreign currency exchange.

We expect that Interferon revenue will continue to decline in both the U.S. and rest of world markets in 2023, compared to 2022, as a result of increasing competition from other MS products.

TYSABRI



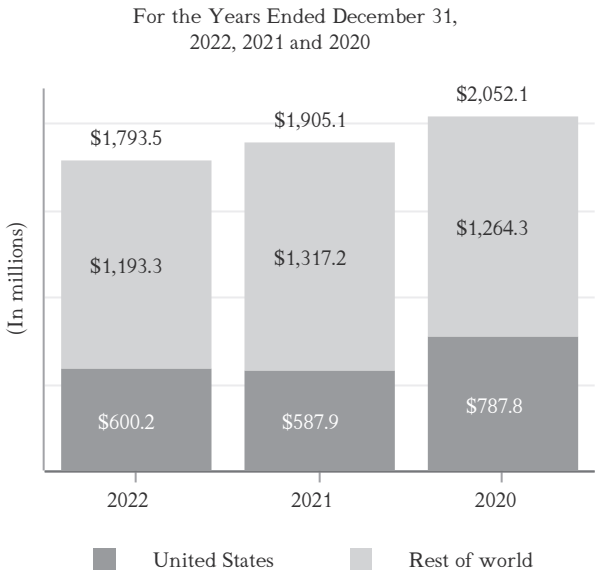
For 2022 compared to 2021, U.S. TYSABRI revenue was relatively flat, with a modest decrease in sales volumes, partially offset by an increase in pricing, net of higher discounts and allowances.

For 2022 compared to 2021, rest of world TYSABRI revenue was relatively flat, with a modest decrease in pricing and the unfavorable impact of foreign currency exchange, partially offset by an increase in sales volumes.

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

Spinal Muscular Atrophy

SPINRAZA



For 2022 compared to 2021, U.S. SPINRAZA revenue was relatively flat, with a modest increase in sales volumes of 3.7%, resulting from the timing of shipments, partially offset by higher discounts and allowances.

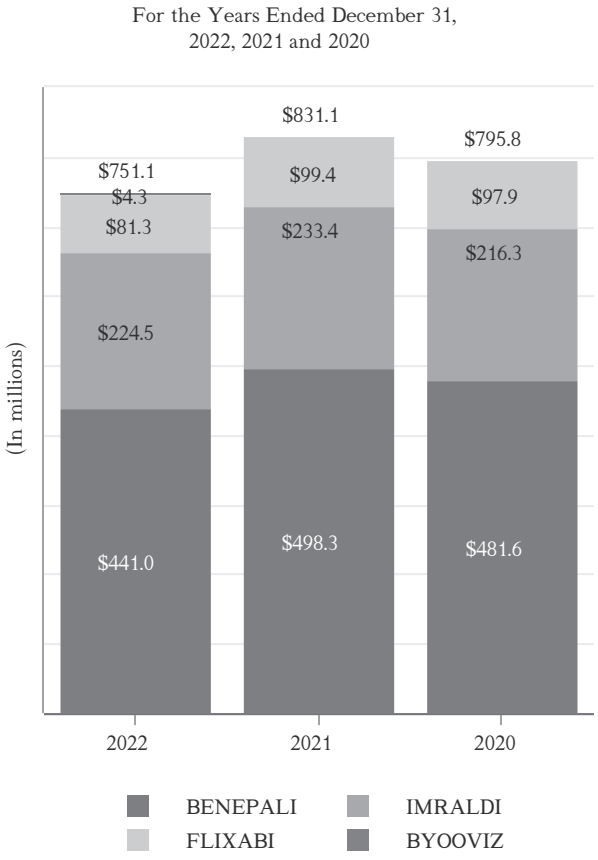
For 2022 compared to 2021, the 9.4% decrease in rest of world SPINRAZA revenue was primarily due to country mix, the unfavorable impact of foreign currency exchange and the timing of shipments, partially offset by an increase in sales volumes. The increase in sales volumes reflects growth in certain Asian markets, partially offset by a decrease in sales volumes from increased competition in certain established markets, particularly Germany and Japan.

Despite competition from a gene therapy product and an oral product, we anticipate SPINRAZA revenue to be relatively flat in 2023, compared to 2022. Moderate growth in the U.S. as well as continued access expansion in emerging markets is expected to offset increased competition and the impact of loading dose dynamics.

For additional information on our collaboration arrangements with Ionis, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Biosimilars

BENEPALI, IMRALDI, FLIXABI and BYOOVIZ



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

For 2022 compared to 2021, the 9.6% decrease in biosimilar revenue was primarily due to unfavorable pricing and the unfavorable impact of foreign currency exchange, partially offset by an increase in sales volumes.

We anticipate modest growth in revenue from our biosimilars business in 2023, compared to 2022, 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.

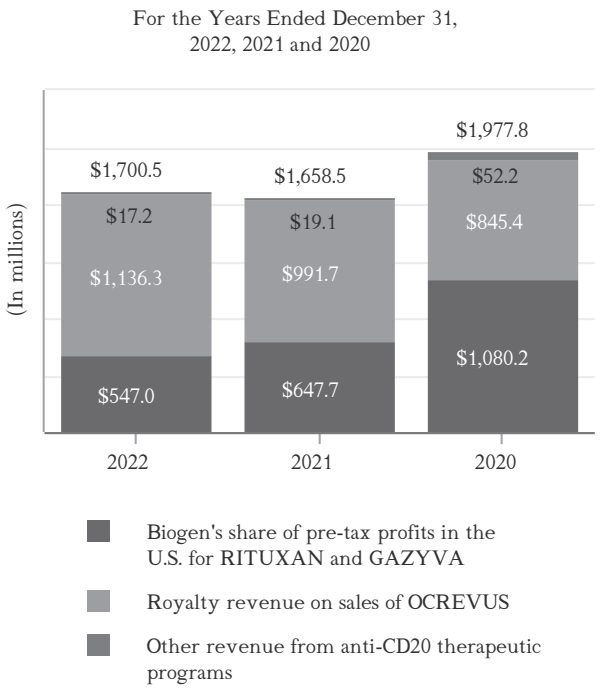
We are currently working with our contract manufacturer for IMRALDI to address facility regulatory inspection deficiencies at two filling locations, which could impact supply and have an adverse impact on 2023 IMRALDI sales, if not resolved. Manufacturing of BENEPALI also utilizes one of these facilities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

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Revenue from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

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



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

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Product revenue, net	$ 1,729.2	$ 2,032.0	$ 3,334.1
Cost and expense	253.6	291.8	433.0
Pre-tax profits in the U.S.	$ 1,475.6	$ 1,740.2	$ 2,901.1
Biogen's share of pre-tax profits	$ 547.0	$ 647.7	$ 1,080.2

For 2022 compared to 2021, the decrease in U.S. product revenue, net was primarily due to a decrease in sales volumes of RITUXAN in the U.S. of 28.4%, primarily due to the onset of competition from multiple biosimilar products.

For 2022 compared to 2021, the decrease in collaboration costs and expense was primarily due to lower cost of sales, selling and marketing expense, distribution costs and other costs and expense related to RITUXAN.

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

Royalty Revenue on Sales of OCREVUS

For 2022 compared to 2021, the increase in royalty revenue on sales of OCREVUS was primarily due to sales growth of OCREVUS in the U.S.

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.

Other Revenue from Anti-CD20 Therapeutic Programs

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

In December 2022 the FDA approved LUNSUMIO, a bispecific antibody for the treatment of relapsed or refractory follicular lymphoma. Our share of pre-tax profits and losses on LUNSUMIO will be included as a component of revenue from anti-CD20 therapeutic programs in our consolidated statements of income. For the year ended December 31, 2022, LUNSUMIO revenue was immaterial.

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

Other Revenue

Other revenue consists of royalty revenue and contract manufacturing and other revenue and is summarized as follows:

Royalty Revenue and Contract Manufacturing and Other Revenue

Contract Manufacturing and Other Revenue

We record contract manufacturing and other revenue primarily from amounts earned under contract manufacturing agreements.

For 2022 compared to 2021, the decrease in contract manufacturing and other revenue was primarily due to lower contract manufacturing revenue related to the timing of batch releases.

Royalty Revenue

We receive royalties from net sales on products related to patents that we have out-licensed, as well as royalty revenue on biosimilar products from our collaboration arrangements with Samsung Bioepis.

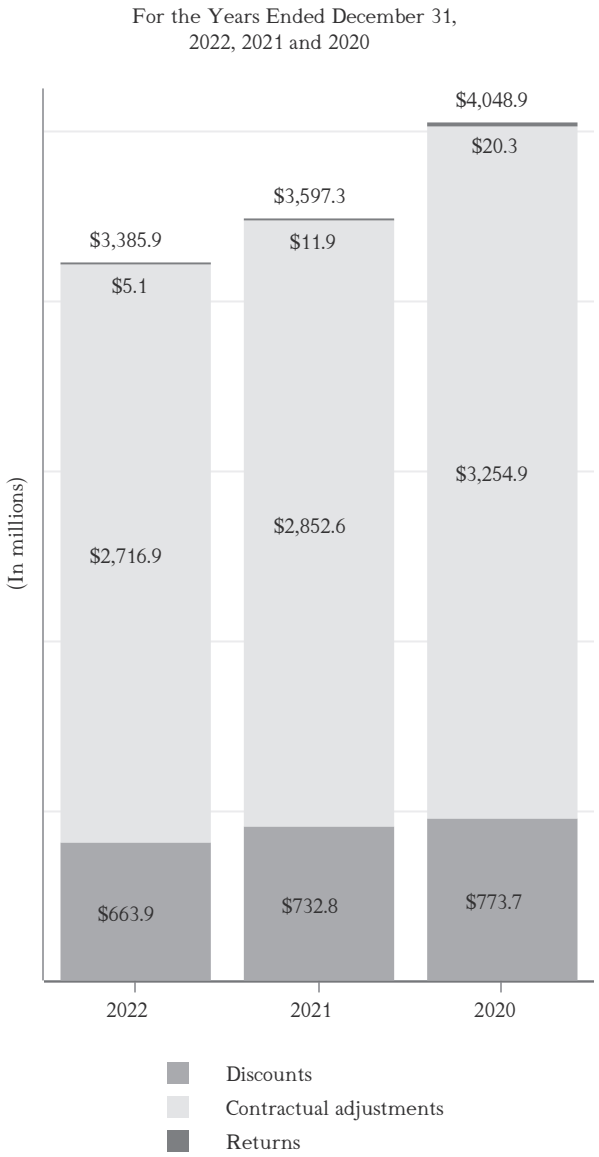
For additional information on our collaborative arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

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.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). These estimates reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

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



For the years ended December 31, 2022, 2021 and 2020, reserves for discounts and allowances as a percentage of gross product revenue were 30.1%, 28.6% and 27.1%, respectively.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For 2022 compared to 2021, the decrease in discounts was primarily due to a decrease in gross sales, driven by lower TECFIDERA sales, offset by higher purchase discounts for TYSABRI.

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 2022 compared to 2021, the decrease in contractual adjustments was primarily driven by lower TECFIDERA sales in the U.S., resulting in lower pharmacy rebates, Medicaid rebates and managed care rebates, as well as lower Medicaid rebates in the U.S. driven by a favorable change in estimates for VUMERITY.

Returns

Product return reserves are established for returns made by wholesalers. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. The majority of wholesaler returns are due to product expiration. Provisions for product returns are recognized in the period the related revenue is recognized, resulting in a reduction to product sales.

For 2022 compared to 2021, return reserves were relatively consistent.

For additional information on our revenue reserves, please read *Note 5, Revenue,* to our consolidated financial statements included in this report.

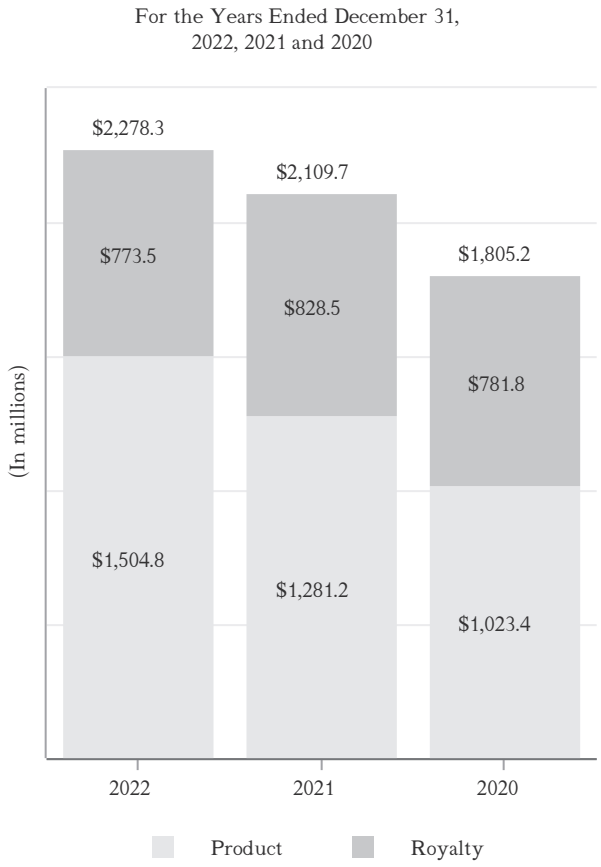
Cost and Expense

A summary of total cost and expense is as follows:

	For the Years Ended December 31,			% Change		$ Change	
(In millions, except percentages)	2022	2021	2020	2022 vs. 2021	2021 vs. 2020	2022 vs. 2021	2021 vs. 2020
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 2,278.3	$ 2,109.7	$ 1,805.2	8.0 %	16.9 %	$ 168.6	$ 304.5
Research and development	2,231.1	2,501.2	3,990.9	(10.8)	(37.3)	(270.1)	(1,489.7)
Selling, general and administrative	2,403.6	2,674.3	2,504.5	(10.1)	6.8	(270.7)	169.8
Amortization and impairment of acquired intangible assets	365.9	881.3	464.8	(58.5)	89.6	(515.4)	416.5
Collaboration profit (loss) sharing	(7.4)	7.2	232.9	(202.8)	(96.9)	(14.6)	(225.7)
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	—	—	(92.5)	—	nm	—	92.5
(Gain) loss on fair value remeasurement of contingent consideration	(209.1)	(50.7)	(86.3)	312.4	(41.3)	(158.4)	35.6
Acquired in-process research and development	—	18.0	75.0	(100.0)	(76.0)	(18.0)	(57.0)
Restructuring charges	131.1	—	—	nm	—	131.1	—
Gain on sale of building	(503.7)	—	—	nm	—	(503.7)	—
Other (income) expense, net	(108.2)	1,095.5	(497.4)	(109.9)	(320.2)	(1,203.7)	1,592.9
Total cost and expense	$ 6,581.6	$ 9,236.5	$ 8,397.1	(28.7)%	10.0 %	$(2,654.9)	$ 839.4

[nm] Not meaningful

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



Cost of sales, as a percentage of total revenue, were 22.4%, 19.2% and 13.4% for the years ended December 31, 2022, 2021 and 2020, respectively.

Product Cost of Sales

For 2022 compared to 2021, the increase in product cost of sales was primarily due to higher charges in 2022 associated with the write-off of excess ADUHELM inventory and purchase commitments, higher gross idle capacity charges associated with our manufacturing facilities and increased product cost of sales driven by product mix.

Inventory amounts written down as a result of excess, obsolescence or unmarketability totaled $336.2 million, $167.6 million and $26.6 million for the years ended December 31, 2022, 2021 and 2020, respectively.

For the years ended December 31, 2022 and 2021, we recorded approximately $286.0 million and $170.0 million, respectively, of charges associated with the write-off of ADUHELM inventory and purchase commitments in excess of forecasted demand.

For the years ended December 31, 2022 and 2021, we recorded approximately $119.0 million and $48.0 million, respectively, of aggregate gross idle capacity charges.

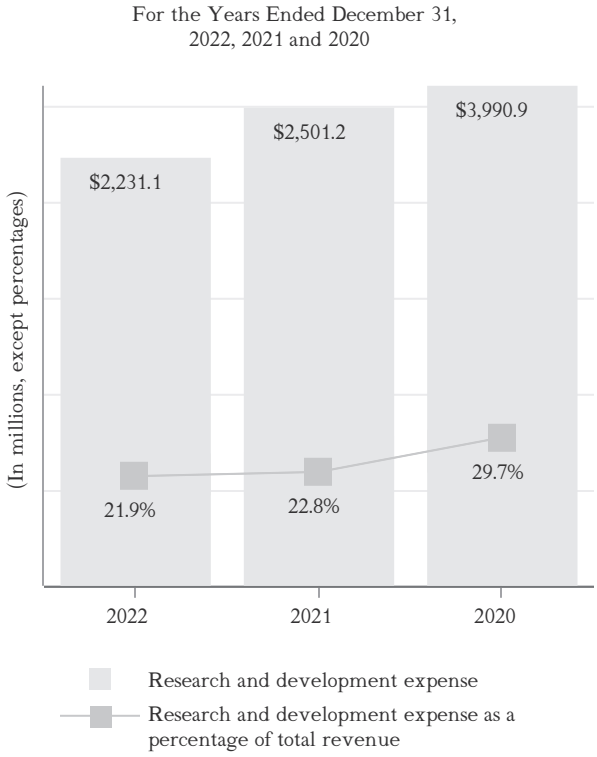
We have also recognized approximately $197.0 million and $99.0 million related to Eisai's 45.0% share of inventory, idle capacity charges and contractual commitments, which was recorded in collaboration profit (loss) sharing within our consolidated statements of income for the years ended December 31, 2022 and 2021, respectively.

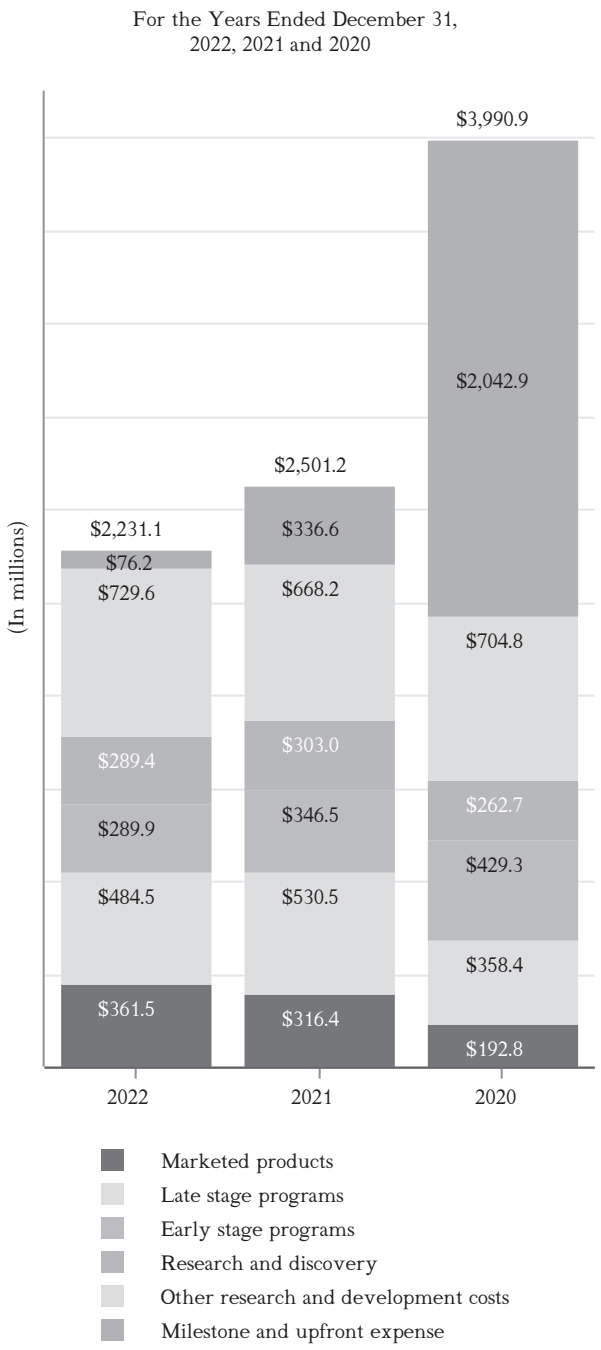
For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Royalty Cost of Sales

For 2022 compared to 2021, the decrease in royalty cost of sales was primarily due to lower royalties payable on lower sales of SPINRAZA, TYSABRI and AVONEX, partially offset by higher royalties payable on higher sales of VUMERITY.

Research and Development





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

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

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

For 2022 compared to 2021, the decrease in research and development expense was primarily due to higher milestone payments in 2021, partially offset by the advancement of BIIB059 (anti-BDCA2) for the potential treatment of SLE and CLE, the development of LUNSUMIO, a bispecific antibody for the treatment of relapsed or refractory follicular lymphoma, the development of BIIB124 (SAGE-324) for the potential treatment of essential tremor, which we are developing in collaboration with Sage, the development of BIIB122 (DNL151) for the potential treatment of Parkinson's disease, which we are developing in collaboration with Denali, and the development of BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA.

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.

Milestone and Upfront Expense

Research and development expense for 2022 includes:

- $37.0 million in charges to research and development expense in connection with milestone payments to Ionis;
- $15.0 million charge to research and development expense in connection with the upfront payment associated with entering into our collaboration with Alectos in the second quarter of 2022; and
- $10.0 million charge to research and development expense in connection with the upfront payment associated with entering into

our collaboration with Alcyone in the fourth quarter of 2022.

Research and development expense for 2021 includes:

- $125.0 million charge to research and development expense in connection with the upfront payment associated with entering into our collaboration with InnoCare in the third quarter of 2021;
- $60.0 million charge to research and development expense upon the exercise of our option under our collaboration agreement with Ionis to develop and commercialize BIIB115, an investigational ASO in development for SMA;
- $30.0 million charge to research and development expense related to the option exercise fee payable to Genentech to jointly develop and commercialize LUNSUMIO; and
- $30.0 million charge to research and development expense in connection with the upfront payment associated with entering into a commercialization and license agreement with Bio-Thera to develop, manufacture and commercialize BIIB800.

The upfront payments associated with these collaborations are classified as research and development expense as the programs they relate to had not achieved regulatory approval as of the payment date.

For additional information about these collaboration arrangements, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Early Stage Programs

For 2022 compared to 2021, the decrease in spending related to our early stage programs was primarily due to a decrease in costs associated with:

- the discontinuation of cinpanemab (BIIB054) in Parkinson's disease;
- the discontinuation of gosuranemab (BIIB092) in Alzheimer's disease;
- the discontinuation of cotoretigene toliparvovec (BIIB112) in X-linked retinitis pigmentosa;
- the advancement of litifilimab (BIIB059) for the potential treatment of SLE into late stage;
- the advancement of BIIB122 for the potential treatment of Parkinson's disease into late stage;
- the discontinuation of vixotrigine (BIIB074) in TGN and DPN; and
- the discontinuation of BIIB078 for the potential treatment of Alzheimer's disease.

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

- an increase in spending in the development of BIIB124 for the potential treatment of essential tremor;
- an increase in spending in the development of litifilimab (BIIB059) for the potential treatment of CLE;
- an increase in spending in the development of BIIB113 for the potential treatment of Alzheimer's disease;
- an increase in spending in the development of BIIB131 for the potential treatment of acute ischemic stroke; and
- an increase in spending in the development of BIIB121 for the potential treatment of Angelman syndrome.

Late Stage Programs

For 2022 compared to 2021, the decrease in spending associated with our late stage programs was primarily due to a decrease in costs associated with:

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

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

- the advancement of litifilimab (BIIB059) for the potential treatment of SLE into late stage;
- the advancement of BIIB122 for the potential treatment of Parkinson's disease into late stage; and
- the advancement of BIIB800, a proposed tocilizumab biosimilar referencing ACTEMRA, into late stage.

Marketed Programs

For 2022 compared to 2021, the increase in spending associated with our marketed programs was primarily due to an increase in costs associated with:

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

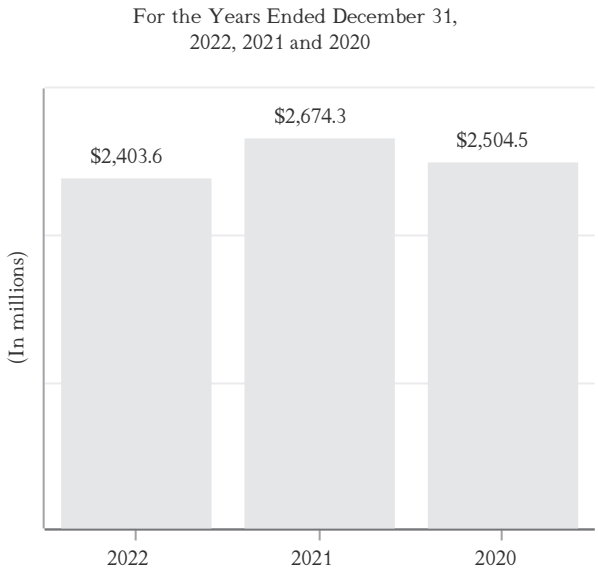
Other Research and Development

In March 2019 Eisai initiated a global Phase 3 trial for the development of LEQEMBI in early Alzheimer's disease. Under our collaboration arrangement, 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. In January 2023 the FDA granted accelerated approval of LEQEMBI. Additionally, in January 2023 Eisai completed the submission of a supplemental BLA to the FDA for approval under the traditional pathway for LEQEMBI.

As of December 31, 2022, we had approximately $89.8 million of work-in-process inventory related to LEQEMBI.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Selling, General and Administrative



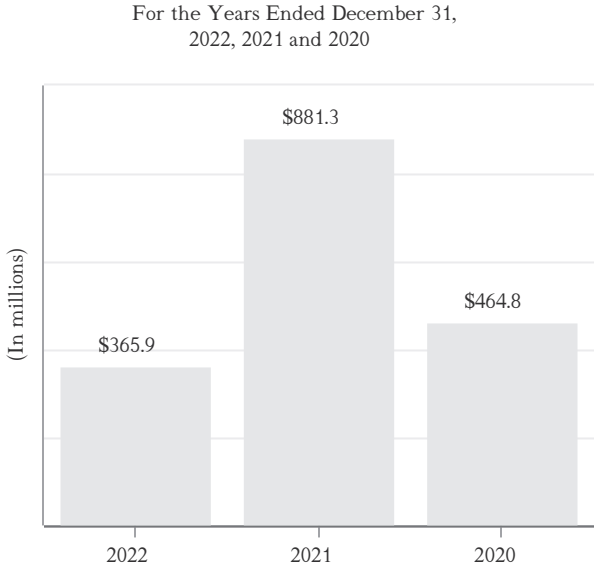
For 2022 compared to 2021, the decrease in selling, general and administrative expense was primarily due to cost-reduction measures realized during 2022.

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

Beginning in the second quarter of 2021 reimbursement from Eisai for its share of U.S. ADUHELM selling, general and administrative expense is recognized in collaboration profit (loss) sharing in our 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 during 2022, which include the substantial elimination of our commercial infrastructure supporting ADUHELM as well as other cost-reduction measures.

Amortization and Impairment of Acquired Intangible Assets



Our amortization expense is based on the economic consumption and impairment of intangible assets. Our most significant amortizable intangible assets are related to our TYSABRI, AVONEX, SPINRAZA, VUMERITY and TECFIDERA (rest of world) products and other programs acquired through business combinations.

For 2022 compared to 2021, the decrease in amortization and impairment of acquired intangible assets was primarily due to higher impairment charges in 2021 of approximately $629.3 million, compared to impairment charges of approximately $119.6 million in 2022.

For the year ended December 31, 2022, amortization and impairment of acquired intangible assets reflects the impact of a $119.6 million impairment charge related to vixotrigine for the potential treatment of DPN.

For the year ended December 31, 2021, amortization and impairment of acquired intangible assets reflects the impact of a $365.0 million impairment charge related to BIIB111, a $220.0 million impairment charge related to BIIB112 and a $44.3 million impairment charge related to vixotrigine for the potential treatment of TGN.

Amortization of acquired intangible assets, excluding impairment charges, totaled $246.3 million, $252.0 million and $255.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

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

IPR&D Related to Business Combinations

IPR&D represents the fair value assigned to research and development assets that we acquired as part of a business combination and had not yet reached technological feasibility at the date of acquisition. We review amounts capitalized as acquired IPR&D for impairment annually, as of October 31, and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable.

Overall, the value of our acquired IPR&D assets is dependent upon several variables, including estimates of future revenue and the effects of competition, our ability to secure sufficient pricing in a competitive market, our ability to confirm safety and efficacy based on data from clinical trials and regulatory feedback, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from one clinical trial phase to the next. We are continually reevaluating our estimates concerning these and other variables, including our life cycle management strategies, research and development priorities and development risk, changes in program and portfolio economics and related impact of foreign currency exchange rates and economic trends and evaluating industry and company data regarding the productivity of clinical research and the development process. Changes in our estimates may result in a significant change to our valuation of our IPR&D assets.

Vixotrigine

In the periods following our acquisition of vixotrigine, there were numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN and for the potential treatment of DPN, another form of neuropathic pain. We engaged with the FDA regarding the design of the potential Phase 3 studies of vixotrigine for the potential treatment of TGN and DPN and performed an additional clinical trial of vixotrigine, which was completed during 2022.

The performance of this additional clinical trial delayed the initiation of the Phase 3 studies of vixotrigine for the potential treatment of TGN, and, as a result, we recognized an impairment charge of $44.3 million related to vixotrigine for the potential treatment of TGN during the first quarter of 2021.

During the fourth quarter of 2022 we discontinued further development of vixotrigine based on regulatory, development and commercialization challenges. For the year ended December 31, 2022, we recognized an impairment charge of approximately $119.6 million related to vixotrigine for the potential treatment of DPN, reducing the remaining book value of this IPR&D intangible asset to zero. We also adjusted the value of our contingent consideration obligations related to this asset resulting in a pre-tax gain of approximately $209.1 million, which was recognized in (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income.

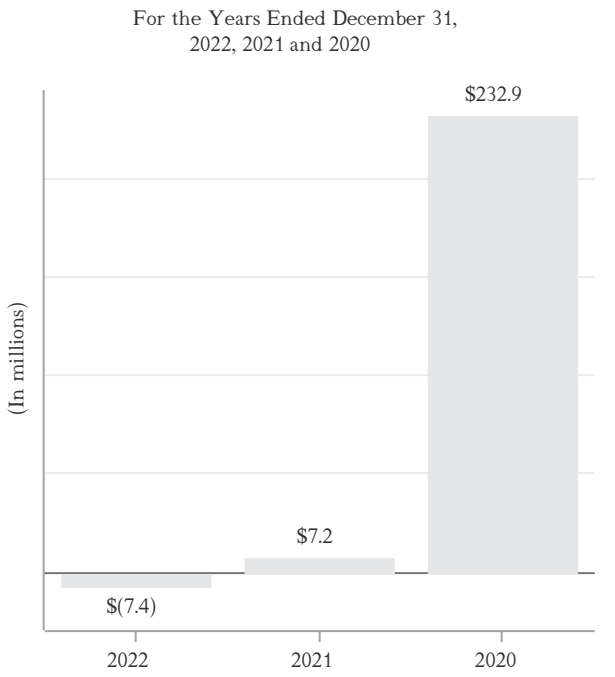
BIIB111 and BIIB112

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112 did not meet their primary endpoints. In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the year ended December 31, 2021, we recognized an impairment charge of $365.0 million related to BIIB111 and an impairment charge of $220.0 million related to BIIB112, reducing the remaining book values of these IPR&D intangible assets to zero.

In addition, as a result of our decision to suspend further development of BIIB111 and BIIB112, we recorded charges of approximately $39.1 million during the third quarter of 2021 related to our manufacturing arrangements and other costs that we expect to incur as a result of suspending these programs. These charges were recognized in research and development expense in our consolidated statements of income for the year ended December 31, 2021.

For additional information on the amortization and impairment of our acquired intangible assets, please read *Note 7, Intangible Assets and Goodwill*, to our consolidated financial statements included in this report.

Collaboration Profit (Loss) Sharing



Collaboration profit (loss) sharing primarily includes Samsung Bioepis' 50.0% share of the profit or loss related to our biosimilars 2013 commercial agreement with Samsung Bioepis and, beginning in the second quarter of 2021, Eisai's 45.0% share of income and expense in the U.S. related to the ADUHELM Collaboration Agreement. 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.

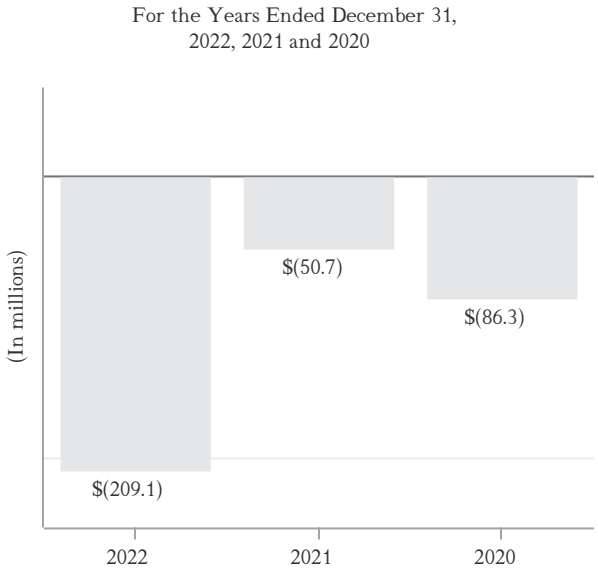
For the years ended December 31, 2022 and 2021, we recognized net profit-sharing expense of $217.4 million and $285.4 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits.

For the years ended December 31, 2022 and 2021 we recognized net reductions to our operating expense of approximately $224.7 million and $233.2 million, respectively, to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

For the year ended December 31, 2021, we also recognized net reductions to our operating expense of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment made to Neurimmune related to the launch of ADUHELM in the U.S. during the second quarter of 2021.

For additional information on our collaboration arrangements with Samsung Bioepis and Eisai, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration

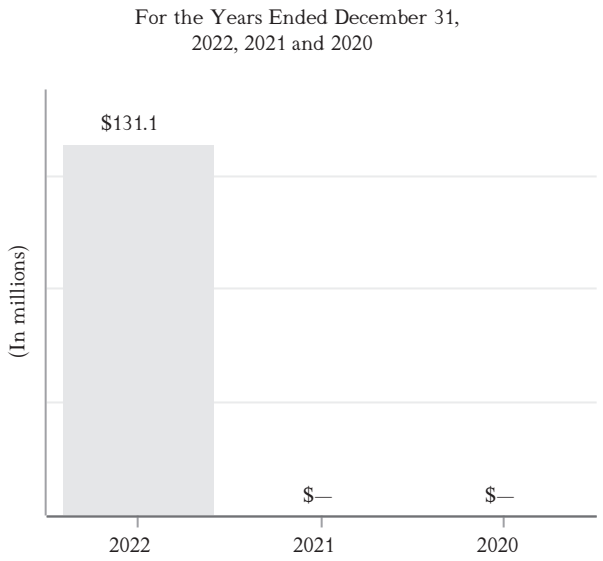


For the year ended December 31, 2022, the changes in fair value of our contingent consideration obligations were primarily due to the discontinuation of further development efforts related to vixotrigine for the potential treatment of TGN and DPN, resulting in a reduction of our contingent consideration obligations of approximately $195.4 million, and changes in the interest rates used to revalue our contingent consideration liabilities.

For the year ended December 31, 2021, the changes in fair value of our contingent consideration obligations were primarily due to reductions in the probability of technical and regulatory success and delays in the expected timing of the achievement of certain remaining developmental milestones related to our vixotrigine programs.

For additional information on our IPR&D intangible assets, please read *Note 7, Intangible Assets and Goodwill*, to our 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 $131.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of December 31, 2022, approximately $35.9 million remained in our restructuring reserve and payments are expected to be made through 2026.

For the year ended December 31, 2022, we recognized approximately $131.1 million of net pre-tax restructuring charges related to our 2022 cost saving initiatives, of which approximately $112.6 million consisted of employee severance costs. Our restructuring reserve is included in accrued expense and other in our 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 consolidated statements of income for the year ended December 31, 2022. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to these consolidated financial statements included in this report.

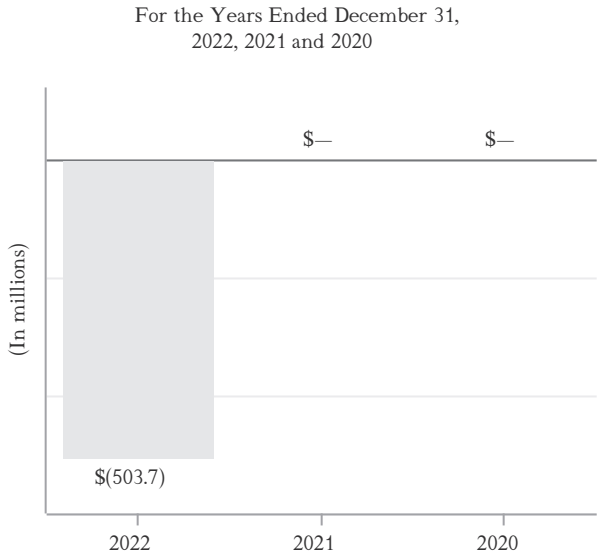
Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, NC. Our decision to cease use of the facility resulted in the immediate expense of certain leasehold improvements and other assets at this facility. As a result, we recognized approximately $10.4 million of accelerated depreciation expense, which was recorded in restructuring charges in our consolidated statements of income for the year ended December 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 year ended December 31, 2022, we recognized other restructuring costs of approximately $13.2 million, which were recorded in restructuring charges in our consolidated statements of income. Other restructuring costs include items such as facility closure costs, employee non-severance expense, asset write-offs and other costs.

The following table summarizes the charges and spending related to our 2022 workforce reductions for the year ended December 31, 2022:

(In millions)	Total
Restructuring reserve, December 31, 2021	$ —
Expense	112.6
Payment	(78.0)
Foreign currency and other adjustments	1.3
Restructuring reserve, December 31, 2022	$ 35.9

Gain on Sale of Building

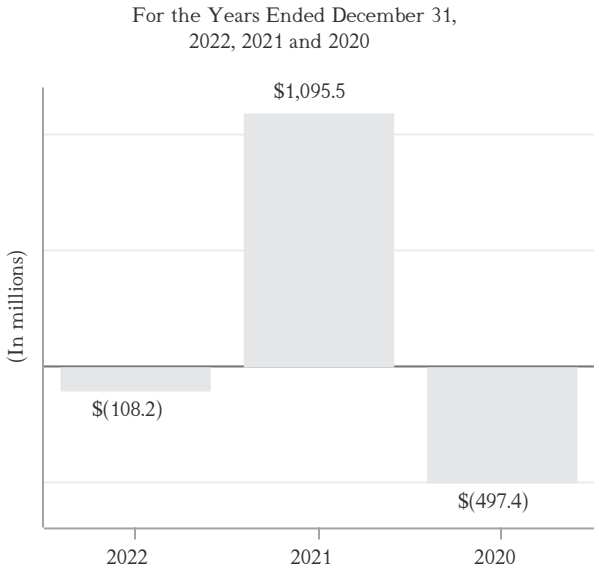


In September 2022 we completed the sale of our building and land parcel located at 125 Broadway for an aggregate sales price of approximately $603.0 million, which is inclusive of a $10.8 million tenant allowance. This sale resulted in a pre-tax gain on sale of approximately $503.7 million, net of transaction costs, for the year ended December 31, 2022.

Simultaneously, with the close of this transaction we leased back the building for a term of approximately 5.5 years, which resulted in the recognition of approximately $168.2 million in new lease liabilities and right-of-use assets recorded within our consolidated balance sheets as of December 31, 2022. The sale and immediate leaseback of this building qualified for sale and leaseback treatment and is classified as an operating lease.

For additional information on our 125 Broadway sale and leaseback transaction, please read *Note 11, Property, Plant and Equipment* and *Note 12, Leases*, to our consolidated financial statements included in this report.

Other (Income) Expense, Net



For 2022 compared to 2021, the change in other (income) expense, net primarily reflects a pre-tax gain during 2022 of approximately $1.5 billion related to the sale of our 49.9% equity interest in Samsung Bioepis, partially offset by a pre-tax charge of $900.0 million, plus settlement fees and expenses, related to a litigation settlement agreement to resolve a qui tam litigation relating to conduct prior to 2015.

For the year ended December 31, 2022, net unrealized losses and realized (gains) losses on our holdings in equity securities were approximately $264.7 million and zero, respectively, compared to net unrealized losses and realized gains of $831.4 million and $10.3 million, respectively, in 2021.

The net unrealized losses recognized during the year ended December 31, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali and Sangamo common stock of approximately $278.0 million.

The net unrealized losses recognized during the year ended December 31, 2021, primarily reflect decreases in the aggregate fair value of our investments in Denali, Sage, Sangamo and Ionis common stock of approximately $819.6 million.

For the year ended December 31, 2022, net interest expense was $157.3 million, compared to $242.6 million in 2021. This decrease was primarily due to higher interest income earned on our investments in 2022, compared to 2021, and lower interest expense in 2022 due to the redemption of our 3.625% Senior Notes due September 15, 2022, with an aggregate principal amount of $1.0 billion.

For 2023 compared to 2022, we anticipate a decrease in net interest expense as a result of lower average debt balances in 2023 and an increase in

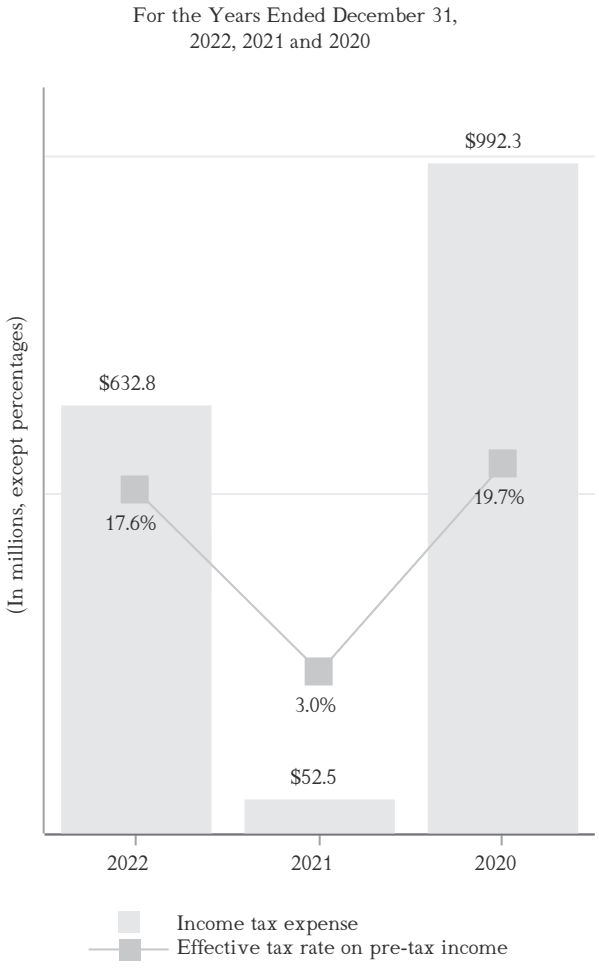
interest income driven by higher interest rates on our cash and marketable securities.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report.

For additional information on the redemption of our Senior Notes, please read *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

For additional information on the litigation settlement agreement, please read *Note 18, Other Consolidated Financial Statement Detail*, to our consolidated financial statements included in this report.

Income Tax Provision



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

For the year ended December 31, 2022, compared to 2021, the increase in our effective tax rate, excluding the impact of the net Neurimmune deferred tax asset, as discussed below, includes the tax impacts of the litigation settlement agreement and the sale of our building at 125 Broadway. These increases were partially offset by the impact of the current year tax benefits related to an international reorganization to align with global tax developments, the impacts of the sale of our equity interest in Samsung Bioepis and the tax impacts of the decision to discontinue development of vixotrigine. Further in 2021, our effective tax rate benefited from the tax effects of the BIIB111 and BIIB112 impairment charges and the non-cash tax effects of changes in the value of our equity instruments.

For additional information on the litigation settlement agreement, please read *Note 18, Other Consolidated Financial Statement Detail*, to our consolidated financial statements included in this report.

Neurimmune Deferred Tax Asset

During 2021 we recorded a net deferred tax asset in Switzerland of approximately $100.0 million on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM.

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 this deferred tax asset to zero.

These adjustments to our net deferred tax asset are each recorded with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our 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 20, Investments in Variable Interest Entities*, to our consolidated financial statements included in this report.

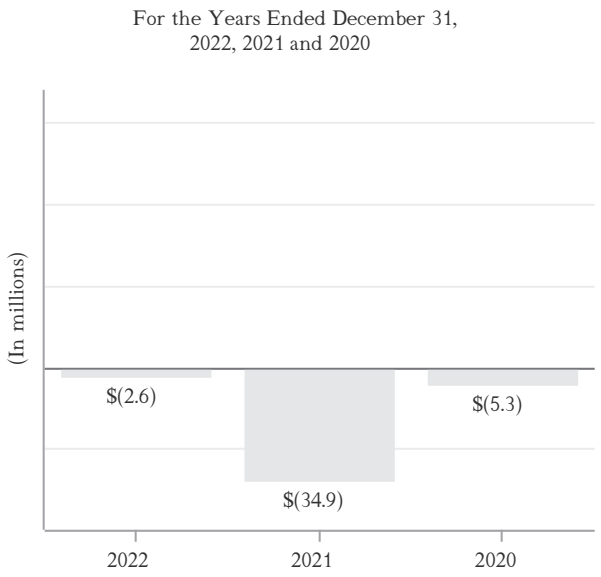
Inflation Reduction Act

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 will be effective for periods after December 31, 2022. The enactment of the IRA did not result in any material adjustments to our income

tax provision or net deferred tax assets as of December 31, 2022.

For additional information on our income taxes, uncertain tax positions and income tax rate reconciliation, please read *Note 17, Income Taxes*, to our consolidated financial statements included in this report.

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



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

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

Prior to this sale, we recognized our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity became available, which was reflected as equity in (income) loss of investee, net of tax in our consolidated statements of income. We also recognized amortization on certain basis differences resulting from our November 2018 investment.

For the year ended December 31, 2022, we recognized net income on our investment of $2.6 million, reflecting our share of Samsung Bioepis' operating profits, net of tax, totaling $17.0 million offset by amortization of basis differences totaling $14.4 million. This amount reflects our share of results prior to the sale of Samsung Bioepis as the results are recognized one quarter in arrears.

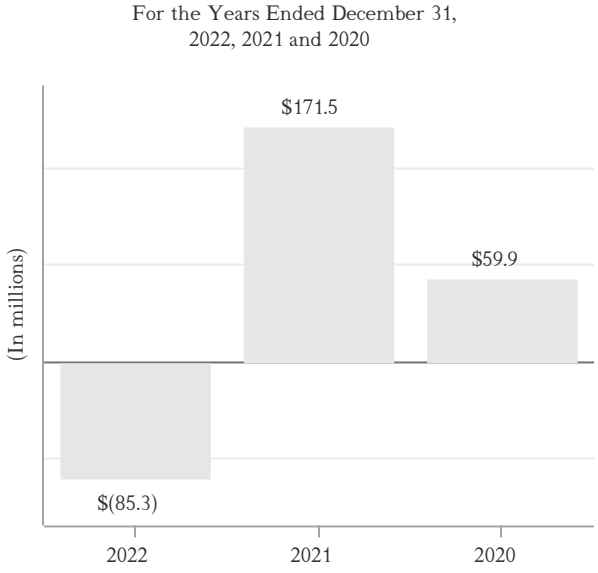
For the year ended December 31, 2021, we recognized net income on our investment of $34.9 million, reflecting our share of Samsung Bioepis' operating profits, net of tax, totaling $64.6 million offset by amortization of basis differences totaling $29.7 million.

Net income on our investment for the year ended December 31, 2021, reflects a $31.2 million benefit related to the release of a valuation allowance on deferred tax assets associated with Samsung Bioepis. The valuation allowance was released in the second quarter of 2021 based on a consideration of the positive and negative evidence, including the historic earnings of Samsung Bioepis.

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Noncontrolling Interests, Net of Tax



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

For 2022 compared to 2021, the change in net income (loss) attributable to noncontrolling interests, net of tax, was primarily due to a deferred tax benefit and milestone payment recorded in 2021, as discussed below.

During 2021 we recorded a net deferred tax asset in Switzerland of approximately $100.0 million on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM.

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 this deferred tax asset to zero.

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

For 2021 the change in net income (loss) attributable to noncontrolling interests, net of tax, was also due to the $100.0 million milestone payment to Neurimmune related to the launch of ADUHELM in the U.S. during 2021.

For additional information on our collaboration agreement with Neurimmune, please read *Note 20, Investments in Variable Interest Entities,* to our consolidated financial statements included in this report.

For additional information on our income taxes please read *Note 17, Income Taxes*, to our 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 December 31, 2022	2021	% Change	$ Change
Financial assets:				
Cash and cash equivalents	$ 3,419.3	$ 2,261.4	51.2 %	$ 1,157.9
Marketable securities — current	1,473.5	1,541.1	(4.4)	(67.6)
Marketable securities — non-current	705.7	892.0	(20.9)	(186.3)
Total cash, cash equivalents and marketable securities	$ 5,598.5	$ 4,694.5	19.3 %	$ 904.0
Borrowings:				
Current portion of notes payable	$ —	$ 999.1	nm	$ (999.1)
Notes payable	6,281.0	6,274.0	0.1	7.0
Total borrowings	$ 6,281.0	$ 7,273.1	(13.6)%	$ (992.1)
Working Capital:				
Current assets	$ 9,791.2	$ 7,856.5	24.6 %	$ 1,934.7
Current liabilities	(3,272.8)	(4,298.2)	(23.9)	1,025.4
Total working capital	$ 6,518.4	$ 3,558.3	83.2 %	$ 2,960.1

[nm] Not meaningful

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 and the impact of biosimilar competition on RITUXAN sales volumes 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.

For the year ended December 31, 2022, certain significant cash flows were as follows:

- $1,384.3 million in net cash flow provided by operating activities;
- $990.3 million in net proceeds received from the sale of our equity interest in Samsung Bioepis;
- $582.6 million in net proceeds received from the sale of one of our buildings;
- $1.0 billion payment made for the redemption of our 3.625% Senior Notes due September 15, 2022;
- $917.0 million in total net payments for a litigation settlement agreement and settlement fees and expenses;
- $932.9 million in total net payments for income taxes;
- $750.0 million used for share repurchases; and
- $240.3 million used for purchases of property, plant and equipment.

For the year ended December 31, 2021, certain significant cash flows were as follows:

- $3,639.9 million in net cash flow provided by operating activities;
- $1.8 billion used for share repurchases;
- $170.0 million used in connection with our private offer to exchange (Exchange Offer) our tendered 5.200% Senior Notes due September 15, 2045 (2045 Senior Notes) for a new series of 3.250% Senior Notes due February 15, 2051 (2051 Senior Notes) and cash, and an offer to purchase our tendered 2045 Senior Notes for cash;
- $258.1 million used for purchases of property, plant and equipment;
- $247.9 million in total net payments for income taxes; and
- $100.0 million milestone payment to Neurimmune.

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

sources should we identify a significant new opportunity.

For additional information on the litigation settlement agreement, please read *Note 18, Other Consolidated Financial Statement Detail*, to our consolidated financial statements included in this report.

For additional information on certain risks that could negatively impact our financial position or future results of operations, please read *Item 1A. Risk Factors* and *Item 7A. Quantitative and Qualitative Disclosures About Market Risk* included in this report.

Cash, Cash Equivalents and Marketable Securities

Until required for another use in our business, we typically invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments, overnight reverse repurchase agreements and other interest-bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type.

As of December 31, 2022, we had cash, cash equivalents and marketable securities totaling approximately $5.6 billion compared to approximately $4.7 billion as of December 31, 2021. The change in cash, cash equivalents and marketable securities at December 31, 2022, from December 31, 2021, was primarily due to net cash flow provided by operating activities, which includes $917.0 million in total net payments for a litigation settlement agreement and settlement fees and expenses, and $990.3 million in net proceeds received from the sale of our equity interest in Samsung Bioepis and $582.6 million in net proceeds received from the sale of one of our buildings, partially offset by $1.0 billion of cash used for the redemption of our 3.625% Senior Notes due September 15, 2022 and $750.0 million used for share repurchases.

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

	As of December 31,	
(In millions)	2022	2021
Denali	$ 370.2	$ 550.7
Sage	238.0	231.9
Sangamo	74.3	173.7
Ionis	108.6	87.5
	$ 791.1	$ 1,043.8

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

Investments and Other Assets

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

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

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report.

Capital Expenditures

In March 2021 we announced our plans to build a new gene therapy manufacturing facility in RTP, NC 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. Construction for this new facility began during the fourth quarter of 2021.

Borrowings

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

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

The following is a summary of our currently outstanding senior unsecured notes issued in 2020 (2020 Senior Notes):

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

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

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

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

In July 2022 we redeemed our 3.625% Senior Notes due September 15, 2022, with an aggregate principal amount of $1.0 billion.

For additional information on our Senior Notes, please read *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

For a summary of the fair values of our outstanding borrowings as of December 31, 2022 and 2021, please read *Note 8, Fair Value Measurements,* to our consolidated financial statements included in this report.

Credit Facility

In January 2020 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio.

As of December 31, 2022 and 2021, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Working Capital

Working capital is defined as current assets less current liabilities. Working capital was $6.5 billion and $3.6 billion as of December 31, 2022 and 2021, respectively. The change in working capital reflects an increase in total current assets of approximately $1.9 billion and a decrease in total current liabilities of approximately $1.0 billion.

Current Assets

The increase in total current assets was primarily driven by the following:

- net increase in cash, cash equivalents and marketable securities due to net cash flow provided by operating activities of approximately $1,384.3 million;
- receipt of approximately $990.3 million in cash, net of expenses, from the sale of our equity interest in Samsung Bioepis;
- recording of a receivable from Samsung BioLogics for approximately $798.8 million as part of the sale of our equity interest in Samsung Bioepis; and
- cash receipt of approximately $582.6 million related to the sale of one of our buildings.

The increase was partially offset by cash used for the redemption of our 3.625% Senior Notes due September 15, 2022, of approximately $1.0 billion and share repurchases of $750.0 million and $917.0 million in total net payments for a litigation settlement agreement and settlement fees and expenses.

Current Liabilities

The decrease in total current liabilities was primarily due to the following:

- redemption of our 3.625% Senior Notes due September 15, 2022, of approximately $1.0 billion, which were classified within current liabilities in 2021; and
- a reduction in our accounts payable.

Share Repurchase Programs

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

Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 3.6 million, 6.0 million and 1.6 million shares of our common stock at a cost of approximately $750.0 million, $1.8 billion and $400.0 million during the years ended December 31, 2022, 2021 and 2020, respectively. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2022.

In December 2019 our Board of Directors authorized our December 2019 Share Repurchase Program, which was a program to repurchase up to $5.0 billion of our common stock, which was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 16.7 million shares of our common stock at a cost of approximately $5.0 billion during the year ended December 31, 2020.

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

In August 2022 the IRA was signed into law. Among other things, the IRA levies a 1.0% excise tax on net stock repurchases after December 31, 2022. Historically, we have made discretionary share repurchases.

Cash Flow

The following table summarizes our cash flow activity:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2022	2021	2020	2022 vs. 2021	2021 vs. 2020
Net cash flow provided by (used in) operating activities	$ 1,384.3	$ 3,639.9	$ 4,229.8	(62.0)%	(13.9)%
Net cash flow provided by (used in) investing activities	1,576.6	(563.7)	(608.6)	379.7	(7.4)
Net cash flow provided by (used in) financing activities	(1,747.3)	(2,086.2)	(5,272.7)	(16.2)	(60.4)

Operating Activities

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

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

- non-cash operating items such as depreciation and amortization, impairment charges, unrealized gain (loss) on strategic investments, acquired IPR&D and share-based compensation;
- changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- changes in the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For 2022 compared to 2021, the decrease in net cash flow provided by operating activities was primarily due to lower revenue in 2022, net payments of $917.0 million for a litigation settlement agreement and settlement fees and expenses, timing of payments and higher net income tax payments in 2022. The higher tax payments are, in part, due to a change in the tax deductibility of payments made for research and development.

Investing Activities

For 2022 compared to 2021, the increase in net cash flow provided by investing activities was primarily due to proceeds received from the sale of our 49.9% equity interest in Samsung Bioepis of $990.3 million, net of expenses, during the second quarter of 2022 as well as $582.6 million in net proceeds received from the sale of one of our buildings during the third quarter of 2022.

Financing Activities

For 2022 compared to 2021, the decrease in net cash flow used in financing activities was primarily due to $1.1 billion in lower share repurchases in 2022, partially offset by $832.2 million in higher debt repayments in 2022.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2022, excluding amounts related to uncertain tax positions, funding commitments, contingent development, regulatory and commercial milestone payments, contingent payments and contingent consideration related to our business combinations, as described below.

	Payments Due by Period				
(In millions)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Non-cancellable operating leases [1][2][3]	$ 364.2	$ 82.7	$ 140.8	$ 110.3	$ 30.4
Long-term debt obligations [4]	10,262.4	232.7	2,197.7	323.7	7,508.3
Purchase and other obligations [5]	917.2	306.7	600.6	1.7	8.2
Defined benefit obligation	90.8	—	—	—	90.8
Total contractual obligations	$ 11,634.6	$ 622.1	$ 2,939.1	$ 435.7	$ 7,637.7

[1] We lease properties and equipment for use in our operations. Amounts reflected within the table above detail future minimum rental commitments under non-cancelable operating leases as of December 31 for each of the periods presented. In addition to the minimum rental commitments, these leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

[2] Obligations are presented net of sublease income expected to be received for our vacated portion of our Weston, MA facility and other facilities throughout the world.

[3] In September 2022 we completed the sale of our building and land parcel located at 125 Broadway. Simultaneously, with the close of this transaction we leased back the building for a term of approximately 5.5 years. For additional information on our 125 Broadway sale and leaseback transaction, please read *Note 11, Property, Plant and Equipment* and *Note 12, Leases*, to our consolidated financial statements included in this report.

[4] Long-term debt obligations are related to our 2015 Senior Notes, our 2020 Senior Notes and our 2021 Exchange Offer Senior Notes, including principal and interest payments.

[5] Purchase and other obligations include $558.0 million related to the remaining payments on a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and $26.0 million related to the fair value of net liabilities on derivative contracts.

Royalty Payments

TYSABRI

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

SPINRAZA

We make royalty payments on annual worldwide net sales of SPINRAZA using a tiered royalty rate between 11.0% and 15.0%, which are recognized as cost of sales in our consolidated statements of income.

VUMERITY

We make royalty payments to Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes) on worldwide net sales of VUMERITY using a royalty rate of 15.0%, which are recognized as cost of sales in our consolidated statements of income.

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

For additional information on our collaboration arrangement with Alkermes, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2022, we could trigger potential future milestone payments to third parties of up to approximately $9.3 billion, including approximately $2.0 billion in development milestones, approximately $0.5 billion in regulatory milestones and approximately $6.8 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 December 31, 2022, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

If certain clinical and commercial milestones are met, we may pay up to $356.2 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 December 31, 2022, 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 $20.4 million in our consolidated balance sheets for expenditures incurred by CROs as of December 31, 2022. We have approximately $929.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2022.

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 December 31, 2022, we have approximately $154.6 million of liabilities associated with uncertain tax positions.

As of December 31, 2022 and 2021, we have accrued income tax liabilities of approximately $558.0 million and $633.0 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of December 31, 2022, approximately $137.8 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight–year period, which started in 2018, and will not accrue interest.

Other Off-Balance Sheet Arrangements

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

New Accounting Standards

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

Legal Matters

For a discussion of legal matters as of December 31, 2022, please read *Note 21, Litigation,* to our consolidated financial statements included in this report.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), 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. Other significant accounting policies are outlined in *Note 1, Summary of Significant Accounting Policies*, to our consolidated financial statements included in this report.

Revenue Recognition

We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue following the five-step model prescribed under Financial Accounting Standards Board (FASB) Accounting Standards Codification 606, *Revenue from Contracts with Customers*: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations.

Product Revenue

In the U.S., we sell our products primarily to wholesale and specialty distributors and specialty pharmacies. In other countries, we sell our products primarily to wholesale distributors, hospitals, pharmacies and other third-party distribution partners. These customers subsequently resell our products to

health care providers and patients. In addition, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and allowances related to our products.

Product revenue is recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

Reserves for Discounts and Allowances

Product revenue is recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Our process for estimating reserves established for these variable consideration components do not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenue, are generally characterized in the following categories: discounts, contractual adjustments and returns.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration are calculated based upon a consistent application of our methodology utilizing the expected value method. These estimates reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

As of December 31, 2022, a 10.0% change in our discounts, contractual adjustments and reserves would have resulted in a decrease of our pre-tax earnings by approximately $338.6 million.

In addition to discounts, rebates and product returns, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services, which are generally reflected as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expense in our consolidated statements of income.

For additional information on our revenue, please read *Note 5, Revenue*, to our consolidated financial statements included in this report.

Inventory

At each reporting period we review our inventories for excess or obsolescence and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. The determination of obsolete or excess inventory requires management to make estimates based on assumptions about the future demand of our products, product expiration dates, estimated future sales and our general future plans. If customer demand subsequently differs from our forecasts, we may be required to record additional charges for excess inventory.

Although we believe that the assumptions we use in estimating inventory write-downs are reasonable, no assurance can be given that significant future changes in these assumptions or changes in future events and market conditions could result in different estimates.

During 2021 we wrote-off approximately $120.0 million of inventory in excess of forecasted demand related to ADUHELM. During the first quarter of 2022 we wrote-off approximately $275.0 million, as a result of the final CMS decision.

As of December 31, 2022, the carrying value of our ADUHELM inventory was immaterial. As of December 31, 2021, we had approximately $223.0 million of ADUHELM inventory.

Acquired Intangible Assets, including IPR&D

When we purchase a business, the acquired IPR&D is measured at fair value, capitalized as an intangible asset and tested for impairment at least annually, as of October 31, until commercialization, after which time the IPR&D is amortized over its estimated useful life. If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to

research and development expense as they are incurred.

We have acquired, and expect to continue to acquire, intangible assets through the acquisition of biotechnology companies or through the consolidation of variable interest entities. These intangible assets primarily consist of technology associated with human therapeutic products and IPR&D product candidates. When significant identifiable intangible assets are acquired, we generally engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Management will determine the fair value of less significant identifiable intangible assets acquired. Discounted cash flow models are typically used in these valuations, and these models require the use of significant estimates and assumptions including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flow from product sales resulting from completed products and in process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates.

If these projects are not successfully developed, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. No assurance can be given that the underlying assumptions used to estimate expected project sales, development costs or profitability, or the events associated with such projects, will transpire as estimated.

Impairment and Amortization of Long-lived Assets

Long-lived assets to be held and used include property, plant and equipment as well as intangible assets, including IPR&D and trademarks. Property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

When performing our impairment assessment, we calculate the fair value using the same methodology as described above under *Acquired Intangible Assets, including IPR&D*. If the carrying value of our acquired IPR&D exceeds its fair value, then the intangible asset is written down to its fair value. Changes in estimates and assumptions used in determining the fair value of our acquired IPR&D could result in an impairment. Impairments are recorded within amortization and impairment of acquired intangible assets in our consolidated statements of income.

Based on our most recent impairment assessment we incurred impairment charges of approximately $119.6 million and $629.3 million for the years ended December 31, 2022 and 2021, respectively, mainly related to the discontinuation of IPR&D programs. For additional information on our impairments, *Note 7, Intangible Assets and Goodwill*, to our consolidated financial statements included in this report.

Our most significant intangible assets are our acquired and in-licensed rights and patents. Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI. We amortize the intangible assets related to our marketed products using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenue of our marketed products is performed annually during our long-range planning cycle and whenever events or changes in circumstances would significantly affect anticipated lifetime revenue of the relevant products.

For additional information on the impairment charges related to our long-lived assets during 2022, 2021 and 2020, please read *Note 7, Intangible Assets and Goodwill,* to our consolidated financial statements included in this report.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. Each reporting period thereafter, we revalue the remaining obligations and record increases or decreases in their fair value as an adjustment to contingent consideration expense in our consolidated statements of income. Changes in the fair value of our contingent consideration obligations can result from changes to one or multiple inputs, including adjustments to the discount rates and achievement and timing of any cumulative sales-based and development milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above, could have a material impact on the amount of contingent consideration expense we record in any given period.

Income Taxes

We prepare and file income tax returns based on our interpretation of each jurisdiction's tax laws and regulations. In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Upon our election in the fourth quarter of 2018 to record deferred taxes for global intangible low-taxed income (GILTI), we have included amounts related to GILTI taxes within temporary difference.

Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our consolidated financial position and results of operations.

We account for uncertain tax positions using a "more likely than not" threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished, through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the "more likely than not" threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews, we have no plans to appeal or litigate any aspect of the tax position and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

ITEM 7A. 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 December 31, 2022, and is not expected to have a material impact on our results of operations or financial position in the future.

Revenue and Operating Expense Hedging Program

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenue and operating expense. We use foreign currency forward contracts and foreign currency options to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 12 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read *Note 10, Derivative Instruments,* to our 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 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 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 December 31, 2022 and 2021, a hypothetical adverse 10.0% movement in foreign currency exchange rates compared to the U.S. dollar across all maturities would result in a hypothetical decrease in the fair value of forward contracts of approximately $293.7 million and $333.1 million, respectively. The estimated fair value change was determined by measuring the impact of the hypothetical exchange rate movement on outstanding forward contracts. Our use of this methodology to quantify the market risk of such instruments is subject to assumptions and actual impact could be significantly different. The quantitative information about market risk is limited because it does not take into account all foreign currency operating transactions.

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 December 31, 2022 and 2021, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $11.7 million and $14.3 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

Credit Risk

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

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

We believe that our allowance for doubtful accounts was adequate as of December 31, 2022 and 2021.

Equity Price Risk

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

Changes in the fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. The potential change in fair value for equity price sensitive instruments has been assessed on a hypothetical 10.0% adverse movement. As of December 31, 2022 and 2021, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $79.1 million and $104.8 million, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is contained on pages F-1 through F-79 of this report and is incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2022. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that:

(a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms; and

(b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2022, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2022, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information concerning our executive officers is set forth under the heading *Information about our Executive Officers* in Item 1 of this report. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.biogen.com, under the "*Corporate Governance*" subsection of the "*Investors*" section of the site. We intend to make all required disclosures regarding any amendments to, or waivers from, provisions of our code of business conduct at the same location of our website.

The response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Proposal 1 - Election of Directors,*" *"Corporate Governance at Biogen"* and "*Miscellaneous - Stockholder Proposals*" contained in the proxy statement for our 2023 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Executive Compensation Matters*" and *"Corporate Governance at Biogen"* contained in the proxy statement for our 2023 annual meeting of stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled *"Stock Ownership"* and *"Equity Compensation Plan Information"* contained in the proxy statement for our 2023 annual meeting of stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Certain Relationships and Related Person Transactions*" and *"Corporate Governance at Biogen"* contained in the proxy statement for our 2023 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto in the section entitled "*Proposal 2 - Ratification of the Selection of our Independent Registered Public Accounting Firm*" contained in the proxy statement for our 2023 annual meeting of stockholders.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

a. (1) Consolidated Financial Statements:

The following financial statements are filed as part of this report:

Certain totals may not sum due to rounding.

(2) Exhibits

The exhibits listed on the Exhibit Index beginning on page 85, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

(3) Financial Statement Schedules

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the consolidated financial statements and notes thereto.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

EXHIBIT INDEX

	Exhibit No.	Description
+	2.1†	Asset Purchase Agreement among Biogen Idec International Holding Ltd., Elan Pharma International Limited and Elan Pharmaceuticals, Inc., dated as of February 5, 2013. Filed as Exhibit 2.1 to our Current Report on Form 8-K/A filed on February 12, 2013.
+	2.2	Separation Agreement between Biogen Inc. and Bioverativ Inc. dated as of January 31, 2017. Filed as Exhibit 2.1 to our Current Report on Form 8-K filed on February 2, 2017.
+	3.1	Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
+	3.2	Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015.
+	3.3	Certificate of Amendment of Biogen Inc.'s Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on June 8, 2021.
+	3.4	Fourth Amended and Restated Bylaws. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on June 9, 2017.
+	4.1	Second Supplemental Indenture, dated April 30, 2020, between Biogen Inc. and U.S. Bank National Association, including the forms of Global Notes attached as Exhibit A and Exhibit B, respectively, thereto. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on April 30, 2020.
+	4.2	Reference is made to Exhibit 3.1 for a description of the rights, preferences and privileges of our Series A Preferred Stock and Series X Junior Participating Preferred Stock.
+	4.3	Indenture between Biogen Inc. and U.S. Bank National Association, dated as of September 15, 2015. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015.
+	4.4	First Supplemental Indenture between Biogen Inc. and U.S. Bank National Association, dated September 15, 2015. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015.
+	4.5	Third Supplemental Indenture, dated February 16, 2021, between Biogen Inc. and U.S. Bank National Association. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on February 16, 2021.
+	4.6	Form of 3.250% Senior Notes due 2051, in the form of a Global Note bearing a private placement legend. Filed as Exhibit 4.3 to our Current Report on Form 8-K filed on February 16, 2021.
+	4.7	Form of 3.250% Senior Notes due 2051, in the form of a Global Note bearing a Regulation S legend. Filed as Exhibit 4.4 to our Current Report on Form 8-K filed on February 16, 2021.
+	4.8	Description of Securities.
+	4.9	Registration Rights Agreement, dated February 16, 2021, between Biogen Inc. and Deutsche Bank Securities Inc. and Citigroup Global Markets, Inc. with respect to the 3.250% Senior Notes due 2051. Filed as Exhibit 4.5 to our Current Report on Form 8-K filed on February 16, 2021.
+	10.1	Credit Agreement between Biogen Inc., Bank of America, N.A., Goldman Sachs Bank USA and other lenders party thereto, dated August 28, 2015. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015.
+	10.2	Credit Agreement, dated as of January 28, 2020, among Biogen Inc., Bank of America, N.A., as administrative agent, swing line lender and the L/C issuer, and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 3, 2020.
+	10.3+	Amendment to Credit Agreement, dated as of February 7, 2023, by and among Biogen Inc., Bank of America, N.A., as administrative agent, swing line lender and the L&C issuer, and the other lenders party thereto.
+	10.4†	Second Amended and Restated Collaboration Agreement between Biogen Idec Inc. and Genentech, Inc., dated as of October 18, 2010. Filed as Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2010.
+	10.5†	Letter Agreement regarding GA101 financial terms between Biogen Idec Inc. and Genentech, Inc., dated October 18, 2010. Filed as Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 31, 2010.
+	10.6	Settlement and License Agreement, dated January 17, 2017, between Biogen Swiss Manufacturing GmbH, Biogen International Holdings ltd., Forward Pharma A/S and other parties thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 1, 2017.
+	10.7*	Biogen Inc. 2017 Omnibus Equity Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2017.
+	10.8*	Form of restricted stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
+	10.9*	Form of market stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
+	10.10*	Form of performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.

	Exhibit No.	Description
+	10.11*	Form of cash-settled performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
+	10.12*	Form of performance stock units award agreement (cash-settled) under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.10 to our Annual Report on Form 10-K for the year ended December 31, 2017.
+	10.13*	Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.11 to our Annual Report on Form 10-K for the year ended December 31, 2017.
+	10.14*	Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.
+	10.15*	Form of performance stock units award agreement (cash settled) under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.
+	10.16*	Form of restricted stock unit award agreement (2018 one-time transition grant) under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.
+	10.17*	Form of market stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan (for grants commencing in July 2019). Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.
+	10.18*	Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan (for grants commencing in July 2019). Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.
+	10.19*	Form of performance stock units award agreement (cash settled) under the Biogen Inc. 2017 Omnibus Equity Plan (for grants commencing in July 2019). Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.
+	10.20	Form of nonqualified stock option award agreement under Biogen Inc. 2017 Omnibus Equity Plan.
+	10.21*	Biogen Idec Inc. 2008 Amended and Restated Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
+	10.22*	Form of performance unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
+	10.23*	Form of market stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
+	10.24*	Form of restricted stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on August 1, 2008.
+	10.25*	Form of nonqualified stock option award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Current Report on Form 8-K filed on August 1, 2008.
+	10.26*	Form of cash-settled performance shares award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
+	10.27*	Biogen Inc. 2006 Non-Employee Directors Equity Plan, as amended. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022.
+	10.28*	Biogen Inc. 2015 Employee Stock Purchase Plan. Filed as Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 30, 2015.
+	10.29*	Biogen Idec Inc. 2008 Performance-Based Management Incentive Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on May 8, 2008.
+	10.30*	Biogen Inc. 2019 Form of Performance-Based Management Incentive Plan, as amended. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021.
+	10.31*	Biogen Idec Inc. Voluntary Executive Supplemental Savings Plan, as amended and restated effective January 1, 2004. Filed as Exhibit 10.13 to our Annual Report on Form 10-K for the year ended December 31, 2003.
+	10.32*	Biogen Idec Inc. Supplemental Savings Plan, as amended. Filed as Exhibit 10.23 to our Annual Report on Form 10-K for the year ended December 31, 2015.
+	10.33*	Biogen Idec Inc. Voluntary Board of Directors Savings Plan, as amended. Filed as Exhibit 10.24 to our Annual Report on Form 10-K for the year ended December 31, 2015.
+	10.34*	Biogen Inc. Executive Severance Policy - U.S. Executive Vice President, as amended effective June 19, 2019. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.
+	10.35*	Biogen Inc. Executive Severance Policy - U.S. Executive Vice President, as amended effective July 13, 2020. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.
+	10.36*	Annual Retainer Summary for Board of Directors (effective January 1, 2020). Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019.

	Exhibit No.	Description
+	10.37*	Form of indemnification agreement for directors and executive officers. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 7, 2011.
+	10.38*	Employment Agreement between Biogen Inc. and Michel Vounatsos dated December 18, 2016 and effective as of January 6, 2017. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on December 19, 2016.
+	10.39*	Letter regarding employment arrangement of Michel Vounatsos dated May 2, 2022. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on May 3, 2022.
+	10.40*	Employment Agreement, dated November 10, 2022, by and between Biogen Inc. and Christopher A. Viehbacher. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on November 10, 2022.
+	10.41*	Letter regarding employment arrangement of Michael McDonnell dated July 16, 2020. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.
+	10.42*	Letter regarding employment arrangement of Susan Alexander dated December 13, 2005. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2009.
+	10.43*	Letter regarding employment arrangement of Chirfi Guindo dated October 12, 2017. Filed as Exhibit 10.41 to our Annual Report on Form 10-K for the year ended December 31, 2020.
+	10.44	Joint Venture Agreement, dated December 6, 2011, by and between Samsung BioLogics Co., Ltd. and Biogen Therapeutics Inc. (f/k/a Biogen Idec Therapeutics Inc.), as amended February 28, 2012, September 29, 2014, and February 20, 2019. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021.
+	10.45	Amended and Restated Collaboration Agreement, dated October 22, 2017, between Biogen MA Inc. and Eisai Co., LTD.
+	10.46	First Amendment to Amended and Restated Collaboration Agreement, dated March 13, 2022, between Biogen MA Inc. and Eisai Co., LTD.
+	21	Subsidiaries.
+	23	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm.
	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 of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
+	101	The following materials from Biogen Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Consolidated Statements of Income, (ii) the Consolidated Statements of Comprehensive Income, (iii) the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flow, (v) the Consolidated Statements of Equity and (vi) Notes to Consolidated Financial Statements.

* Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit.

\+ Exhibit filed with the SEC, but not printed herein.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ CHRISTOPHER A. VIEHBACHER
Christopher A. Viehbacher
Chief Executive Officer

Date: February 15, 2023

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ Christopher A. Viehbacher Christopher A. Viehbacher	Director and Chief Executive Officer (principal executive officer)	February 15, 2023
/s/ Michael R. McDonnell Michael R. McDonnell	Executive Vice President and Chief Financial Officer (principal financial officer)	February 15, 2023
/s/ Robin C. Kramer Robin C. Kramer	Senior Vice President, Chief Accounting Officer (principal accounting officer)	February 15, 2023
/s/ Stelios Papadopoulos Stelios Papadopoulos	Director and Chairman of the Board of Directors	February 15, 2023
/s/ Alexander J. Denner Alexander J. Denner	Director	February 15, 2023
/s/ Caroline D. Dorsa Caroline D. Dorsa	Director	February 15, 2023
/s/ Maria C. Freire Maria C. Freire	Director	February 15, 2023
/s/ William A. Hawkins William A. Hawkins	Director	February 15, 2023
/S/ William D. Jones William D. Jones	Director	February 15, 2023
/s/ Jesus B. Mantas Jesus B. Mantas	Director	February 15, 2023
/s/ Richard C. Mulligan Richard C. Mulligan	Director	February 15, 2023
/s/ Eric K. Rowinsky Eric K. Rowinsky	Director	February 15, 2023
/s/ Stephen A. Sherwin Stephen A. Sherwin	Director	February 15, 2023

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(In millions, except per share amounts)

	For the Years Ended December 31,		
	2022	2021	2020
Revenue:			
Product, net	$ 7,987.8	$ 8,846.9	$ 10,692.2
Revenue from anti-CD20 therapeutic programs	1,700.5	1,658.5	1,977.8
Other	485.1	476.3	774.6
Total revenue	10,173.4	10,981.7	13,444.6
Cost and expense:			
Cost of sales, excluding amortization and impairment of acquired intangible assets	2,278.3	2,109.7	1,805.2
Research and development	2,231.1	2,501.2	3,990.9
Selling, general and administrative	2,403.6	2,674.3	2,504.5
Amortization and impairment of acquired intangible assets	365.9	881.3	464.8
Collaboration profit (loss) sharing	(7.4)	7.2	232.9
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	—	—	(92.5)
(Gain) loss on fair value remeasurement of contingent consideration	(209.1)	(50.7)	(86.3)
Acquired in-process research and development	—	18.0	75.0
Restructuring charges	131.1	—	—
Gain on sale of building	(503.7)	—	—
Other (income) expense, net	(108.2)	1,095.5	(497.4)
Total cost and expense	6,581.6	9,236.5	8,397.1
Income before income tax expense and equity in loss of investee, net of tax	3,591.8	1,745.2	5,047.5
Income tax (benefit) expense	632.8	52.5	992.3
Equity in (income) loss of investee, net of tax	(2.6)	(34.9)	(5.3)
Net income	2,961.6	1,727.6	4,060.5
Net income (loss) attributable to noncontrolling interests, net of tax	(85.3)	171.5	59.9
Net income attributable to Biogen Inc.	$ 3,046.9	$ 1,556.1	$ 4,000.6
Net income per share:			
Basic earnings per share attributable to Biogen Inc.	$ 20.96	$ 10.44	$ 24.86
Diluted earnings per share attributable to Biogen Inc.	$ 20.87	$ 10.40	$ 24.80
Weighted-average shares used in calculating:			
Basic earnings per share attributable to Biogen Inc.	145.3	149.1	160.9
Diluted earnings per share attributable to Biogen Inc.	146.0	149.6	161.3

See accompanying notes to these consolidated financial statements.

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In millions)

	For the Years Ended December 31,		
	2022	2021	2020
Net income attributable to Biogen Inc.	$ 3,046.9	$ 1,556.1	$ 4,000.6
Other comprehensive income:			
Unrealized gains (losses) on securities available for sale, net of tax	(13.5)	(3.6)	(2.8)
Unrealized gains (losses) on cash flow hedges, net of tax	(38.7)	232.8	(186.8)
Gains (losses) on net investment hedges, net of tax	(25.5)	34.0	(33.6)
Unrealized gains (losses) on pension benefit obligation, net of tax	43.7	21.5	(33.5)
Currency translation adjustment	(24.2)	(92.4)	92.9
Total other comprehensive income (loss), net of tax	(58.2)	192.3	(163.8)
Comprehensive income (loss) attributable to Biogen Inc.	2,988.7	1,748.4	3,836.8
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	(85.3)	172.1	60.9
Comprehensive income (loss)	$ 2,903.4	$ 1,920.5	$ 3,897.7

See accompanying notes to these consolidated financial statements.

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

	As of December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,419.3	$ 2,261.4
Marketable securities	1,473.5	1,541.1
Accounts receivable, net	1,705.0	1,549.4
Due from anti-CD20 therapeutic programs	431.4	412.3
Inventory	1,344.4	1,351.5
Other current assets	1,417.6	740.8
Total current assets	9,791.2	7,856.5
Marketable securities	705.7	892.0
Property, plant and equipment, net	3,298.6	3,416.4
Operating lease assets	403.9	375.4
Intangible assets, net	1,850.1	2,221.3
Goodwill	5,749.0	5,761.1
Deferred tax asset	1,226.4	1,415.1
Investments and other assets	1,529.2	1,939.5
Total assets	$ 24,554.1	$ 23,877.3
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$ —	$ 999.1
Taxes payable	259.9	174.7
Accounts payable	491.5	589.2
Accrued expense and other	2,521.4	2,535.2
Total current liabilities	3,272.8	4,298.2
Notes payable	6,281.0	6,274.0
Deferred tax liability	334.7	694.5
Long-term operating lease liabilities	333.0	330.4
Other long-term liabilities	944.2	1,320.5
Total liabilities	11,165.7	12,917.6
Commitments, contingencies and guarantees (Notes 22 and 23)		
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	73.3	68.2
Accumulated other comprehensive loss	(164.9)	(106.7)
Retained earnings	16,466.5	13,911.7
Treasury stock, at cost; 23.8 million and 23.8 million shares, respectively	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	13,397.9	10,896.2
Noncontrolling interests	(9.5)	63.5
Total equity	13,388.4	10,959.7
Total liabilities and equity	$ 24,554.1	$ 23,877.3

See accompanying notes to these consolidated financial statements.

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOW
(In millions)

	For the Years Ended December 31,		
	2022	2021	2020
Cash flow from operating activities:			
Net income	$ 2,961.6	$ 1,727.6	$ 4,060.5
Adjustments to reconcile net income to net cash flow from operating activities:			
Depreciation and amortization	518.4	487.7	457.2
Impairment of intangible assets	119.6	629.3	209.7
Excess and obsolescence charges related to inventory	336.2	167.6	26.6
Acquired in-process research and development	—	18.0	75.0
Share-based compensation	254.1	238.6	198.3
Contingent consideration	(209.1)	(50.7)	(86.3)
(Gain)/loss on divestiture of Hillerød, Denmark manufacturing operations	—	—	(92.5)
Deferred income taxes	(168.6)	(426.8)	149.0
(Gain) loss on strategic investments	265.9	826.8	(681.8)
(Gain) loss on equity method investment	(2.6)	(34.9)	(3.3)
Gain on sale of equity interest in Samsung Bioepis	(1,505.4)	—	—
Gain on sale of building	(503.7)	—	—
Other	208.2	202.2	104.6
Changes in operating assets and liabilities, net:			
Accounts receivable	(203.4)	324.8	2.8
Due from anti-CD20 therapeutic programs	(19.0)	1.2	176.7
Inventory	(320.2)	(462.4)	(316.3)
Accrued expense and other current liabilities	(113.4)	(95.4)	154.2
Income tax assets and liabilities	(142.3)	230.8	(67.5)
Other changes in operating assets and liabilities, net	(92.0)	(144.5)	(137.1)
Net cash flow provided by (used in) operating activities	1,384.3	3,639.9	4,229.8
Cash flow from investing activities:			
Purchases of property, plant and equipment	(240.3)	(258.1)	(424.8)
Proceeds from sales and maturities of marketable securities	3,671.0	3,405.4	7,299.4
Purchases of marketable securities	(3,448.5)	(3,808.7)	(6,397.7)
Proceeds from sale of equity interest in Samsung Bioepis	990.3	—	—
Proceeds from sale of building	582.6	—	—
Purchase of Sangamo Therapeutics, Inc. stock	—	—	(141.8)
Purchase of Denali Therapeutics Inc. stock	—	—	(423.7)
Purchase of Sage Therapeutics, Inc. stock	—	—	(441.0)
Proceeds from divestiture of Hillerød, Denmark manufacturing operations	—	28.1	—
Acquired in-process research and development	—	(18.0)	(75.0)
Acquisitions of intangible assets	(2.9)	(18.8)	(52.0)
Proceeds from sales of strategic investments	—	93.5	74.9
Other	24.4	12.9	(26.9)
Net cash flow provided by (used in) investing activities	1,576.6	(563.7)	(608.6)
Cash flow from financing activities:			
Purchase of treasury stock	(750.0)	(1,800.0)	(6,679.1)
Payments related to issuance of stock for share-based compensation arrangements, net	(1.9)	(0.7)	(4.6)
Repayments of borrowings and premiums paid on debt exchange	(1,002.2)	(170.0)	—
Proceeds from borrowings	—	—	2,967.4
Repayments of borrowings	—	—	(1,500.0)
Net (distribution) contribution to noncontrolling interest	12.4	(94.4)	(71.0)
Other	(5.6)	(21.1)	14.6
Net cash flow provided by (used in) financing activities	(1,747.3)	(2,086.2)	(5,272.7)
Net increase (decrease) in cash and cash equivalents	1,213.6	990.0	(1,651.5)
Effect of exchange rate changes on cash and cash equivalents	(55.7)	(59.8)	69.0
Cash and cash equivalents, beginning of the year	2,261.4	1,331.2	2,913.7
Cash and cash equivalents, end of the year	$ 3,419.3	$ 2,261.4	$ 1,331.2

See accompanying notes to these consolidated financial statements.

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(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	—	—	—	—	—	—	3,046.9	—	—	3,046.9	(85.3)	2,961.6
Other comprehensive income (loss), net of tax	—	—	—	—	—	(58.2)	—	—	—	(58.2)	—	(58.2)
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	—	—
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	12.3	12.3
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(3.6)	(750.0)	(750.0)	—	(750.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(3.6)	—	(257.9)	—	(492.1)	3.6	750.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	44.2	—	—	—	—	44.2	—	44.2
Issuance of common stock under stock award plan	—	—	0.5	—	(46.0)	—	—	—	—	(46.0)	—	(46.0)
Compensation expense related to share-based payments	—	—	—	—	263.5	—	—	—	—	263.5	—	263.5
Other	—	—	—	—	1.3	—	—	—	—	1.3	—	1.3
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

See accompanying notes to these consolidated financial statements.

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(In millions)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2020	—	$ —	176.2	$ 0.1	$ —	$ (299.0)	$13,976.3	(23.8)	$(2,977.1)	$ 10,700.3	$ (14.2)	$10,686.1
Net income	—	—	—	—	—	—	1,556.1	—	—	1,556.1	171.5	1,727.6
Other comprehensive income (loss), net of tax	—	—	—	—	—	192.3	—	—	—	192.3	0.6	192.9
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(100.0)	(100.0)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	5.6	5.6
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(6.0)	(1,800.0)	(1,800.0)	—	(1,800.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(6.0)	—	(231.9)	—	(1,568.1)	6.0	1,800.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	54.4	—	—	—	—	54.4	—	54.4
Issuance of common stock under stock award plan	—	—	0.4	—	(2.4)	—	(52.6)	—	—	(55.0)	—	(55.0)
Compensation expense related to share-based payments	—	—	—	—	246.6	—	—	—	—	246.6	—	246.6
Other	—	—	—	—	1.5	—	—	—	—	1.5	—	1.5
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

See accompanying notes to these consolidated financial statements.

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY - (Continued)
(In millions)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2019	—	$ —	198.0	$ 0.1	$ —	$ (135.2)	$16,455.4	(23.8)	$(2,977.1)	$ 13,343.2	$ (4.1)	$13,339.1
Net income	—	—	—	—	—	—	4,000.6	—	—	4,000.6	59.9	4,060.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	(163.8)	—	—	—	(163.8)	1.0	(162.8)
Distribution to noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(75.0)	(75.0)
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	4.0	4.0
Repurchase of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(1.6)	(400.0)	(400.0)	—	(400.0)
Retirement of common stock pursuant to the 2020 Share Repurchase Program, at cost	—	—	(1.6)	—	(60.8)	—	(339.2)	1.6	400.0	—	—	—
Repurchase of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(16.7)	(5,000.0)	(5,000.0)	—	(5,000.0)
Retirement of common stock pursuant to the December 2019 Share Repurchase Program, at cost	—	—	(16.7)	—	(121.3)	—	(4,878.7)	16.7	5,000.0	—	—	—
Repurchase of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(4.1)	(1,279.1)	(1,279.1)	—	(1,279.1)
Retirement of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	(4.1)	—	(71.0)	—	(1,208.1)	4.1	1,279.1	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	49.3	—	—	—	—	49.3	—	49.3
Issuance of common stock under stock award plan	—	—	0.4	—	—	—	(53.7)	—	—	(53.7)	—	(53.7)
Compensation expense related to share-based payments	—	—	—	—	204.5	—	—	—	—	204.5	—	204.5
Other	—	—	—	—	(0.7)	—	—	—	—	(0.7)	—	(0.7)
Balance, December 31, 2020	—	$ —	176.2	$ 0.1	$ —	$ (299.0)	$13,976.3	(23.8)	$(2,977.1)	$ 10,700.3	$ (14.2)	$10,686.1

See accompanying notes to these consolidated financial statements.

Note 1: Summary of Significant Accounting Policies

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

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering innovative therapies for people living with serious and complex diseases worldwide. We have a broad portfolio of medicines to treat multiple sclerosis (MS), have introduced the first approved treatment for spinal muscular atrophy (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 Co., Ltd. (Eisai) on the commercialization of LEQEMBI for the treatment of Alzheimer's disease, which was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in January 2023. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions; RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL; GAZYVA for the treatment of CLL and follicular lymphoma; OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS); 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, Inc. (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 major depressive disorder (MDD) and postpartum depression (PPD), BIIB080 for Alzheimer's disease, tofersen for amyotrophic lateral sclerosis (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 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Consolidation

Our consolidated financial statements reflect our financial statements, those of our wholly-owned subsidiaries and 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 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 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 in Ukraine within our consolidated financial statements and there may be changes to those estimates in future periods.

Revenue Recognition

We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenue following the five-step model prescribed under Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations.

Product Revenue

In the U.S., we sell our products primarily to wholesale and specialty distributors and specialty pharmacies. In other countries, we sell our products primarily to wholesale distributors, hospitals, pharmacies and other third-party distribution partners. These customers subsequently resell our products to health care providers and patients. In addition, we enter into arrangements with health care providers and payors that provide for government-mandated or privately-negotiated discounts and allowances related to our products.

Product revenue is recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

Reserves for Discounts and Allowances

Product revenue is recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate.

Product revenue reserves, which are classified as a reduction in product revenue, are generally characterized in the following categories: discounts, contractual adjustments and returns.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration are calculated based upon a consistent application of our methodology utilizing the expected value method. These estimates reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts may ultimately differ from our

estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Discounts include trade term discounts and wholesaler incentives. Trade term discounts and wholesaler incentives primarily relate to estimated obligations for credits to be granted to wholesalers for remitting payment on their purchases within established incentive periods and credits to be granted to wholesalers for compliance with various contractually-defined inventory management practices, respectively. We determine these reserves based on our historical experience, including the timing of customer payments.

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

- *Medicaid rebates:* relate to our estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expense and other current liabilities in our consolidated balance sheets. Our liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end.
- *Governmental rebates:* or chargebacks, including VA and PHS discounts, represent our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices we charge to wholesalers which provide those products. The wholesaler charges us for the difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Rebate and chargeback reserves are established in the same period as the related revenue is recognized, resulting in a reduction of product revenue and a reduction in the net accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and we generally issue credits for such amounts within a few weeks of the wholesaler notifying us about the resale. Our reserves for VA, PHS and other chargebacks consist of amounts for inventory that exists at the wholesalers that we expect will be sold to qualified healthcare providers and chargebacks that wholesalers have claimed for which we have not issued a credit.
- *Managed care rebates:* represent our estimated obligations to third-parties, primarily pharmacy benefit managers. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expense and other current liabilities in our consolidated balance sheets. These rebates result from performance-based goals, formulary position and price increase limit allowances (price protection). The calculation of the accrual for these rebates is based on an estimate of the coverage patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period.
- *Copay assistance:* represents financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The calculation of the accrual for copay is based on an estimate of claims and the cost per claim that we expect to receive associated with inventory that exists in the distribution channel at period end.
- *Pharmacy rebates:* represent our estimated obligations resulting from contractual commitments to sell products to specific pharmacies. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expense and other current liabilities in our consolidated balance sheets. These rebates result from contracted discounts on product purchased or product dispensed. The calculation of the accrual for these rebates is based on an estimate of the pharmacy's buying or dispensing patterns and the resulting applicable contractual rebate rate(s) to be earned over the contractual period.
- *Other governmental rebates:* non-U.S. pharmaceutical taxes or applicable allowances primarily relate to mandatory rebates and discounts in international markets where government-sponsored healthcare systems are the primary payors for healthcare.

Product return reserves are established for returns made by wholesalers and are recorded in the period the related revenue is recognized, resulting in a reduction to product revenue. 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. Expired product return reserves are estimated through a comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product.

In addition to discounts, rebates and product returns, we also maintain certain customer service contracts with distributors and other customers in the distribution channel that provide us with inventory management, data and distribution services, which are generally reflected as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expense in our consolidated statements of income.

Revenue from Anti-CD20 Therapeutic Programs

Our collaboration with Genentech is within the scope of ASC 808, *Collaborative Agreements*, which provides guidance on the presentation and disclosure of collaborative arrangements. For purposes of this footnote, we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

Our share of the pre-tax co-promotion profits on RITUXAN and GAZYVA and royalty revenue on the sale of OCREVUS resulted from an exchange of a license. As we do not have future performance obligations under the license or collaboration agreement, revenue is recognized as the underlying sales occur.

Revenue from anti-CD20 therapeutic programs consist of:

(i) our share of pre-tax profits and losses in the U.S. for RITUXAN and GAZYVA;

(ii) royalty revenue on sales of OCREVUS; and

(ii) other revenue from anti-CD20 therapeutic programs, which consists of our share of pre-tax co-promotion profits on RITUXAN in Canada.

Pre-tax co-promotion profits on RITUXAN and GAZYVA are calculated and paid to us by Genentech and the Roche Group. Pre-tax co-promotion profits consist of net sales to third-party customers less applicable costs to manufacture, third-party royalty expense, distribution, selling and marketing expense and joint development expense incurred by Genentech and the Roche Group. Our share of the pre-tax profits on RITUXAN and GAZYVA include estimates that are based on information received from Genentech and the Roche Group. These estimates are subject to change and actual results may differ.

We recognize royalty revenue on sales of OCREVUS 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.

In January 2022 we exercised our option with Genentech to participate in the joint development and commercialization of LUNSUMIO, which was later approved by the FDA in December 2022. Under our collaboration with Genentech, we will be entitled to co-promotion operating profits and losses in the U.S. for LUNSUMIO.

Prior to regulatory approval, we record our share of the expense incurred by the collaboration for the development of anti-CD20 products within research and development expense and pre-commercialization costs within selling, general and administrative expense in our 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.

Accordingly, Biogen recorded its share of the expense incurred in connection with the development of LUNSUMIO within research and development expense and its share of pre-commercialization costs within selling, general and administrative expense through December 2022, when regulatory approval was granted by the FDA. Beginning in January 2023, our share of any pre-tax profits and losses in the U.S. for LUNSUMIO will be reflected as a component of revenue from anti-CD20 therapeutic programs within our consolidated statements of income.

For additional information on our relationship with Genentech, please read *Note 19, Collaborative and Other Relationships,* to these consolidated financial statements.

Other Revenue

Contract Manufacturing and Other Revenue

We record contract manufacturing and other revenue primarily from amounts earned under contract manufacturing agreements. Revenue under contract manufacturing agreements is recognized when the customer obtains control of the product, which may occur at a point in time or over time depending on the terms and conditions of the agreement.

Royalty Revenue

Royalty revenue 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 collaboration arrangements with Samsung Bioepis Co., Ltd. (Samsung Bioepis). These arrangements resulted from an exchange of a license and utilize the sales and usage based royalty exception. Therefore, royalties received are recognized as the underlying sales occur.

Collaborative and Other Relationships

We also have a number of significant collaborative and other third-party relationships for revenue and for the development, regulatory approval, commercialization and marketing of certain of our products and product candidates. Where we are the principal on sales transactions with third parties, we recognize revenue, cost of sales and operating expense on a gross basis in their respective lines in our consolidated statements of income. Where we are not the principal on sales transactions with third parties, our share of the revenue, cost of sales and operating expense is recorded as a component of other revenue in our consolidated statements of income.

Our development and commercialization arrangements with Genentech, Eisai and Samsung Bioepis represent collaborative arrangements as each party is an active participant in one or more joint operating activities and is exposed to significant risks and rewards of these arrangements. These arrangements resulted from an exchange of a license and utilize the sales and usage based royalty exception, as applicable. Therefore, revenue relating to royalties or profit-sharing amounts received is recognized as the underlying sales occur.

For additional information on our collaboration arrangements with Genentech, Eisai and Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Fair Value Measurements

We have certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- *Level 1* — Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access;
- *Level 2* — Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves, foreign currency spot rates and option pricing valuation models; and
- *Level 3* — Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The majority of our financial assets have been classified as Level 2. Our financial assets (which typically include our cash equivalents, marketable debt securities and certain of our marketable equity securities, derivative contracts and plan assets for deferred compensation) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or option pricing valuation models. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events.

We validate the prices provided by our third-party pricing services by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances. The option pricing valuation models use assumptions within the model, including the term, stock price volatility, constant maturity risk-free interest rate and dividend yield. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2022 and 2021.

Other Assets and Liabilities

The carrying amounts reflected in our consolidated balance sheets for current accounts receivable, due from anti-CD20 therapeutic programs, other current assets, accounts payable and accrued expense and other, approximate fair value due to their short-term maturities.

Cash and Cash Equivalents

We consider only those investments that are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. As of December 31, 2022 and 2021, cash equivalents were comprised of money market funds, commercial paper, overnight reverse repurchase agreements and other debt securities with maturities less than three months from the date of purchase.

Accounts Receivable

The majority of our accounts receivable arise from product sales and primarily represent amounts due from our wholesale and other third-party distributors, public hospitals, pharmacies and other government entities and have standard payment terms that generally require payment within 30 to 90 days.

We do not adjust our receivables for the effects of a significant financing component at contract inception if we expect to collect the receivables in one year or less from the time of sale.

We provide reserves against accounts receivable for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve.

Receivables from Samsung BioLogics

In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics Co., Ltd (Samsung BioLogics), which resulted in a receivable of approximately $1.3 billion in cash to be deferred over two payments of approximately $812.5 million due at the first anniversary and approximately $437.5 million due at the second anniversary of the closing of this transaction. The payments due to us from Samsung BioLogics have been recorded at their estimated fair values through the use of risk-adjusted discount rates. For additional information on the accounting for the sale of our equity interest in Samsung Bioepis and these receivables, please read *Note 3, Dispositions*, to these consolidated financial statements.

Concentration of 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 as previously defined by us. 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.

Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the wide variety of customers and markets using our products, as well as their dispersion across many different geographic areas. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions and assess their possible impact on our business.

Marketable Securities and Other Investments

Marketable Debt Securities

Available-for-sale marketable debt securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive income (loss) in equity, net of related tax effects, unless the security has experienced a credit loss, we have determined that we have the intent to sell the security or we have determined that it is more likely than not that we will have to sell the security before its expected recovery. Realized gains and losses are reported in other (income) expense, net on a specific identification basis.

Marketable Equity Securities and Venture Capital Funds

Our marketable equity securities are recorded at fair market value and unrealized gains and losses are included in other (income) expense, net in our consolidated statements of income. Our marketable equity securities represent investments in publicly traded equity securities and are included in investments and other assets in our consolidated balance sheets.

Our investments in venture capital funds are recorded at net asset value, which approximates fair value, and unrealized gains and losses are included in other (income) expense, net in our consolidated statements of income. The underlying investments of the venture capital funds in which we invest are in equity securities of certain biotechnology companies and are included in investments and other assets in our consolidated balance sheets.

Non-Marketable Equity Securities

We also invest in equity securities of companies whose securities are not publicly traded and where fair value is not readily available. These investments are recorded using either the equity method of accounting or the cost minus impairment adjusted for observable price changes, depending on our ownership percentage and other factors that suggest we have significant influence. We monitor these investments to evaluate whether any increase or decline in their value has occurred, based on the implied value of recent company financings, public market prices of comparable companies and general market conditions. These investments are included in investments and other assets in our consolidated balance sheets.

Evaluating Marketable Debt Securities for Other-than-Temporary Impairments

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

Equity Method of Accounting

In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, we utilize the equity method of accounting for recording investment activity. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, the voting and protective rights we hold, any participation in the governance of the other company and other relevant factors such as the presence of a collaborative or other business relationship. Under the equity method of accounting, we record in our consolidated statements of income our share of income or loss of the other company. If our share of losses exceeds the carrying value of our investment, we will suspend recognizing additional losses and will continue to do so unless we commit to providing additional funding.

Inventory

Inventories are stated at the lower of cost or net realizable value with cost based on the first-in, first-out method. We classify our inventory costs as long-term when we expect to utilize the inventory beyond our normal operating cycle and include these costs in investments and other assets in our consolidated balance sheets. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in a clinical manufacturing campaign.

Capitalization of Inventory Costs

We capitalize inventory costs associated with our products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is

expected to be realized. We consider numerous attributes in evaluating whether the costs to manufacture a particular product should be capitalized as an asset. We assess the regulatory approval process and where the particular product stands in relation to that approval process, including any known safety or efficacy concerns, potential labeling restrictions and other impediments to approval. We evaluate our anticipated research and development initiatives and constraints relating to the product and the indication in which it will be used. We consider our manufacturing environment including our supply chain in determining logistical constraints that could hamper approval or commercialization. We consider the shelf life of the product in relation to the expected timeline for approval and we consider patent related or contract issues that may prevent or delay commercialization. We also base our judgment on the viability of commercialization, trends in the marketplace and market acceptance criteria. Finally, we consider the reimbursement strategies that may prevail with respect to the product and assess the economic benefit that we are likely to realize. We expense previously capitalized costs related to pre-approval inventory upon changes in such judgments, due to, among other potential factors, a denial or significant delay of approval by necessary regulatory bodies.

Obsolescence and Unmarketable Inventory

At each reporting period we review our inventories for excess or obsolescence and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated by us, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Additionally, our products are subject to strict quality control and monitoring that we perform throughout the manufacturing process. In the event that certain batches or units of product no longer meet quality specifications, we will record a charge to cost of sales to write-down any unmarketable inventory to its estimated net realizable value. In all cases, product inventory is carried at the lower of cost or its estimated net realizable value. Amounts written-down due to unmarketable inventory are charged to cost of sales in our consolidated statements of income.

Property, Plant and Equipment

Property, plant and equipment are carried at cost, subject to reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The cost of normal, recurring or periodic repairs and maintenance activities related to property, plant and equipment are expensed as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if the repair will result in future economic benefits.

Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset. We also capitalize certain direct and incremental costs associated with the validation effort required for licensing by regulatory agencies of new manufacturing equipment for the production of a commercially approved drug. These costs primarily include direct labor and material and are incurred in preparing the equipment for its intended use. The validation costs are either amortized over the life of the related equipment or expensed as cost of sales when the product produced in the validation process is sold.

In addition, we capitalize certain internal use computer software development costs. If the software is an integral part of production assets, these costs are included in machinery and equipment and are amortized on a straight-line basis over the estimated useful lives of the related software, which generally range from three to five years.

We generally depreciate or amortize the cost of our property, plant and equipment using the straight-line method over the estimated useful lives of the respective assets, which are summarized as follows:

Asset Category	Useful Lives
Land	Not depreciated
Buildings	15 to 40 years
Leasehold Improvements	Lesser of the useful life or the term of the respective lease
Furniture and Fixtures	5 to 7 years
Machinery and Equipment	5 to 20 years
Computer Software and Hardware	3 to 5 years

When we dispose of property, plant and equipment, we remove the associated cost and accumulated depreciation from the related accounts in our consolidated balance sheets and include any resulting gain or loss in our consolidated statements of income.

Leases

We determine if an arrangement is a lease at contract inception. Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that they will be exercised.

We use the implicit rate when readily determinable and use our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. Our incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

The lease payments used to determine our operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in our operating lease assets in our consolidated balance sheets. Our lease agreements may include both lease and non-lease components, which we account for as a single lease component when the payments are fixed. Variable payments included in the lease agreement are expensed as incurred. For certain equipment leases, such as vehicles, we apply a portfolio approach to effectively account for the operating lease assets and liabilities.

Our operating leases are reflected in operating lease assets, accrued expense and other and in long-term operating lease liabilities in our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We also have real estate lease agreements which are subleased to third-parties. Operating leases for which we are the sublessor are included in accrued expense and other and other long-term liabilities in our consolidated balance sheets. We recognize sublease income on a straight-line basis over the lease term in our consolidated statements of income.

For additional information on our leases, please read *Note 12, Leases*, to these consolidated financial statements.

Intangible Assets

Our intangible assets consist of completed technology (comprised of acquired and in-licensed rights and patents, developed technology, out-licensed patents), in-process research and development (IPR&D) acquired after January 1, 2009, trademarks and trade names. Our intangible assets are recorded at fair value at the time of their acquisition and are stated in our consolidated balance sheets net of accumulated amortization and impairments, if applicable.

Intangible assets related to acquired and in-licensed rights and patents, developed technology and out-licensed patents are amortized over their estimated useful lives using the economic consumption method if anticipated future revenue can be reasonably estimated. The straight-line method is used when revenue cannot be reasonably estimated. Amortization is recorded within amortization and impairment of acquired intangible assets in our consolidated statements of income.

We amortize the intangible assets related to our marketed products using the economic consumption method based on revenue generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenue of our marketed products is performed annually during our long-range planning cycle and whenever events or changes in circumstances would significantly affect anticipated lifetime revenue of the relevant products.

Intangible assets related to trademarks, trade names and IPR&D prior to commercialization are not amortized because they have indefinite lives; however, they are subject to review for impairment. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Acquired In-process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects and discounting the net cash flow to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing a new drug. Additionally, the projections consider the relevant market sizes and growth factors, expected trends in technology and the nature and expected timing of new product introductions by us and our competitors. The rates utilized to discount the net cash flow to present value are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections. Upon the acquisition of IPR&D, we complete an assessment of whether our acquisition constitutes the purchase of a single asset or a group of assets. We consider multiple factors in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flow, the development process and stage of completion, quantitative significance and our rationale for entering into the transaction.

If we acquire a business as defined under applicable accounting standards, then the acquired IPR&D is capitalized as an intangible asset. If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense in our consolidated statements of income as they are incurred.

When performing our impairment assessment, we calculate the fair value using the same methodology as described above. If the carrying value of our acquired IPR&D exceeds its fair value, then the intangible asset is written down to its fair value. Changes in estimates and assumptions used in determining the fair value of our acquired IPR&D could result in an impairment. Impairments are recorded within amortization and impairment of acquired intangible assets in our consolidated statements of income.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but is reviewed for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the goodwill may not be recoverable.

We compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of our reporting unit, we would record an impairment loss equal to the difference. As described in *Note 25, Segment Information,* to these consolidated financial statements, we operate as one operating segment, which is our only reporting unit.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment, and definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flow resulting from the use of the asset and its eventual disposition. In the event that such cash flow is not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

Contingent Consideration

The consideration for our acquisitions often includes future payments that are contingent upon the occurrence of a particular event or events. We record an obligation for such contingent payments at fair value on the acquisition date. We estimate the fair value of contingent consideration obligations through valuation models that incorporate probability-adjusted assumptions related to the achievement of the milestones and thus likelihood of making related payments. We revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations are recognized in our consolidated statements of income. Changes in the fair value of the contingent consideration obligations can result from changes to one or multiple inputs, including adjustments to the discount rates, changes in the amount or timing of expected expenditures associated with product development, changes in the amount or timing of cash flow and reserves associated with products upon

commercialization, changes in the assumed achievement or timing of any cumulative sales-based and development milestones, changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval.

Discount rates in our valuation models represent a measure of the credit risk associated with settling the liability. The period over which we discount our contingent obligations is based on the current development stage of the product candidates, our specific development plan for that product candidate adjusted for the probability of completing the development step and when the contingent payments would be triggered. In estimating the probability of success, we utilize data regarding similar milestone events from several sources, including industry studies and our own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period.

Derivative Instruments and Hedging Activities

Cash Flow and Fair Value Derivative Instruments

We recognize all derivative instruments as either assets or liabilities at fair value in our consolidated balance sheets. Changes in the fair value of our derivative instruments are recognized each period in current earnings or accumulated other comprehensive income (loss), depending on whether the derivative instrument is designated as part of a hedge transaction and, if so, the type of hedge transaction. We classify the cash flow from these instruments in the same category as the cash flow from the hedged items. We do not hold or issue derivative instruments for trading or speculative purposes.

We assess at inception and on an ongoing basis, whether the derivative instruments that are used in hedging transactions are highly effective in offsetting the changes in cash flow or fair values of the hedged items. We exclude the forward points portion of the derivative instruments used in a hedging transaction from the effectiveness test and record the fair value gain or loss related to this portion each period in our consolidated statements of income in the same line as the underlying hedged item. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

Net Investment Derivative Instruments

Designated net investment hedges are recognized as either assets or liabilities, at fair value, in our consolidated balance sheets. We hedge the changes in the spot exchange rate in accumulated other comprehensive income (loss) and exclude changes to the forward rate and amortize the forward points in other (income) expense, net in our consolidated statements of income over the term of the contract. We classify the cash flow from these instruments in the same category as the cash flow from the hedged items.

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 3, Dispositions*, to these consolidated financial statements.

For additional information on our derivative instruments and hedging activities, please read *Note 10, Derivative Instruments*, to these consolidated financial statements.

Translation of Foreign Currencies

The functional currency for most of our foreign subsidiaries is their local currency. For our non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income (loss), as a separate component of equity. For subsidiaries where the functional currency of the assets and liabilities differ from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other (income) expense, net in our consolidated statements of income.

Royalty Cost of Sales

We make royalty payments to a number of third-parties under license or purchase agreements associated with our acquisition of intellectual property. These royalty payments are typically calculated as a percentage (royalty rate) of the sales of our products in a particular year. That royalty rate may remain constant, increase or decrease within each year based on the total amount of sales during the annual period. Each quarterly period, we estimate our total royalty obligation for the full year and recognize the proportional amount as cost of sales based on actual quarterly sales as a percentage of full year estimated sales. For example, if the level of net sales in any calendar year increases the royalty rate within the year, we will record our cost of sales at an even rate over the year, based on the estimated blended royalty rate.

Accounting for Share-Based Compensation

Our share-based compensation programs grant awards that have included stock options, restricted stock units that vest based on stock performance known as market stock units (MSUs), performance-vested restricted stock units that settle in cash (CSPUs), time-vested restricted stock units (RSUs), performance-vested restricted stock units that can be settled in cash or shares of our common stock (PUs) at the sole discretion of the Compensation and Management Development Committee of our Board of Directors, performance-vested stock units that settle in stock or cash (PSUs) and shares issued under our employee stock purchase plan (ESPP). Compensation expense is recognized based on the estimated fair value of the awards at grant date. We recognize compensation expense for the number of awards expected to vest after taking into consideration an estimate of award forfeitures over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance, where a portion of the award vests upon retirement eligibility), we estimate and recognize expense based on the period from the grant date to the date the employee becomes retirement eligible.

The fair values of our stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the stock options are then expensed over the options' vesting periods.

The fair values of our MSUs are estimated using a lattice model with a Monte Carlo simulation. We apply an accelerated attribution method to recognize share-based compensation expense over the applicable service period for our MSUs. The probability of actual shares expected to be earned is considered in the grant date valuation, therefore the expense is not adjusted to reflect the actual units earned.

The fair values of our RSUs are based on the market value of our stock on the date of grant. Compensation expense for RSUs is recognized straight-line over the applicable service period.

We apply an accelerated attribution method to recognize share-based compensation expense when accounting for our CSPUs, PUs and PSUs that settle in cash, and the fair value of the liability is remeasured at the end of each reporting period through expected settlement. Compensation expense associated with CSPUs, PUs and PSUs that settle in cash are based upon the stock price and the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the targeted payout level associated with the performance criteria expected to be achieved. Cumulative adjustments are recorded each quarter to reflect changes in the stock price and estimated outcome of the performance-related conditions until the date results are determined and settled. If performance criteria are not met or not expected to be met, any compensation expense previously recognized to date associated with the awards will be reversed.

The fair values of PSUs that settle in stock are based upon the stock price on the date of grant. Compensation expense is recognized for the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the targeted payout level associated with the performance criteria expected to be achieved. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. If performance criteria are not met or not expected to be met, any compensation expense previously recognized to date associated with the awards will be reversed.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities, which include compensation and benefits, facilities and overhead expense, clinical trial expense and fees paid to contract research organizations (CROs), clinical supply and manufacturing expense, write-offs of inventory that was previously capitalized in anticipation of product launch and determined to no longer be realizable and other outside expense and upfront fees and milestones paid to third-party collaborators. Research and development

expense is expensed as incurred. Upfront and milestone payments made to third-party collaborators are expensed as incurred up to the point of regulatory approval. Milestone payments made upon regulatory approval are capitalized and amortized over the remaining useful life of the related product. Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets in our consolidated balance sheets and are expensed as the services are provided. We also accrue the costs of ongoing clinical trials associated with programs that have been terminated or discontinued for which there is no future economic benefit at the time the decision is made to terminate or discontinue the program.

From time to time, we enter into development agreements in which we share expenses with a collaborative partner. We record payments received from our collaborative partners for their share of the development costs as a reduction of research and development expense, except as discussed in *Note 19, Collaborative and Other Relationships,* to these consolidated financial statements. Expenses incurred by Genentech in the ongoing development of RITUXAN, GAZYVA and other products for which an initial indication has been approved are not recorded as research and development expense, but rather reduce our share of profits recorded as a component of revenue from anti-CD20 therapeutic programs.

For collaborations with commercialized products, if we are the principal, we record revenue and the corresponding operating costs in their respective line items in our consolidated statements of income. If we are not the principal, we record operating costs as a reduction of revenue.

Selling, General and Administrative Expense

Selling, general and administrative expense is primarily comprised of compensation and benefits associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expense and other general and administrative costs.

Advertising costs are expensed as incurred. For the years ended December 31, 2022, 2021 and 2020, advertising costs totaled $54.1 million, $98.7 million and $111.8 million, respectively.

Income Taxes

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. We evaluate the realizability of our deferred tax assets and establish a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized. We recognize deferred taxes associated with our global intangible low-taxed income (GILTI) tax calculations.

The income tax consequences from the intra-entity transfers of inventory within our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through our consolidated statements of income when the inventory is sold to a third-party. The income tax consequences from the intra-entity transfer of assets other than inventory and associated changes to deferred taxes are recognized when the transfer occurs.

We account for uncertain tax positions using a “more likely than not” threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax (benefit) expense in our consolidated statements of income.

Contingencies

We are currently involved in various claims and legal proceedings. Loss contingency provisions are recorded if the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated or a range of loss can be determined. These accruals represent management’s best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. Significant judgment is

required in both the determination of probability and as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may change our estimates. Legal costs associated with legal proceedings are expensed when incurred.

Earnings per Share

Basic earnings per share is computed by dividing undistributed net income attributable to Biogen Inc. by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed based on the treasury method by dividing net income by the weighted-average number of common shares outstanding during the period plus potentially dilutive common equivalent shares outstanding.

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 or may have a material impact on our consolidated financial statements or disclosures.

Fair Value Measurements

In June 2022 the FASB issued Accounting Standards Update (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 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 Therapeutics, Inc. (Sage).

Income Taxes

In December 2019 the FASB issued ASU No. 2019-12, *Income Taxes* (Topic 740): *Simplifying the Accounting for Income Taxes*. This standard removes certain exceptions to the general principles in Topic 740 and simplifies certain other aspects of the accounting for income taxes. This standard became effective for us on January 1, 2021, and did not have a material impact on our consolidated financial statements and related disclosures.

Note 2: Acquisitions

BIIB118 Acquisition

In March 2020 we acquired BIIB118 (CK1 inhibitor) for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). In connection with this acquisition, we made an upfront payment of $75.0 million to Pfizer, which was accounted for as an asset acquisition and recorded as acquired IPR&D in our consolidated statements of income for the year ended December 31, 2020. In 2022 we discontinued further development of BIIB118 based on the decision by management as part of its strategic review process.

Note 3: Dispositions

Sale of Joint Venture Equity Interest in Samsung Bioepis

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

Prior to the sale, the carrying value of our investment in Samsung Bioepis totaled $581.6 million. For the year ended December 31, 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 consolidated statements of income. This pre-tax gain included reclassifications from accumulated other comprehensive income (loss) to net income of approximately $58.9 million in cumulative translation losses, partially offset by approximately $57.0 million in gains resulting from the termination of our net investment hedge.

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

We elected the fair value option and measured the payments due to us from Samsung BioLogics at fair value. As of December 31, 2022, the estimated fair values of the first and second payments using risk-adjusted discount rates of 5.7% and 5.9%, respectively, were approximately $798.8 million and $405.4 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 consolidated balance sheets.

For the year ended December 31, 2022, we recognized a gain of approximately $10.7 million and a loss of approximately $1.4 million to reflect the changes in fair value related to our first and second payments, respectively. These changes were recorded in other (income) expense, net in our 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.

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

Additionally, for the year ended December 31, 2022, we recorded a discrete tax expense of approximately $257.9 million related to this transaction, which is reflected in income tax (benefit) expense in our consolidated statements of income.

Note 4: Restructuring

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 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 $131.0 million, primarily related to severance. These amounts were substantially incurred during 2022. As of December 31, 2022, approximately $35.9 million remained in our restructuring reserve and payments are expected to be made through 2026.

For the year ended December 31, 2022, we recognized approximately $131.1 million of net pre-tax restructuring charges related to our 2022 cost saving initiatives, of which approximately $112.6 million consisted of employee severance costs. These costs were recorded in restructuring charges in our consolidated statements of income. Our restructuring reserve is included in accrued expense and other in our consolidated balance sheets.

In September 2022 we entered into an agreement to partially terminate a portion of our lease located at 300 Binney Street, Cambridge, MA (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 consolidated statements of income for the year ended December 31, 2022. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to these consolidated financial statements.

Following an evaluation of our current capacity needs, in March 2022 we ceased using a patient services office space in Durham, NC. 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 consolidated statements of income for the year ended December 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 year ended December 31, 2022, we recognized other restructuring costs of approximately $13.2 million, which were recorded in restructuring charges in our consolidated statements of income. Other restructuring costs include items such as facility closure costs, employee non-severance expense, asset write-offs and other costs.

The following table summarizes the charges and spending related to our 2022 workforce reductions for the year ended December 31, 2022:

(In millions)	Total
Restructuring reserve, December 31, 2021	$ —
Expense	112.6
Payment	(78.0)
Foreign currency and other adjustments	1.3
Restructuring reserve, December 31, 2022	$ 35.9

Note 5: Revenue

Product Revenue

Revenue by product are summarized as follows:

	For the Years Ended December 31,								
	2022			2021			2020		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	$ 417.7	$1,026.2	$ 1,443.9	$ 680.6	$1,271.3	$ 1,951.9	$2,677.7	$1,163.4	$ 3,841.1
VUMERITY[1]	521.3	32.1	553.4	408.9	1.5	410.4	64.3	—	64.3
Total Fumarate	939.0	1,058.3	1,997.3	1,089.5	1,272.8	2,362.3	2,742.0	1,163.4	3,905.4
AVONEX	649.2	324.3	973.5	830.2	378.5	1,208.7	1,083.4	408.5	1,491.9
PLEGRIDY	148.4	183.5	331.9	152.9	204.5	357.4	190.1	195.5	385.6
Total Interferon	797.6	507.8	1,305.4	983.1	583.0	1,566.1	1,273.5	604.0	1,877.5
TYSABRI	1,123.4	907.5	2,030.9	1,142.2	920.9	2,063.1	1,096.8	849.3	1,946.1
FAMPYRA	—	96.6	96.6	—	105.2	105.2	—	103.1	103.1
Subtotal: MS	2,860.0	2,570.2	5,430.2	3,214.8	2,881.9	6,096.7	5,112.3	2,719.8	7,832.1
Spinal Muscular Atrophy:									
SPINRAZA	600.2	1,193.3	1,793.5	587.9	1,317.2	1,905.1	787.8	1,264.3	2,052.1
Biosimilars:									
BENEPALI	—	441.0	441.0	—	498.3	498.3	—	481.6	481.6
IMRALDI	—	224.5	224.5	—	233.4	233.4	—	216.3	216.3
FLIXABI	—	81.3	81.3	—	99.4	99.4	—	97.9	97.9
BYOOVIZ[2]	4.3	—	4.3	—	—	—	—	—	—
Subtotal: Biosimilars	4.3	746.8	751.1	—	831.1	831.1	—	795.8	795.8
Other:									
FUMADERM	—	8.2	8.2	—	11.0	11.0	—	12.2	12.2
ADUHELM	4.8	—	4.8	3.0	—	3.0	—	—	—
Total product revenue	$3,469.3	$4,518.5	$ 7,987.8	$3,805.7	$5,041.2	$ 8,846.9	$5,900.1	$4,792.1	$10,692.2

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

We recognized revenue from two wholesalers accounting for 26.8% and 11.1% of gross product revenue in 2022, 28.8% and 10.1% of gross product revenue in 2021 and 30.5% and 15.3% of gross product revenue in 2020, respectively.

As of December 31, 2022, two wholesale distributors individually accounted for approximately 22.7% and 10.9% of net accounts receivable associated with our product sales, as compared to 21.9% and 10.2% as of December 31, 2021, respectively.

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

	December 31, 2022			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 137.7	$ 759.6	$ 38.0	$ 935.3
Current provisions relating to sales in current year	666.6	2,715.5	12.3	3,394.4
Adjustments relating to prior years	(2.8)	1.4	(7.2)	(8.6)
Payments/credits relating to sales in current year	(514.9)	(2,060.7)	(1.2)	(2,576.8)
Payments/credits relating to sales in prior years	(132.8)	(558.1)	(18.4)	(709.3)
Ending balance	$ 153.8	$ 857.7	$ 23.5	$ 1,035.0

	December 31, 2021			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 141.4	$ 1,093.0	$ 41.6	$ 1,276.0
Current provisions relating to sales in current year	736.7	2,948.7	15.2	3,700.6
Adjustments relating to prior years	(4.0)	(96.1)	(3.3)	(103.4)
Payments/credits relating to sales in current year	(599.3)	(2,283.1)	(0.4)	(2,882.8)
Payments/credits relating to sales in prior years	(137.1)	(902.9)	(15.1)	(1,055.1)
Ending balance	$ 137.7	$ 759.6	$ 38.0	$ 935.3

	December 31, 2020			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 131.1	$ 1,027.3	$ 40.5	$ 1,198.9
Current provisions relating to sales in current year	774.7	3,308.8	19.0	4,102.5
Adjustments relating to prior years	(1.0)	(54.0)	1.3	(53.7)
Payments/credits relating to sales in current year	(635.1)	(2,426.1)	—	(3,061.2)
Payments/credits relating to sales in prior years	(128.3)	(763.0)	(19.2)	(910.5)
Ending balance	$ 141.4	$ 1,093.0	$ 41.6	$ 1,276.0

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

	As of December 31,	
(In millions)	2022	2021
Reduction of accounts receivable	$ 143.4	$ 133.2
Component of accrued expense and other	891.6	802.1
Total revenue-related reserves	$ 1,035.0	$ 935.3

Revenue from Anti-CD20 Therapeutic Programs

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Royalty revenue on sales of OCREVUS	$ 1,136.3	$ 991.7	$ 845.4
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	547.0	647.7	1,080.2
Other revenue from anti-CD20 therapeutic programs	17.2	19.1	52.2
Total revenue from anti-CD20 therapeutic programs	$ 1,700.5	$ 1,658.5	$ 1,977.8

Approximately 16.7%, 15.1% and 14.7% of our total revenue in 2022, 2021 and 2020, respectively, was derived from our collaboration arrangements with Genentech. For additional information on our collaboration

arrangements with Genentech, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Other Revenue

Other revenue consists of royalty revenue and contract manufacturing and other revenue and is summarized as follows:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Contract manufacturing and other revenue	$ 417.7	$ 427.7	$ 719.1
Royalty revenue	67.4	48.6	55.5
Total other revenue	$ 485.1	$ 476.3	$ 774.6

Contract Manufacturing and Other Revenue

Contract manufacturing and other revenue primarily reflects amounts earned under contract manufacturing agreements with our strategic customers.

During the third quarter of 2019, we amended our agreement with a contract manufacturing customer pursuant to which we licensed certain of our manufacturing-related intellectual property to the customer. In the second quarter of 2020, the customer received regulatory approval for its product that is being manufactured using certain of our manufacturing-related intellectual property. As a result we were entitled to $500.0 million in a series of three payments. The first payment became due upon a regulatory approval of such product and was received during the second quarter of 2020. The second payment became due upon the first anniversary of the regulatory approval and was received during the second quarter of 2021. The third payment became due upon the second anniversary of the regulatory approval and was received during the second quarter of 2022.

Contract manufacturing and other revenue for the year ended December 31, 2020, reflects $346.2 million related to the delivery of the license for certain of our manufacturing-related intellectual property under the amended agreement, as discussed above, and the performance of manufacturing product supply services for such customer. We allocated the remaining $153.8 million of the $500.0 million transaction price to the performance of manufacturing product supply services for the customer, which we expect to perform through 2026. The value allocated to the manufacturing services was based on expected demand for supply and the fair value of comparable manufacturing and development services.

Royalty Revenue

Royalty revenue 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 collaboration arrangements with Samsung Bioepis.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Note 6: Inventory

The components of inventory are summarized as follows:

(In millions)	As of December 31, 2022	2021
Raw materials	$ 413.2	$ 349.6
Work in process[1]	751.9	814.0
Finished goods	200.4	187.9
Total inventory	$ 1,365.5	$ 1,351.5
Balance Sheet Classification:		
Inventory	$ 1,344.4	$ 1,351.5
Investments and other assets	21.1	—
Total inventory	$ 1,365.5	$ 1,351.5

[1] Work in process inventory as of December 31, 2022, includes approximately $89.8 million related to LEQEMBI.

Long-term inventory is included in investments and other assets in our consolidated balance sheets.

Inventory amounts written down as a result of excess, obsolescence or unmarketability are charged to cost of sales, and totaled $336.2 million, $167.6 million and $26.6 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Inventory Write-Offs

In April 2022 the Centers for Medicare and Medicaid Services (CMS) released the final National Coverage Decision (NCD) for the class of anti-amyloid treatments in Alzheimer's disease, including ADUHELM. The final NCD confirmed coverage with evidence development, in which patients with Medicare can only access treatment if they are part of an approved clinical trial. We expect that this decision will reduce future demand for ADUHELM to a minimal level. During the first quarter of 2022 we wrote-off approximately $275.0 million of inventory related to ADUHELM, as a result of this CMS decision, which was recognized in cost of sales within our consolidated statements of income for the year ended December 31, 2022. We have recognized approximately $136.0 million related to Eisai's 45.0% share of these charges in collaboration profit (loss) sharing within our consolidated statements of income for the year ended December 31, 2022.

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

As of December 31, 2022, the carrying value of our ADUHELM inventory was immaterial. As of December 31, 2021, we had approximately $223.0 million of ADUHELM inventory. For additional information please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Note 7: Intangible Assets and Goodwill

Intangible Assets

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

		As of December 31, 2022			As of December 31, 2021		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,415.3	$ (5,629.2)	$ 1,786.1	$ 7,413.1	$ (5,388.5)	$ 2,024.6
In-process research and development	Indefinite until commercialization	—	—	—	132.7	—	132.7
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 7,479.3	$ (5,629.2)	$ 1,850.1	$ 7,609.8	$ (5,388.5)	$ 2,221.3

Amortization and Impairments

Amortization and impairment of acquired intangible assets totaled $365.9 million, $881.3 million and $464.8 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Amortization of acquired intangible assets, excluding impairment charges, totaled $246.3 million, $252.0 million and $255.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. The decrease in amortization of acquired intangible assets, excluding impairment charges, over the three years was primarily due to a lower rate of amortization for acquired intangible assets.

For the year ended December 31, 2022, amortization and impairment of acquired intangible assets reflects the impact of a $119.6 million impairment charge related to vixotrigine (BIIB074) for the potential treatment of diabetic painful neuropathy (DPN).

For the year ended December 31, 2021, amortization and impairment of acquired intangible assets reflects the impact of a $365.0 million impairment charge related to BIIB111 (timrepigene emparvovec), a $220.0 million impairment charge related to BIIB112 (cotoretigene toliparvovec) and a $44.3 million impairment charge related to vixotrigine for the potential treatment of trigeminal neuralgia (TGN).

For the year ended December 31, 2020, amortization and impairment of acquired intangible assets reflects the impact of a $115.0 million impairment charge related to BIIB111, a $75.4 million impairment charge related to BIIB054 (cinpanemab) and a $19.3 million impairment charge related to one of our other IPR&D intangible assets.

Completed Technology

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

IPR&D Related to Business Combinations

IPR&D represents the fair value assigned to research and development assets that we acquired as part of a business combination and had not yet reached technological feasibility at the date of acquisition. Included in IPR&D balances are adjustments related to foreign currency exchange rate fluctuations. We review amounts capitalized as acquired IPR&D for impairment annually, as of October 31, and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable. The carrying value associated with our IPR&D assets as of December 31, 2021, relates to the IPR&D programs we acquired in connection with our acquisition of Convergence Pharmaceuticals Holdings Ltd. (Convergence). As of December 31, 2022, as a result of our decision to discontinue development of vixotrigine, we recognized an impairment charge reducing the remaining book value to zero.

Vixotrigine

In connection with our acquisition of Convergence, we recognized $424.6 million of acquired IPR&D intangible assets for vixotrigine. In the periods following our acquisition of vixotrigine, there were numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN and for the potential treatment of DPN, another form of neuropathic pain. We engaged with the FDA regarding the design of the potential Phase 3 studies of vixotrigine for the potential treatment of TGN and DPN and performed an additional clinical trial of vixotrigine, which was completed during 2022.

The performance of this additional clinical trial delayed the initiation of the Phase 3 studies of vixotrigine for the potential treatment of TGN, and, as a result, we recognized an impairment charge of $44.3 million related to vixotrigine for the potential treatment of TGN during the first quarter of 2021.

During the fourth quarter of 2022 we discontinued further development of vixotrigine based on regulatory, development and commercialization challenges. For the year ended December 31, 2022, we recognized an impairment charge of approximately $119.6 million related to vixotrigine for the potential treatment of DPN, reducing the remaining book value of this IPR&D intangible asset to zero. We also adjusted the value of our contingent consideration obligations related to this asset resulting in a pre-tax gain of approximately $209.1 million, which was recognized in (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income.

BIIB111 and BIIB112

In connection with our acquisition of Nightstar Therapeutics plc, we recognized $480.0 million and $220.0 million of acquired IPR&D intangible assets for BIIB111 and BIIB112, respectively. During the fourth quarter of 2020 we recognized an impairment charge of $115.0 million related to BIIB111 as a result of third-party manufacturing delays that impacted the timing and increased the costs associated with advancing BIIB111 through Phase 3 development.

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112 did not meet their primary endpoints. In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the year ended December 31, 2021, we recognized an impairment charge of $365.0 million related to BIIB111 and an impairment charge of $220.0 million related to BIIB112, reducing the remaining book values of these IPR&D intangible assets to zero.

In addition, as a result of our decision to suspend further development of BIIB111 and BIIB112, we recorded charges of approximately $39.1 million during the third quarter of 2021 related to our manufacturing arrangements and other costs that we expect to incur as a result of suspending these programs. These charges were recognized in research and development expense in our consolidated statements of income for the year ended December 31, 2021.

BIIB054

In connection with our acquisition of Biogen International Neuroscience GmbH (BIN), we recognized a $110.9 million acquired IPR&D intangible asset. In February 2021 we announced that we discontinued development of BIIB054 as a potential treatment of Parkinson's disease as our Phase 2 SPARK study did not meet its primary or secondary endpoints. Although we made this determination in February 2021, it was based on conditions that existed as of December 31, 2020. As a result, we recognized an impairment charge of approximately $75.4 million during the fourth quarter of 2020 to reduce the fair value of the related IPR&D intangible asset to zero.

The IPR&D impairment charges were included in amortization and impairment of acquired intangible assets and the gain resulting from the remeasurement of our contingent consideration obligation was recorded in (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of income. The fair value of the intangible assets and contingent consideration obligations were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenue, costs and probabilities of success.

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 December 31, 2022
2023	$ 215.0
2024	195.0
2025	190.0
2026	175.0
2027	165.0

Goodwill

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

	As of December 31,	
(In millions)	2022	2021
Goodwill, beginning of year	$ 5,761.1	$ 5,762.1
Other	(12.1)	(1.0)
Goodwill, end of year	$ 5,749.0	$ 5,761.1

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

Note 8: Fair Value Measurements

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

	As of 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 3, Dispositions*, to these consolidated financial statements.

	As of December 31, 2021			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 1,632.2	$ —	$ 1,632.2	$ —
Marketable debt securities:				
Corporate debt securities	1,108.2	—	1,108.2	—
Government securities	1,192.7	—	1,192.7	—
Mortgage and other asset backed securities	132.2	—	132.2	—
Marketable equity securities	1,048.5	181.7	866.8	—
Derivative contracts	80.9	—	80.9	—
Plan assets for deferred compensation	33.4	—	33.4	—
Total	$ 5,228.1	$ 181.7	$ 5,046.4	$ —
Liabilities:				
Derivative contracts	$ 10.8	$ —	$ 10.8	$ —
Contingent consideration obligations	209.1	—	—	209.1
Total	$ 219.9	$ —	$ 10.8	$ 209.1

The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities was determined through third-party pricing services. In 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 Therapeutics, Inc. (Sangamo) and Denali Therapeutics Inc. (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. Prior to the expiration of these holding period restrictions the investments were classified as Level 2 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 these consolidated financial statements.

There have been no material impairments of our assets measured and carried at fair value as of December 31, 2022 and 2021. In addition, there have been no changes in valuation techniques as of December 31, 2022 and 2021.

For a description of our validation procedures related to prices provided by third-party pricing services and our option pricing valuation model, please read the *Fair Value Measurements section* within *Note 1, Summary of Significant Accounting Policies,* to these consolidated financial statements.

Level 3 Assets and Liabilities Held at Fair Value

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

	Quantitative Information about Level 3 Fair Value Measurements						
	Fair Value				Range	Weighted Average	
(In millions)	2022[1]	2021	Valuation Technique	Significant Unobservable Input(s)	2021	2022[1]	2021
Liabilities:							
Contingent consideration obligations	$ —	$ 209.1	Discounted cash flow	Discount rate	1.30%	— %	1.30 %
				Expected timing of achievement of development milestones	2023 to 2027	—	—

[1] During the year ended December 31, 2022, we discontinued the development of vixotrigine and as a result we adjusted the fair value of our contingent consideration obligations to zero.

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

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

Contingent Consideration Obligations

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

	As of December 31,	
(In millions)	2022	2021
Fair value, beginning of year	$ 209.1	$ 259.8
Changes in fair value	(209.1)	(50.7)
Fair value, end of year	$ —	$ 209.1

As of December 31, 2021, approximately $209.1 million of the fair value of our total contingent consideration obligations was reflected as a component of other long-term liabilities in our consolidated balance sheets. Changes in the fair values of our contingent consideration obligations are recorded in (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of income.

For the year ended December 31, 2022, the changes in fair value of our contingent consideration obligations were primarily due to the discontinuation of 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, and changes in the interest rates used to revalue our contingent consideration liabilities.

For the year ended December 31, 2021, the changes in fair value of our contingent consideration obligations were primarily due to reductions in the probability of technical and regulatory success and delays in the expected timing of the achievement of certain remaining developmental milestones related to our vixotrigine programs.

The fair values of the contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs. For additional information on the valuation techniques and inputs utilized in the valuation of our financial assets and liabilities, please read *Note 1, Summary of Significant Accounting Policies,* to these consolidated financial statements.

Convergence Pharmaceuticals Holdings Limited

In connection with our acquisition of Convergence in February 2015 we recorded a contingent consideration obligation of $274.5 million. As of December 31, 2021, the fair value of this contingent consideration obligation was $209.1 million. During the fourth quarter of 2022 we discontinued further development of vixotrigine based on regulatory, development and commercialization challenges. As a result, the fair value of the contingent consideration obligations related to Convergence has been adjusted to zero, resulting in a pre-tax gain of approximately $209.1 million for the year ended December 31, 2022. This pre-tax gain was recorded in (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income.

Biogen International Neuroscience GmbH

In connection with our acquisition of BIN in December 2010 we recorded a contingent consideration obligation of $81.2 million. We discontinued further development of BIIB054 for the potential treatment of Parkinson's disease based on the results of a Phase 2 study of BIIB054. Additionally, during the third and fourth quarters of 2020 we discontinued other programs related to our acquisition of BIN for which we had immaterial contingent consideration obligations. As a result, the fair value of the contingent consideration obligations related to our acquisition of BIN was adjusted to zero, resulting in a gain of $101.5 million for the year ended December 31, 2020. This pre-tax gain was recorded in (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income.

Nonrecurring Fair Value Measurements

For the year ended December 31, 2022, we recorded impairment charges of $119.6 million related to vixotrigine. As a result, the remaining book values associated with these programs were reduced to zero. For the year ended December 31, 2021, we recorded impairment charges of $365.0 million related to BIIB111 and $220.0 million related to BIIB112. As a result, the remaining book values associated with these programs were reduced to zero.

For additional information on our impairments for intangible assets, please read *Note 7, Intangible Assets and Goodwill*, to these consolidated financial statements.

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 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 values of our debt instruments, which are Level 2 liabilities, are summarized as follows:

	Fair Value As of December 31,	
(In millions)	2022	2021
3.625% Senior Notes due September 15, 2022[(1)]	$ —	$ 1,020.0
4.050% Senior Notes due September 15, 2025	1,699.9	1,895.2
2.250% Senior Notes due May 1, 2030	1,219.0	1,475.9
5.200% Senior Notes due September 15, 2045	1,033.2	1,463.0
3.150% Senior Notes due May 1, 2050	989.0	1,457.7
3.250% Senior Notes due February 15, 2051	469.1	692.9
Total	$ 5,410.2	$ 8,004.7

[(1)] In July 2022 we redeemed our 3.625% Senior Notes due September 15, 2022 in full. For additional information on the redemption, please read *Note 13, Indebtedness*, to these consolidated financial statements.

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 December 31, 2022, compared to 2021, are primarily related to increases in U.S. treasury yields used to value our Senior Notes since December 31, 2021. For additional information related to our Senior Notes, please read *Note 13, Indebtedness*, to these consolidated financial statements.

Note 9: Financial Instruments

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

	As of December 31,	
(In millions)	2022	2021
Commercial paper	$ 177.2	$ 247.6
Overnight reverse repurchase agreements	59.0	200.0
Money market funds	2,581.5	901.6
Short-term debt securities	29.9	283.0
Total	$ 2,847.6	$ 1,632.2

The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and short-term debt securities approximate fair value due to their short-term maturities.

Our marketable equity securities gains (losses) are recorded in other (income) expense, net in our consolidated statements of income. The following tables summarize our marketable debt and equity securities, classified as available for sale:

	As of December 31, 2022			
(In millions)	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, current	$ 1,133.8	$ —	$ (342.7)	$ 791.1
Total marketable equity securities	$ 1,133.8	$ —	$ (342.7)	$ 791.1

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

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

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

	As of December 31,			
	2022		2021	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$ 1,473.5	$ 1,483.3	$ 1,541.1	$ 1,541.7
Due after one year through five years	694.4	703.7	868.2	870.2
Due after five years	11.3	12.1	23.8	24.0
Total marketable debt securities	$ 2,179.2	$ 2,199.1	$ 2,433.1	$ 2,435.9

The average maturity of our marketable debt securities classified as available-for-sale as of December 31, 2022 and 2021, was approximately 8 months and 10 months, respectively.

Proceeds from Marketable Debt Securities

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Proceeds from maturities and sales	$ 3,671.0	$ 3,405.4	$ 7,299.4
Realized gains	—	0.2	17.7
Realized losses	12.6	4.0	26.0

Realized losses for the year ended December 31, 2022, 2021 and 2020, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities.

Strategic Investments

As of December 31, 2022, our strategic investment portfolio comprised of investments totaling $846.0 million which are included in investments and other assets in our consolidated balance sheets. As of December 31, 2021, our strategic investment portfolio comprised of investments totaling $1,110.3 million, which are included in other current assets and investments and other assets in our 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 8, Fair Value Measurements*, to these consolidated financial statements, venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.

The decrease in our strategic investment portfolio for the year ended December 31, 2022, was primarily due to a decrease in the fair value of our investments in Denali and Sangamo 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 these consolidated financial statements.

Note 10: Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts and foreign currency options in effect as of December 31, 2022 and 2021, had durations of 1 to 12 months and 1 to 15 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 accumulated other comprehensive income (loss) (referred to as AOCI in the table below). Realized gains and losses of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized and in operating expense when the expense in the currency being hedged is recorded. We recognize all cash flow hedge reclassifications from accumulated other comprehensive income (loss) and fair value changes of excluded portions in the same line item in our 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 As of December 31,	
(In millions)	2022	2021
Euro	$ 1,495.5	$ 1,828.0
British pound	162.8	166.2
Japanese yen	—	72.7
Canadian dollar	57.2	59.9
Total foreign currency forward contracts	$ 1,715.5	$ 2,126.8

The pre-tax portion of the fair value of these foreign currency forward contracts and foreign currency options that were included in accumulated other comprehensive income (loss) in total equity is summarized as follows:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Unrealized gains	$ 29.9	$ 60.8	$ —
Unrealized (losses)	(21.3)	(7.0)	(212.5)
Net unrealized gains (losses)	$ 8.6	$ 53.8	$ (212.5)

We expect the net unrealized gains of approximately $8.6 million to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of December 31, 2022 and 2021, credit risk did not materially change the fair value of our foreign currency forward contracts.

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

For the Years Ended December 31,							
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)				Net Gains/(Losses) Recognized in Operating Income (in millions)			
Location	2022	2021	2020	Location	2022	2021	2020
Revenue	$ 201.6	$ (60.0)	$ 18.3	Revenue	$ (8.6)	$ (8.4)	$ (9.9)
Operating expense	(5.5)	(0.8)	3.3	Operating expense	—	—	—

Interest Rate Contracts - Hedging Instruments

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

Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes due September 15, 2020, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which were originally set to expire on September 15, 2020. The interest rate swap contracts were designated as hedges of the fair value changes in our 2.90% Senior Notes attributable to changes in interest rates. In May 2020 we settled our interest rate swap contracts, in conjunction with our early redemption of our 2.90% Senior Notes, resulting in a gain of approximately $3.3 million, which was recorded as a component of interest expense in our consolidated statements of income during the year ended December 31, 2020.

Net Investment Hedges - Hedging Instruments

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

In order to mitigate these currency fluctuations between the U.S. dollar and South Korean won, we entered into foreign currency forward contracts. These contracts were designated as net investment hedges. In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics and closed these foreign currency forward contracts. Upon completing this sale, the cumulative gains on our net investment hedges of $57.0 million were reclassified from accumulated other comprehensive income (loss) and reflected within the total pre-tax gain recognized from the sale, which was recorded in other (income) expense, net in our consolidated statements of income. For additional information on the sale of our equity interest in Samsung Bioepis please read *Note 3, Dispositions*, to these consolidated financial statements.

Prior to the sale of our 49.9% equity interest in Samsung Bioepis, we recognized changes in the spot exchange rate of these foreign currency forward contracts in accumulated other comprehensive income (loss). The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net gains of $10.6 million as of December 31, 2021. We excluded fair value changes related to the forward rate from our hedging relationship and amortized the forward points in other (income) expense, net in our consolidated statements of income over the term of the contract. The pre-tax portion of the fair value of the forward points that were included in accumulated other comprehensive income (loss) in total equity reflected net losses of $3.6 million as of December 31, 2021.

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

	For the Years Ended December 31,										
	Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)				Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)				Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)			
Location	2022	2021	2020		Location	2022	2021	2020	Location	2022	2021	2020
Gains (losses) on net investment hedge[1]	$ 20.4	$ 46.0	$(35.1)		Gains (losses) on net investment hedge[1]	$(3.2)	$(3.2)	$ 4.5	Other (income) expense[1]	$(4.6)	$(0.6)	$ 2.9

[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 3, Dispositions*, to these consolidated financial statements.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships*, to these 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 $1,238.8 million and $1,268.0 million as of December 31, 2022 and 2021, respectively. Net losses of $34.7 million, net losses of $43.3 million and net gains of $30.1 million related to these contracts were recorded as a component of other (income) expense, net for the years ended December 31, 2022, 2021 and 2020, 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 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 consolidated balance sheets of our outstanding derivative instruments, including those designated as hedging instruments:

(In millions)	Balance Sheet Location	As of December 31, 2022	As of December 31, 2021
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ 37.9	$ 66.2
	Investments and other assets	—	5.5
Liability derivative instruments	Accrued expense and other	18.4	6.6
Net Investment Hedging Instruments:[(1)]			
Asset derivative instruments	Other current assets	—	4.1
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	25.1	5.1
Liability derivative instruments	Accrued expense and other	7.6	4.2

[(1)] Beginning in the second quarter of 2022 we no longer held net investment hedges as they were closed with the sale of our 49.9% equity interest in Samsung Bioepis in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to these consolidated financial statements.

Note 11: Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Components of property, plant and equipment, net are summarized as follows:

(In millions)	As of December 31, 2022	As of December 31, 2021
Land	$ 202.4	$ 207.5
Buildings	1,592.9	1,699.7
Leasehold improvements	107.7	121.0
Machinery and equipment	1,611.5	1,585.5
Computer software and hardware	999.9	971.6
Furniture and fixtures	61.1	67.4
Construction in progress	888.8	770.3
Total cost	5,464.3	5,423.0
Less: accumulated depreciation	(2,165.7)	(2,006.6)
Total property, plant and equipment, net	$ 3,298.6	$ 3,416.4

Depreciation expense totaled $272.4 million, $235.3 million and $201.9 million for the years ended December 31, 2022, 2021 and 2020, respectively.

For the years ended December 31, 2022, 2021 and 2020, we capitalized interest costs related to construction in progress totaling approximately $17.1 million, $36.3 million and $65.2 million, respectively.

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 December 31, 2022 and 2021, we had approximately $711.1 million and $677.0 million, respectively, capitalized as construction in progress related to this facility. In the second quarter of 2021 a portion of the facility received a Good Manufacturing Practice multi-product license from the Swiss Agency for Therapeutic Products, resulting in approximately $1.2 billion of fixed assets being placed in service during the second quarter of 2021. Solothurn has been approved for the manufacture of ADUHELM and

LEQEMBI by the FDA. We estimate the second manufacturing suite at the Solothurn facility will be operational by the end of 2023.

125 Broadway Building Sale

In September 2022 we completed the sale of our building and land parcel located at 125 Broadway for an aggregate sales price of approximately $603.0 million, which is inclusive of a $10.8 million tenant allowance. This sale resulted in a pre-tax gain on sale of approximately $503.7 million, net of transaction costs, which is reflected within gain on sale of building in our consolidated statements of income for the year ended December 31, 2022. This transaction included approximately $79.2 million of property, plant and equipment, net, which comprised of approximately $72.6 million for buildings, approximately $1.6 million for land and approximately $5.0 million for machinery and equipment.

Note 12: Leases

We lease real estate, including laboratory and office space, and certain equipment.

Our leases have remaining lease terms ranging from less than one year to eight years. Certain leases include one or more options to renew, exercised at our sole discretion, with renewal terms that can extend the lease term from one year to six years.

In addition, we sublease certain real estate to third parties. Our sublease portfolio consists of operating leases, with remaining lease terms ranging from two years to six years. Our subleases do not include an option to renew as they are coterminous with our operating leases.

All of our leases qualify as operating leases. The following table summarizes the presentation in our consolidated balance sheets of our operating leases:

		As of December 31,	
(In millions)	Balance sheet location	2022	2021
Assets:			
Operating lease assets	Operating lease assets	$ 403.9	$ 375.4
Liabilities			
Current operating lease liabilities	Accrued expense and other	$ 97.2	$ 89.1
Non-current operating lease liabilities	Long-term operating lease liabilities	333.0	330.4
Total operating lease liabilities		$ 430.2	$ 419.5

The following table summarizes the effect of lease costs in our consolidated statements of income:

		For the Years Ended December 31,		
(In millions)	Income Statement Location	2022	2021	2020
Operating lease cost	Research and development	$ 2.0	$ 3.4	$ 5.2
	Selling, general and administrative	95.9	95.9	93.1
Variable lease cost	Research and development	0.4	0.8	1.1
	Selling, general and administrative	25.4	25.7	21.1
Sublease income	Selling, general and administrative	(24.0)	(23.9)	(24.2)
	Other (income) expense, net	(4.1)	(4.0)	(3.9)
Net lease cost		$ 95.6	$ 97.9	$ 92.4

Variable lease cost primarily related to operating expense, taxes and insurance associated with our operating leases. As these costs are generally variable in nature, they are not included in the measurement of the operating lease asset and related lease liability.

The minimum lease payments for the next five years and thereafter is expected to be as follows:

(In millions)	As of December 31, 2022
2023	$ 111.0
2024	107.0
2025	80.5
2026	65.7
2027	69.5
Thereafter	36.6
Total lease payments	$ 470.3
Less: interest	40.1
Present value of operating lease liabilities	$ 430.2

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

	As of December 31,	
	2022	2021
Weighted average remaining lease term in years	4.64	5.43
Weighted average discount rate	3.7 %	2.9 %

Supplemental disclosure of cash flow information related to our operating leases included in cash flow provided by operating activities in our consolidated statements of cash flow is as follows:

	As of December 31,		
(In millions)	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities	$ 107.4	$ 105.8	$ 100.2
Operating lease assets obtained in exchange for lease obligations	108.3	18.1	59.0

125 Broadway Building Sale and Leaseback Transaction

In connection with the sale of our building at 125 Broadway, we simultaneously leased back the building for a term of approximately 5.5 years, which resulted in the recognition of approximately $168.2 million in new lease liabilities and right-of-use assets recorded within our consolidated balance sheets as of December 31, 2022. The sale and immediate leaseback of this building qualified for sale and leaseback treatment and is classified as an operating lease. For additional information on the sale of our building, please read *Note 11, Property, Plant and Equipment*, to these consolidated financial statements.

300 Binney Street Lease Modification

In September 2022 we entered into an agreement to partially terminate a portion of our lease located at 300 Binney Street, Cambridge MA, as well as to reduce the lease term for the majority of the remaining space. The agreement was driven by our 2022 efforts to reduce costs by consolidating real estate locations. The transaction was treated as a lease modification as of the effective date and resulted in the derecognition of right of use assets of approximately $47.4 million and lease liabilities of approximately $52.7 million, which resulted in a gain of approximately $5.3 million, which was recorded within restructuring charges in our consolidated statements of income for the year ended December 31, 2022.

Note 13: Indebtedness

Our indebtedness is summarized as follows:

	As of December 31,	
(In millions)	2022	2021
Current portion:		
3.625% Senior Notes due September 15, 2022[1]	$ —	$ 999.1
Current portion of notes payable	$ —	$ 999.1
Non-current portion:		
4.050% Senior Notes due September 15, 2025	$ 1,744.7	$ 1,742.9
2.250% Senior Notes due May 1, 2030	1,492.9	1,492.0
5.200% Senior Notes due September 15, 2045	1,100.3	1,099.9
3.150% Senior Notes due May 1, 2050	1,473.8	1,473.2
3.250% Senior Notes due February 15, 2051	469.3	466.0
Non-current portion of notes payable	$ 6,281.0	$ 6,274.0

[1] Our 3.625% Senior Notes due September 15, 2022, were redeemed in full in July 2022.

Exchange Offer

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

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

In addition, we redeemed an aggregate principal amount of approximately $8.9 million of our 2045 Senior Notes for aggregate cash payments of approximately $12.1 million, excluding accrued and unpaid interest. The redemption has been accounted for as a debt extinguishment; as such, we recognized a pre-tax charge of $3.2 million upon the extinguishment of such 2045 Senior Notes. This charge, which was recognized in interest expense in other (income) expense, net in our consolidated statements of income for the year ended December 31, 2021, reflects the payment of an early call premium and the write-off of the remaining unamortized original debt issuance costs and discount balances associated with such 2045 Senior Notes.

Upon settlement, we also made aggregate cash payments of approximately $13.8 million to settle all accrued and unpaid interest from the last interest payment date on our 2045 Senior Notes that were exchanged or redeemed. We incurred approximately $6.1 million of costs associated with our Exchange Offer, which was recognized in interest expense in other (income) expense, net in our consolidated statements of income for the year ended December 31, 2021.

2020 Senior Notes

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

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

Our 2020 Senior Notes are senior unsecured obligations and may be redeemed at our option at any time at 100.0% of the principal amount plus accrued interest and, until a specified period before maturity, a specified make-whole amount. Our 2020 Senior Notes contain a change-of-control provision that, under certain circumstances, may require us to purchase our 2020 Senior Notes at a price equal to 101.0% of the principal amount plus accrued and unpaid interest to the date of repurchase.

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

2015 Senior Notes

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

- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and
- $1.12 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

The original costs associated with this offering of approximately $47.5 million have been recorded as a reduction to the carrying amount of the debt in our consolidated balance sheets. These costs along with the discounts will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity.

Our 2015 Senior Notes are senior unsecured obligations and may be redeemed at our option at any time at 100.0% of the principal amount plus accrued interest and a specified make-whole amount. Our 2015 Senior Notes contain a change of control provision that may require us to purchase the notes at a price equal to 101.0% of the principal amount plus accrued and unpaid interest to the date of purchase under certain circumstances.

On September 15, 2015, we issued $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020, at 99.792% of par. Our 2.90% Senior Notes were senior unsecured obligations. In connection with the 2.90% Senior Notes, we entered into interest rate swap contracts where we received a fixed rate and paid a variable rate. In May 2020 we used the net proceeds from the sale of our 2020 Senior Notes to redeem our 2.90% Senior Notes prior to their maturity and recognized a net pre-tax charge of $9.4 million upon the extinguishment of these notes. This charge, which was recognized in interest expense in other (income) expense, net in our consolidated statements of income for the year ended December 31, 2020, reflects the payment of a $12.7 million early call premium and the write off of remaining unamortized original debt issuance costs and discount balances, partially offset by a $3.3 million gain related to the settlement of the associated interest rate swap contracts. For additional information on our interest rate contracts, please read *Note 10, Derivative Instruments,* to these consolidated financial statements.

3.625% Senior Notes due September 15, 2022

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

These charges were recognized as interest expense in other (income) expense, net in our consolidated statements of income for the year ended December 31, 2022.

2020 Credit Facility

In January 2020 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. This revolving credit facility replaced the revolving credit facility that we entered into in August 2015. As of December 31, 2022, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Debt Maturity

The total gross payments due under our debt arrangements are as follows:

(In millions)	As of December 31, 2022
2023	$ —
2024	—
2025	1,750.0
2026	—
2027	—
2028 and thereafter	4,817.3
Total debt	$ 6,567.3
Less: debt discount and issuance fees	(286.3)
Total long-term debt	$ 6,281.0

The fair value of our debt is disclosed in *Note 8, Fair Value Measurements,* to these consolidated financial statements.

Note 14: Equity

Preferred Stock

We have 8.0 million shares of Preferred Stock authorized, of which 1.75 million shares are authorized as Series A, 1.0 million shares are authorized as Series X junior participating and 5.25 million shares are undesignated. Shares may be issued without a vote or action of shareholders from time to time in classes or series with the designations, powers, preferences and the relative, participating, optional or other special rights of the shares of each such class or series and any qualifications, limitations or restrictions thereon as set forth in the instruments governing such shares. Any such Preferred Stock may rank prior to common stock as to dividend rights, liquidation preference or both, and may have full or limited voting rights and may be convertible into shares of common stock. No shares of Preferred Stock were issued and outstanding during 2022, 2021 and 2020.

Common Stock

The following table describes the number of shares authorized, issued and outstanding of our common stock as of December 31, 2022, 2021 and 2020:

	As of December 31, 2022			As of December 31, 2021			As of December 31, 2020		
(In millions)	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding
Common stock	1,000.0	167.9	144.0	1,000.0	170.8	147.0	1,000.0	176.2	152.4

Share Repurchases

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 3.6 million, 6.0 million and 1.6 million shares of our common stock at a cost of approximately $750.0 million, $1.8 billion and $400.0 million during the years ended December

31, 2022, 2021 and 2020, respectively. Approximately $2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2022.

In December 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (December 2019 Share Repurchase Program), which was completed as of September 30, 2020. All shares repurchased under our December 2019 Share Repurchase Program were retired. Under our December 2019 Share Repurchase Program, we repurchased and retired approximately 16.7 million shares of our common stock at a cost of approximately $5.0 billion during the year ended December 31, 2020.

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

In August 2022 the Inflation Reduction Act of 2022 (the IRA) was signed into law. Among other things, the IRA levies a 1.0% excise tax on net stock repurchases after December 31, 2022. Historically, we have made discretionary share repurchases.

Amounts paid to repurchase shares in excess of their par value are allocated between additional paid-in capital and retained earnings, with payments in excess of our additional paid-in-capital balance recorded as a reduction to retained earnings.

Accumulated Other Comprehensive Income (Loss)

The following tables summarize the changes in accumulated other comprehensive income (loss), net of tax by component:

	December 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	(23.5)	137.3	12.6	43.7	(83.1)	87.0
Amounts reclassified from accumulated other comprehensive income (loss)	10.0	(176.0)	(38.1)	—	58.9	(145.2)
Net current period other comprehensive income (loss)	(13.5)	(38.7)	(25.5)	43.7	(24.2)	(58.2)
Balance, December 31, 2022	$ (15.7)	$ 15.1	$ —	$ (1.1)	$ (163.2)	$ (164.9)

[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 3, Dispositions*, to these consolidated financial statements.

	December 31, 2021					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedges, Net of Tax	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2020	$ 1.4	$ (179.0)	$ (8.5)	$ (66.3)	$ (46.6)	$ (299.0)
Other comprehensive income (loss) before reclassifications	(6.6)	178.2	33.4	21.5	(92.4)	134.1
Amounts reclassified from accumulated other comprehensive income (loss)	3.0	54.6	0.6	—	—	58.2
Net current period other comprehensive income (loss)	(3.6)	232.8	34.0	21.5	(92.4)	192.3
Balance, December 31, 2021	$ (2.2)	$ 53.8	$ 25.5	$ (44.8)	$ (139.0)	$ (106.7)

	December 31, 2020					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Gains (Losses) on Net Investment Hedges, Net of Tax	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments	Total
Balance, December 31, 2019	$ 4.2	$ 7.8	$ 25.1	$ (32.8)	$ (139.5)	$ (135.2)
Other comprehensive income (loss) before reclassifications	(9.3)	(165.0)	(30.7)	(33.5)	92.9	(145.6)
Amounts reclassified from accumulated other comprehensive income (loss)	6.5	(21.8)	(2.9)	—	—	(18.2)
Net current period other comprehensive income (loss)	(2.8)	(186.8)	(33.6)	(33.5)	92.9	(163.8)
Balance, December 31, 2020	$ 1.4	$ (179.0)	$ (8.5)	$ (66.3)	$ (46.6)	$ (299.0)

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

	Amounts Reclassified from Accumulated Other Comprehensive Income (Loss)			
	For the Years Ended December 31,			
(In millions)	2022	2021	2020	Income Statement Location
Gains (losses) on securities available for sale	$ (12.6)	$ (3.8)	$ (8.2)	Other (income) expense
	2.6	0.8	1.7	Income tax (benefit) expense
Gains (losses) on cash flow hedges	201.6	(60.0)	18.3	Revenue
	(5.5)	(0.8)	3.3	Operating expense
	(0.3)	0.2	0.3	Other (income) expense
	(19.8)	6.0	(0.1)	Income tax (benefit) expense
Gains (losses) on net investment hedges[1]	38.1	(0.6)	2.9	Other (income) expense
Currency Translation Adjustments	(58.9)	—	—	Other (income) expense
Total reclassifications, net of tax	$ 145.2	$ (58.2)	$ 18.2	

[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 3, Dispositions*, to these consolidated financial statements.

Note 15: Earnings per Share

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Numerator:			
Net income attributable to Biogen Inc.	$ 3,046.9	$ 1,556.1	$ 4,000.6
Denominator:			
Weighted average number of common shares outstanding	145.3	149.1	160.9
Effect of dilutive securities:			
Time-vested restricted stock units	0.5	0.3	0.2
Market stock units	0.1	0.1	0.1
Performance stock units settled in stock	0.1	0.1	0.1
Dilutive potential common shares	0.7	0.5	0.4
Shares used in calculating diluted earnings per share	146.0	149.6	161.3

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

Earnings per share for the years ended December 31, 2022, 2021 and 2020, reflects the repurchase of approximately 3.6 million shares, 6.0 million shares and 22.4 million shares of our common stock, respectively, under our share repurchase programs. For additional information on our share repurchase programs, please read *Note 14, Equity*, to these consolidated financial statements.

Note 16: Share-Based Payments

Share-Based Compensation Expense

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Research and development	$ 98.5	$ 89.3	$ 80.0
Selling, general and administrative	175.1	169.5	131.3
Subtotal	273.6	258.8	211.3
Capitalized share-based compensation costs	(9.3)	(8.0)	(6.2)
Share-based compensation expense included in total cost and expense	264.3	250.8	205.1
Income tax effect	(49.2)	(46.7)	(33.5)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 215.1	$ 204.1	$ 171.6

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Market stock units	$ 13.2	$ 45.6	$ 40.5
Time-vested restricted stock units	202.3	159.8	142.6
Cash settled performance units	—	—	(1.7)
Performance units	—	—	(0.1)
Performance stock units settled in stock	35.0	23.9	7.9
Performance stock units settled in cash	10.1	12.2	8.6
Employee stock purchase plan	12.7	17.3	13.5
Stock options	0.3	—	—
Subtotal	273.6	258.8	211.3
Capitalized share-based compensation costs	(9.3)	(8.0)	(6.2)
Share-based compensation expense included in total cost and expense	$ 264.3	$ 250.8	$ 205.1

As of December 31, 2022, unrecognized compensation cost related to unvested share-based compensation was approximately $290.5 million, net of estimated forfeitures. We expect to recognize the cost of these unvested awards over a weighted-average period of 2.0 years.

Share-Based Compensation Plans

We have three share-based compensation plans pursuant to which awards are currently being made: (i) the Biogen Inc. 2006 Non-Employee Directors Equity Plan (2006 Directors Plan); (ii) the Biogen Inc. 2017 Omnibus Equity Plan (2017 Omnibus Equity Plan); and (iii) the Biogen Inc. 2015 Employee Stock Purchase Plan (2015 ESPP).

Directors Plan

In May 2006 our shareholders approved the 2006 Directors Plan for share-based awards to our directors. Awards granted from the 2006 Directors Plan may include stock options, shares of restricted stock, RSUs, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by

a committee of our Board of Directors, subject to the provisions of the 2006 Directors Plan. We have reserved a total of 1.6 million shares of common stock for issuance under the 2006 Directors Plan. The 2006 Directors Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares reserved under the plan in a 1.5-to-1 ratio. In June 2015 our shareholders approved an amendment to extend the term of the 2006 Directors Plan until June 2025.

Omnibus Plan

In June 2017 our shareholders approved the 2017 Omnibus Equity Plan for share-based awards to our employees. Awards granted from the 2017 Omnibus Equity Plan may include stock options, shares of restricted stock, RSUs, performance shares, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the 2017 Omnibus Equity Plan. Shares of common stock available for grant under the 2017 Omnibus Equity Plan consist of 8.0 million shares reserved for this purpose, plus shares of common stock that remained available for grant under the Biogen Idec Inc. 2008 Omnibus Equity Plan (2008 Omnibus Equity Plan) as of June 7, 2017, or that could again become available for grant if outstanding awards under the 2008 Omnibus Equity Plan as of June 7, 2017, are cancelled, surrendered or terminated in whole or in part. The 2017 Omnibus Equity Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares available under the plan in a 1.5-to-1 ratio.

We have not made any awards pursuant to the 2008 Omnibus Equity Plan since our shareholders approved the 2017 Omnibus Equity Plan, and do not intend to make any awards pursuant to the 2008 Omnibus Equity Plan in the future, except that unused shares under the 2008 Omnibus Equity Plan have been carried over for use under the 2017 Omnibus Equity Plan.

Stock Options

During the year ended December 31, 2022, we granted approximately 81,000 stock options to our Chief Executive Officer (CEO) (2022 CEO Grant) under the 2017 Omnibus Plan with a grant date fair value of $139.10 per option for a total of approximately $11.2 million. The fair values of our stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the stock options are then expensed over the options' vesting periods. The 2022 CEO Grant is eligible to vest in equal annual installments over a three-year period from the grant date, subject to the CEO’s continued employment. The outstanding stock options have a 10-year term and are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant.

The total intrinsic value related to the remaining stock options previously granted in 2010 that were exercised in 2020 totaled $2.9 million.

The following table summarizes the amount of tax benefit realized for stock options and cash received from the exercise of the remaining stock options previously granted in 2010:

	For the year ended December 31,
(In millions)	2020
Tax benefit realized for stock options	$ 2.9
Cash received from the exercise of stock options	0.7

Market Stock Units (MSUs)

MSUs awarded to employees prior to 2014 vested in four equal annual increments beginning on the first anniversary of the grant date. Participants may ultimately earn between zero and 150.0% of the target number of units granted based on actual stock performance.

MSUs awarded to employees in 2014 and thereafter vest in three equal annual increments beginning on the first anniversary of the grant date, and participants may ultimately earn between zero and 200.0% of the target number of units granted based on actual stock performance.

The vesting of these awards is subject to the respective employee’s continued employment. The number of MSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain market-based criteria involving our stock price. The number of MSUs earned is calculated at each annual anniversary from the date of grant over the respective vesting periods, resulting in multiple performance periods.

Accordingly, additional MSUs may be issued or currently outstanding MSUs may be cancelled upon final determination of the number of awards earned.

Beginning in 2022 we no longer grant MSUs as part of our long term incentive program and have replaced with granting performance-vested RSUs.

The following table summarizes our MSU activity:

	December 31, 2022	
	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	257,000	$ 372.08
Granted	—	—
Vested	(87,000)	369.22
Forfeited	(57,000)	371.24
Unvested at December 31, 2022	113,000	$ 366.52

We value grants of MSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, the 30 calendar day average closing stock price on the date of grant for MSUs, expected volatility of our stock price, risk-free rates of return and expected dividend yield.

The assumptions used in our valuation are summarized as follows:

	For the Years Ended December 31,	
	2021	2020
Expected dividend yield	—%	—%
Range of expected stock price volatility	54.8% - 61.6%	37.8% - 44.1%
Range of risk-free interest rates	0.06% - 0.21%	1.41% - 1.48%
30 calendar day average stock price on grant date	$262.23 - $360.31	$257.83 - $325.40
Weighted-average per share grant date fair value	$358.77	$398.61

The fair values of MSUs vested in 2022, 2021 and 2020 totaled $18.8 million, $22.5 million and $26.9 million, respectively.

Cash Settled Performance Units (CSPUs)

CSPUs awarded to employees vest in three equal annual increments beginning on the first anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment with such awards settled in cash. The number of CSPUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between zero and 200.0% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional CSPUs may be issued or currently outstanding CSPUs may be cancelled upon final determination of the number of units earned. CSPUs are classified as liability awards and will be settled in cash based on the 30 calendar day average closing stock price through each vesting date, once the actual vested and earned number of units is known. Since no shares are issued, these awards do not dilute equity. All remaining CSPUs were fully vested as of December 31, 2020.

The cash paid in settlement of CSPUs vested in 2020 totaled $3.8 million.

Performance-vested Restricted Stock Units (PUs)

PUs are granted to certain employees in the form of RSUs that may be settled in cash or shares of our common stock at the sole discretion of the Compensation and Management Development Committee of our Board of Directors. These awards are structured and accounted for the same way as the CSPUs, and vest in three equal annual increments beginning on the first anniversary of the grant date. The number of PUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between zero and 200.0% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional PUs may be issued or currently outstanding PUs may be cancelled upon final determination of the number of units earned. PUs settling in cash are based on the 30 calendar

day average closing stock price through each vesting date once the actual vested and earned number of units is known. All remaining PUs were fully vested as of December 31, 2020.

All PUs that vested in 2020 were settled in cash totaling $3.4 million.

Performance Stock Units (PSUs)

PSUs Settled in Stock

During the first quarter of 2018 we began granting awards for performance-vested RSUs that will settle in stock. PSUs awarded to employees have a three-year performance period and vest on the third anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment. The number of PSUs granted represents the target number of units that are eligible to be earned based on the achievement of cumulative three-year performance measures established at the beginning of the performance period, which ends on December 31 of the third year of the performance period.

Participants may ultimately earn between zero and 200.0% of the target number of PSUs granted based on the degree of achievement of the applicable performance metric. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned.

Beginning in 2022 we no longer grant MSUs as part of long term incentive program and have replaced with granting PSUs with a performance metric based on a three-year cumulative relative total shareholder return (rTSR) metric. The PSUs will vest on the third anniversary of the date of grant, with the number of PSUs earned based on this cumulative rTSR metric.

The following table summarizes our PSUs that settle in stock activity:

	December 31, 2022	
	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	196,000	$ 289.94
Granted [1]	270,000	294.43
Vested	(44,000)	316.83
Forfeited	(86,000)	279.09
Unvested at December 31, 2022	336,000	$ 292.95

[1] PSUs settled in stock granted in 2022 include awards granted in conjunction with our annual awards made in February 2022 and PSUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

We value grants of PSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, the 30 calendar day average closing stock price on the date of grant for PSUs, expected volatility of our stock price, risk-free rates of return and expected dividend yield.

The assumptions used in our valuation are summarized as follows:

	December 31, 2022
Expected dividend yield	—%
Range of expected stock price volatility	44.0% - 45.9%
Range of risk-free interest rates	1.8% - 3.9%
30 calendar day average stock price on grant date	$231.31 - $294.86
Weighted-average per share grant date fair value	$294.43

The fair values of PSUs settled in stock that vested in 2022 and 2021 totaled $9.5 million and $15.5 million, respectively

PSUs Settled in Cash

During the first quarter of 2018 we began granting awards for performance-vested restricted stock units that will settle in cash. PSUs awarded to employees have three performance periods and vest on the third anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment. The number of PSUs granted represents the target number of units that are eligible to be earned based on the

achievement of three annual performance measures established when the performance objectives are defined, which will be at the beginning of each year and will end on December 31 of such year.

Participants may ultimately earn between zero and 200.0% of the target number of PSUs granted based on the degree of achievement of the applicable performance metric. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned. PSUs are classified as liability awards and will be settled in cash based on the 30 calendar day average closing stock price through the vesting date, once the actual vested and earned number of PSUs is determined. Since no shares are issued, these awards do not dilute equity.

Beginning in 2022 we no longer grant this type of PSUs as part of our long term incentive program and have replaced with granting time-vested RSUs.

The following table summarizes our PSUs that settle in cash activity:

	December 31, 2022
	Shares
Unvested at December 31, 2021	134,000
Granted [1]	24,000
Vested	(49,000)
Forfeited	(26,000)
Unvested at December 31, 2022	83,000

[1] PSUs settled in cash granted in 2022 include awards granted in conjunction with our annual awards made in February 2022 and PSUs granted in conjunction with the hiring of employees. These grants reflect the target number of shares eligible to be earned at the time of grant.

The fair values of PSUs settled in cash that vested in 2022 and 2021 totaled $11.0 million and $9.9 million, respectively.

Time-Vested Restricted Stock Units (RSUs)

RSUs awarded to employees generally vest no sooner than one-third per year over three years on the anniversary of the date of grant, or upon the third anniversary of the date of the grant, provided the employee remains continuously employed with us, except as otherwise provided in the plan. Shares of our common stock will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. RSUs awarded to directors for service on our Board of Directors vest on the first anniversary of the date of grant, provided in each case that the director continues to serve on our Board of Directors through the vesting date. Shares of our common stock will be delivered to the director upon vesting and are not subject to any withholding taxes.

The following table summarizes our RSU activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	1,202,000	$ 291.54
Granted [1]	1,751,000	221.28
Vested	(539,000)	297.72
Forfeited	(468,000)	244.03
Unvested at December 31, 2022	1,946,000	$ 237.90

[1] RSUs granted in 2022 primarily represent RSUs granted in conjunction with our annual awards made in February 2022 and awards made in conjunction with the hiring of new employees. RSUs granted in 2022 also include approximately 15,000 RSUs granted to our Board of Directors.

RSUs granted in 2021 and 2020 had weighted average grant date fair values of $276.90 and $318.87, respectively.

The fair values of RSUs vested in 2022, 2021 and 2020 totaled $116.3 million, $132.2 million and $140.5 million, respectively.

Employee Stock Purchase Plan (ESPP)

In June 2015 our shareholders approved the 2015 ESPP. The maximum aggregate number of shares of our common stock that may be purchased under the 2015 ESPP is 6.2 million.

The following table summarizes our ESPP activity:

	For the Years Ended December 31,		
(In millions, except share amounts)	2022	2021	2020
Shares issued under the 2015 ESPP	241,000	248,000	212,000
Cash received under the 2015 ESPP	$ 44.2	$ 54.4	$ 48.6

Note 17: Income Taxes

Income Tax Expense

Income before income tax expense and the income tax expense consist of the following:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Income before income tax (benefit) expense:			
Domestic	$ 1,842.0	$ 448.3	$ 3,290.0
Foreign	1,749.8	1,296.9	1,757.5
Total income before income tax (benefit) expense	$ 3,591.8	$ 1,745.2	$ 5,047.5
Income tax (benefit) expense:			
Current:			
Federal	$ 694.5	$ 319.1	$ 647.0
State	39.0	23.1	41.2
Foreign	67.9	137.1	155.1
Total current	801.4	479.3	843.3
Deferred:			
Federal	(328.3)	(242.5)	(1,749.9)
State	2.5	(11.9)	(6.8)
Foreign	157.2	(172.4)	1,905.7
Total deferred	(168.6)	(426.8)	149.0
Total income tax (benefit) expense	$ 632.8	$ 52.5	$ 992.3

Transition Toll Tax

The Tax Cuts and Jobs Act of 2017 eliminated the deferral of U.S. income tax on the historical unrepatriated earnings by imposing the one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). The Transition Toll Tax was assessed on our share of our foreign corporations' accumulated foreign earnings that were not previously taxed. Earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%.

As of December 31, 2022 and 2021, we have accrued income tax liabilities of $558.0 million and $633.0 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of December 31, 2022, approximately $137.8 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight–year period, which started in 2018, and will not accrue interest.

Unremitted Earnings

At December 31, 2022, we considered our earnings not to be permanently reinvested outside the U.S. and therefore recorded deferred tax liabilities associated with an estimate of the total withholding taxes expected as a result of our repatriation of earnings. Other than for earnings, we are permanently reinvested for book/tax basis differences of approximately $1.5 billion as of December 31, 2022, primarily arising through the impacts of

purchase accounting. These permanently reinvested basis differences could reverse through sales of the foreign subsidiaries, as well as various other events, none of which were considered probable as of December 31, 2022. The residual U.S. tax liability, if these differences reverse, would be between $300.0 million and $400.0 million as of December 31, 2022.

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.

As of December 31, 2020, we assessed the realizability of our deferred tax assets that are dependent on future expected sales of TECFIDERA in the U.S. and reduced the net value of certain deferred tax assets by approximately $1.7 billion and reduced the net value of deferred tax liabilities associated with GILTI and tax credits by approximately $1.6 billion. For the year ended December 31, 2020, the income tax expense associated with these reductions was approximately $90.3 million. We continue to assess the realizability of these deferred tax assets. For the years ended December 31, 2022 and 2021, we recorded increases in these deferred tax assets of approximately $17.4 million and $108.5 million, respectively, and increases in these deferred tax liabilities of approximately $16.7 million and $103.9 million, respectively.

Deferred Tax Assets and Liabilities

Significant components of our deferred tax assets and liabilities are summarized as follows:

	As of December 31,	
(In millions)	2022	2021
Deferred tax assets:		
Tax credits	$ 112.6	$ 121.0
Inventory, other reserves and accruals	202.8	199.4
Intangibles, net	1,370.3	1,477.5
Neurimmune's tax basis in ADUHELM	470.3	475.8
IRC Section 174 capitalized research and development	271.8	—
Net operating loss	1,845.9	1,973.0
Share-based compensation	37.2	31.7
Other	280.7	208.8
Valuation allowance	(2,003.3)	(1,961.3)
Total deferred tax assets	$ 2,588.3	$ 2,525.9
Deferred tax liabilities:		
Purchased intangible assets	$ (76.1)	$ (256.6)
Samsung Bioepis investment installments	(138.0)	—
GILTI	(1,002.0)	(1,037.6)
Tax credits	(228.7)	(260.2)
Depreciation, amortization and other	(251.8)	(250.9)
Total deferred tax liabilities	$ (1,696.6)	$ (1,805.3)

The change in the valuation allowance between December 31, 2022 and 2021, was primarily related to the establishment of a valuation allowance against the deferred tax asset related to Neurimmune SubOne AG's (Neurimmune) tax basis in ADUHELM, as discussed below, and the adjustment of a valuation against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S., as discussed above.

In addition to deferred tax assets and liabilities, we have recorded deferred charges related to intra-entity sales of inventory. As of December 31, 2022 and 2021, the total deferred charges were $56.6 million and $39.6 million, respectively.

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 will be effective for periods after December 31, 2022. The enactment of the IRA did not result in any material adjustments to our income tax provision or net deferred tax assets as of December 31, 2022.

Tax Rate

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

	For the Years Ended December 31,		
	2022	2021	2020
Statutory rate	21.0 %	21.0 %	21.0 %
State taxes	1.1	0.8	0.7
Taxes on foreign earnings	(4.9)	(10.5)	(3.3)
Tax credits	(1.7)	(3.8)	(1.2)
Purchased intangible assets	0.3	(1.6)	0.7
TECFIDERA impairment	—	—	1.8
GILTI	0.7	1.3	1.3
Sale of Samsung Bioepis	(1.6)	—	—
Litigation settlement agreement	2.6	—	—
Neurimmune tax impacts	2.3	(5.3)	(0.1)
Internal reorganization	(1.4)	—	—
Other	(0.8)	1.1	(1.2)
Effective tax rate	17.6 %	3.0 %	19.7 %

Changes in Tax Rate

For the year ended December 31, 2022, compared to 2021, the increase in our effective tax rate, excluding the impact of the net Neurimmune deferred tax asset, as discussed below, includes the tax impacts of the litigation settlement agreement and the sale of our building at 125 Broadway. These increases were partially offset by the impact of the current year tax benefits related to an international reorganization to align with global tax developments, the impacts of the sale of our equity interest in Samsung Bioepis and the tax impacts of the decision to discontinue development of vixotrigine. Further in 2021, our effective tax rate benefited from the tax effects of the BIIB111 and BIIB112 impairment charges and the non-cash tax effects of changes in the value of our equity instruments.

For the year ended December 31, 2021, compared to 2020, the decrease in our effective tax rate, excluding the impact of the Neurimmune deferred tax asset, as discussed below, was primarily due to the change in the territorial mix of our profitability, which included the adverse effect of generic competition for TECFIDERA in the U.S. market, the tax impacts of the BIIB111 and BIIB112 impairment charges and the impact of the non-cash tax effects of changes in the value of our equity investments, where we recorded net unrealized losses in 2021 and net unrealized gains in 2020. Our 2020 effective tax rate also reflected an income tax expense related to the establishment of a valuation allowance against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S.

For additional information on the litigation settlement agreement, please read *Note 18, Other Consolidated Financial Statement Detail*, to these consolidated financial statements.

Neurimmune Deferred Tax Asset

During 2021 we recorded a net deferred tax asset in Switzerland of approximately $100.0 million on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM.

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 this deferred tax asset to zero.

These adjustments to our net deferred tax asset are each recorded with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our 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 20, Investments in Variable Interest Entities*, to these consolidated financial statements.

Tax Attributes

As of December 31, 2022, we had general business credit carry forwards for U.S. federal income tax purposes of approximately $8.1 million, which begin to expire in 2027. For U.S. state income tax purposes, we had research and investment credit carry forwards of approximately $132.7 million that begin to expire in 2023 and net operating losses of approximately $24.8 million that begin to expire in 2036. For foreign income tax purposes, we had $15.5 billion of federal net operating loss carryforwards that begin to expire in 2027 and $15.4 billion of Swiss cantonal net operating loss carryforwards that begin to expire in 2027.

In assessing the realizability of our deferred tax assets, we have considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial reporting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies. Based upon the level of historical taxable income and income tax liability and projections for future taxable income over the periods in which the deferred tax assets are utilizable, we believe it is more likely than not that we will realize the net benefits of the deferred tax assets of our wholly owned subsidiaries, net of the recorded valuation allowance. In the event that actual results differ from our estimates or we adjust our estimates in future periods, we may need to adjust or establish a valuation allowance, which could materially impact our consolidated financial position and results of operations.

Accounting for Uncertainty in Income Taxes

A reconciliation of the beginning and ending amount of our unrecognized tax benefits is summarized as follows:

(In millions)	2022	2021	2020
Beginning balance	$ 563.4	$ 75.7	$ 129.9
Additions based on tax positions related to the current period	36.3	4.2	1.5
Additions for tax positions of prior periods	23.4	509.9	51.7
Reductions for tax positions of prior periods	(14.9)	(18.8)	(63.6)
Statute expirations	(1.6)	(3.2)	(7.9)
Settlement refund (payment)	(0.2)	(4.4)	(35.9)
Ending balance	$ 606.4	$ 563.4	$ 75.7

During the year ended December 31, 2021, we increased our gross unrecognized tax benefits by approximately $455.0 million, related to a deferred tax asset for Swiss tax purposes for Neurimmune's tax basis in ADUHELM. This unrecognized tax benefit was recorded as a reduction to the gross deferred tax asset, resulting in the net deferred tax asset, as discussed above, and not as a separate liability on our consolidated balance sheets. As of December 31, 2022, the unrecognized tax benefit related to Neurimmune was approximately $450.0 million, as a result of changes in exchange rates.

Our 2020 activity reflects the impact of the effective settlement of certain tax matters. 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.

Included in the balance of unrecognized tax benefits as of December 31, 2022, 2021 and 2020, are $134.0 million, $87.5 million and $68.8 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in future periods.

We recognize potential interest and penalties related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2022, 2021 and 2020, we recognized total interest and penalty expense of $0.7 million, $2.7 million and $1.0 million, respectively. We have accrued $25.2 million and $24.8 million for the payment of interest and penalties as of December 31, 2022 and 2021, respectively.

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.

Note 18: Other Consolidated Financial Statement Detail

Supplemental Cash Flow Information

Supplemental disclosure of cash flow information for the years ended December 31, 2022, 2021 and 2020, is as follows:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Cash paid during the year for:			
Interest	$ 262.5	$ 280.8	$ 272.7
Income taxes	932.9	247.9	906.7

Other (Income) Expense, Net

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Gain on sale of equity interest in Samsung Bioepis[1]	$ (1,505.4)	$ —	$ —
Litigation settlement agreement and settlement fees	917.0	—	—
Interest income	(89.3)	(11.0)	(42.0)
Interest expense	246.6	253.6	222.5
(Gains) losses on investments, net	277.3	824.9	(685.7)
Foreign exchange (gains) losses, net	35.5	22.4	10.7
Other, net	10.1	5.6	(2.9)
Total other (income) expense, net	$ (108.2)	$ 1,095.5	$ (497.4)

[1] Reflects the pre-tax gain, net of transaction costs, recognized from the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics in April 2022. For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to these consolidated financial statements.

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.

During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million, plus settlement fees and expenses, related to a litigation settlement agreement to resolve a qui tam litigation relating to conduct prior to 2015. This charge is included within other (income) expense, net in our consolidated statements of income for the year ended December 31, 2022.

The following table summarizes our (gains) losses on investments, net that relates to our equity securities held as of December 31, 2022, 2021 and 2020:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Net (gains) losses recognized on equity securities	$ 264.7	$ 821.1	$ (693.9)
Less: Net (gains) losses realized on equity securities	—	(10.3)	(12.1)
Unrealized (gains) losses recognized on equity securities	$ 264.7	$ 831.4	$ (681.8)

The net unrealized losses recognized during the year ended December 31, 2022, primarily reflect a decrease in the aggregate fair value of our investments in Denali and Sangamo common stock of approximately $278.0 million. The net unrealized losses recognized during the year ended December 31, 2021, primarily reflect decreases in the aggregate fair value of our investments in Denali, Sage, Sangamo and Ionis common stock of approximately $819.6 million.

Accrued Expense and Other

Accrued expense and other consists of the following:

	As of December 31,	
(In millions)	2022	2021
Revenue-related reserves for discounts and allowances	$ 891.6	$ 802.1
Employee compensation and benefits	395.6	345.1
Collaboration expense	277.9	324.7
Royalties and licensing fees	209.4	234.7
Other	746.9	828.6
Total accrued expense and other	$ 2,521.4	$ 2,535.2

Other long-term liabilities were $944.2 million and $1,320.5 million as of December 31, 2022 and 2021, respectively, and included accrued income taxes totaling $541.7 million and $664.5 million, respectively.

Note 19: Collaborative and Other Relationships

In connection with our business strategy, we have entered into various collaboration agreements that provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. Terms of the various collaboration agreements may require us to make milestone payments upon the achievement of certain product research and development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

Depending on the collaborative arrangement, we may record funding receivable or payable balances with our collaboration partners, based on the nature of the cost-sharing mechanism and activity within the collaboration. Our significant collaborative arrangements are discussed below.

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.

If we undergo a change in control, as defined in our collaboration agreement, Genentech has the right to present an offer to buy the rights to RITUXAN and we must either accept Genentech's offer or purchase Genentech's rights on the same terms as its offer. Genentech will also be deemed concurrently to have purchased our rights to the remaining products in the collaboration on the terms set forth below.

Our collaboration with Genentech was created through a contractual arrangement and not through a joint venture or other legal entity.

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. could impact 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 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.

If we undergo a change in control, as defined in our collaboration agreement, Genentech will be deemed to have purchased our rights to OCREVUS in exchange for the continued payment of the current royalties on net sales (as defined in our collaboration agreement and summarized above) in the U.S. only, until the 11 year anniversary of the first commercial sale of OCREVUS in the U.S.

LUNSUMIO (mosunetuzumab)

In January 2022 we exercised our option with Genentech to participate in the joint development and commercialization of LUNSUMIO. In connection with this exercise, we recorded a $30.0 million option exercise fee payable to Genentech in December 2021, which was recognized in research and development expense in our consolidated statements of income for the year ended December 31, 2021. We also recorded a charge of approximately $20.0 million to reimburse Genentech for our 30.0% share of the costs incurred in developing this product candidate during 2021, which was recognized in research and development expense in our consolidated statements of income for the year ended December 31, 2021. For the year ended December 31, 2022, we recorded approximately $28.4 million in research and development expense and approximately $13.0 million in sales and marketing expense in our consolidated statements of income related to this collaboration.

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.

If we undergo a change in control, as defined in our collaboration agreement, Genentech will be deemed to have purchased our rights to LUNSUMIO in exchange for 30.0% of the U.S. co-promotion operating profits or losses until the 11 year anniversary of the first commercial sale of LUNSUMIO in the U.S.

Glofitamab

In December 2022 we entered into an agreement with Genentech related to the commercialization and sharing of economics for glofitamab, a late-stage bispecific antibody in development for B-cell non-Hodgkin's lymphoma and other blood cancers. Under the terms of this agreement, we will have no payment obligations and will receive tiered royalties on potential net sales of glofitamab in the U.S. Genentech will have sole decision-making rights on the commercialization of glofitamab within the U.S and, in the event of approval, we are eligible to receive tiered royalties in the mid-single digit range on potential net sales of glofitamab in the U.S.

If we undergo a change in control, as defined in our collaboration agreement, Genentech will be deemed to have purchased our rights to Glofitamab in exchange for a mid-single digit royalty on net sales (as defined in our collaboration agreement) in the U.S. only, until the 11 year anniversary of the first commercial sale of the product in the U.S.

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.

Our share of RITUXAN pre-tax profits in the U.S. in excess of $50.0 million for the years ended December 31, 2022, 2021 and 2020, was 37.5%.

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.

Our share of GAZYVA pre-tax profits in excess of $50.0 million for the years ended December 31, 2022, 2021 and 2020, was 37.5%.

If we undergo a change in control, as defined in our collaboration agreement, Genentech will be deemed to have purchased our rights to GAZYVA in exchange for the continued payment of the compensation payable for GAZYVA under the collaboration arrangement (and set forth above) until the 11 year anniversary of the first commercial sale of GAZYVA in the U.S.

Revenue from Anti-CD20 Therapeutic Programs

Revenue from anti-CD20 therapeutic programs is summarized as follows:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Royalty revenue on sales of OCREVUS	$ 1,136.3	$ 991.7	$ 845.4
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	547.0	647.7	1,080.2
Other revenue from anti-CD20 therapeutic programs	17.2	19.1	52.2
Total revenue from anti-CD20 therapeutic programs	$ 1,700.5	$ 1,658.5	$ 1,977.8

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 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.

Ionis Pharmaceuticals, Inc.

SPINRAZA

In January 2012 we entered into a collaboration and license agreement with Ionis Pharmaceuticals Inc. (Ionis) pursuant to which we have an exclusive, worldwide license to develop and commercialize SPINRAZA for the treatment of SMA.

Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net sales of SPINRAZA using a tiered royalty rate between 11.0% and 15.0%, which are recognized in cost of sales within our consolidated statements of income. Royalty cost of sales related to sales of SPINRAZA for the years ended December 31, 2022, 2021 and 2020, totaled approximately $243.1 million, $267.1 million and $286.6 million, respectively.

2018 Ionis Agreement

In June 2018 we entered into a 10-year exclusive collaboration agreement with Ionis to develop novel antisense oligonucleotide (ASO) drug candidates for a broad range of neurological diseases for a total payment of $1.0 billion, consisting of an upfront payment of $375.0 million and the purchase of approximately 11.5 million shares of Ionis common stock at a cost of $625.0 million.

Upon closing, we recorded $50.9 million of the $375.0 million upfront payment as prepaid services in our consolidated balance sheets and recognized the remaining $324.1 million as research and development expense in our consolidated statements of income. The amount recorded as prepaid services represented the value of the employee resources committed to the arrangement to provide research and discovery services over the term of the agreement.

We have the option to license therapies arising out of this agreement and will be responsible for the development and commercialization of such therapies. We may pay development milestones to Ionis of up to $125.0 million or $270.0 million for each program, depending on the indication plus an annual license fee, as well as royalties on potential net commercial sales.

During the years ended December 31, 2022, 2021 and 2020, we incurred milestones of $10.0 million, $22.5 million and $11.3 million, respectively, related to the advancement of neurological targets identified under this agreement, which were recorded as research and development expense in our consolidated statements of income.

2017 SMA Collaboration Agreement

In December 2017 we entered into a collaboration agreement with Ionis to identify new ASO drug candidates for the potential treatment of SMA. Under this agreement, we have the option to license therapies arising out of this collaboration and will be responsible for their development and commercialization of such therapies.

Upon entering into this agreement, we made a $25.0 million upfront payment to Ionis and we may pay Ionis up to $260.0 million in additional development and regulatory milestone payments if new drug candidates advance to marketing approval. Upon commercialization, we may also pay Ionis up to $800.0 million in additional performance-based milestone payments and tiered royalties on potential net sales of such therapies.

In December 2021 we exercised our option with Ionis and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB115, an investigational ASO in development for SMA. In connection with this option exercise, we made an opt-in payment of $60.0 million to Ionis, which was recorded as research and development expense in our consolidated statements of income for the year ended December 31, 2021.

2013 Long-term Strategic Research Agreement

In September 2013 we entered into a six-year research collaboration agreement with Ionis under which both companies collaborate to perform discovery level research and subsequent development and commercialization activities of antisense or other therapeutics for the potential treatment of neurological diseases. Under this agreement, Ionis performs research on a set of neurological targets identified within the agreement.

Ionis is eligible to receive milestone payments, license fees and royalty payments for all product candidates developed through this collaboration, with the specific amount dependent upon the modality of the product candidate advanced by us under the terms of the agreement.

For non-ALS antisense product candidates, Ionis is responsible for global development through the completion of a Phase 2 trial and we provide advice on the clinical trial design and regulatory strategy. For ALS antisense product candidates, we are responsible for global development, clinical trial design and regulatory strategy. We have an option to license a product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay Ionis up to a $70.0 million license fee and assume global development, regulatory and commercialization responsibilities. Ionis could receive additional milestone payments upon the achievement of certain regulatory milestones of up to $130.0 million, plus additional amounts related to the cost of clinical trials conducted by Ionis under the collaboration, and royalties on future sales if we successfully develop the product candidate after option exercise.

In December 2018 we exercised our option with Ionis and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize tofersen (BIIB067), an investigational treatment for ALS with superoxide dismutase 1 (SOD1) mutations. Potential post-licensing milestone payments may include up to $55.0 million and royalties in the low- to mid-teen percentages on potential annual worldwide net sales. We are solely responsible for the costs and expense related to the development, manufacturing and commercialization of tofersen following the option exercise.

During the years ending December 31, 2022, 2021 and 2020, we incurred milestones of $17.0 million, $10.0 million and $28.0 million, respectively, related to the advancement of programs under this agreement, which were recorded as research and development expense in our consolidated statements of income.

2012 Ionis Agreement

In December 2012 we entered into an agreement with Ionis for the development and commercialization of up to three gene targets.

Under this agreement, Ionis is responsible for global development of any product candidate through the completion of a Phase 2 trial and we will provide advice on the clinical trial design and regulatory strategy. We have an option to license the product candidate until completion of the Phase 2 trial. If we exercise our option, we will pay a license fee of up to $70.0 million to Ionis and assume global development, regulatory and commercialization responsibilities. Ionis is eligible to receive up to $130.0 million in additional milestone payments upon the achievement of certain regulatory milestones as well as royalties on future sales if we successfully develop the product candidate after option exercise.

In December 2019 we exercised our option with Ionis and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB080 (tau ASO), which is currently in Phase 2 development for the potential treatment of Alzheimer's disease. In connection with the option exercise, we made a payment of $45.0 million to Ionis, which was recorded as research and development expense in our consolidated statements of income. Future payments may include additional milestone payments of up to $155.0 million and royalties on future sales in the low- to mid-teens if we successfully develop the product candidate after option exercise.

During the year ended December 31, 2022, we incurred a milestone payment of $10.0 million, related to the advancement of BIIB080 under this agreement, which was recorded within research and development expense in our consolidated statements of income.

Eisai Co., Ltd.

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.

The LEQEMBI Collaboration also provided Eisai with an option to jointly develop and commercialize ADUHELM (aducanumab) (ADUHELM Option), and an option to jointly develop and commercialize one of our anti-tau monoclonal antibodies (Anti-Tau Option). In October 2017 Eisai exercised its ADUHELM Option and we entered into a new collaboration agreement for the joint development and commercialization of ADUHELM (aducanumab) (the ADUHELM Collaboration Agreement).

On March 14, 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. In March 2022 we also amended the LEQEMBI Collaboration Agreement with Eisai to eliminate the Anti-Tau Option.

If either company undergoes a change of control, as defined in our LEQEMBI Collaboration Agreement, the non-acquired party may elect to initiate an operational separation, as defined in the LEQEMBI Collaboration Agreement. In the event of an operational separation, we would work with Eisai to effect a timely transition of any development, manufacturing or commercial responsibilities regarding LEQEMBI from us to Eisai. In this scenario, as of six months following the change of control, our ongoing responsibility for LEQEMBI related cost-sharing would be reduced to an amount equal to 80.0% of what we would have owed prior to the operational separation, and all other economic rights would remain unchanged.

In addition, in the event either company undergoes a change of control in which the acquirer is engaged in commercialization of a competing product, as defined in the LEQEMBI Collaboration Agreement, the non-acquired party may also request that the acquired party cease commercializing the competing product. Should the acquired party elect to continue commercializing the competing product, the non-acquired party may terminate the LEQEMBI Collaboration Agreement. Furthermore, in the event we are the non-acquired party, we may choose either to sell our interest in LEQEMBI to Eisai or purchase Eisai's interest in LEQEMBI, subject to the parameters set forth in the LEQEMBI Collaboration Agreement.

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total development expense incurred by the collaboration related to the advancement of LEQEMBI	$ 347.2	$ 323.0	$ 219.3
Biogen's share of the LEQEMBI Collaboration development expense reflected in research and development expense in our consolidated statements of income	173.6	161.5	109.6
Total sales and marketing expense incurred by the LEQEMBI Collaboration	104.6	27.2	9.8
Biogen's share of the LEQEMBI Collaboration sales and marketing expense reflected in selling, general and administrative expense in our consolidated statements of income	52.3	13.6	4.9

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.

On March 14, 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, sales and marketing expense and milestone payments related to the ADUHELM Collaboration Agreement is as follows:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total ADUHELM development expense	$ 149.4	$ 183.7	$ 152.0
Biogen's share of the ADUHELM Collaboration development expense reflected in research and development expense in our consolidated statements of income	82.2	101.1	83.6
Total ADUHELM sales and marketing expense incurred by the ADUHELM Collaboration Agreement	134.2	562.3	353.0
Biogen's share of the ADUHELM Collaboration sales and marketing expense reflected in selling, general and administrative expense and collaboration profit (loss) sharing in our consolidated statements of income	71.5	301.4	193.7
Total ADUHELM Collaboration third party milestones	—	100.0	75.0
Biogen's share of reimbursement from Eisai of ADUHELM milestone payments reflected in collaboration profit (loss) sharing in our consolidated statements of income	—	45.0	33.8

ADUHELM Co-promotion Profits and Losses

In the U.S. we recognize revenue on sales of ADUHELM to third parties as a component of product revenue, net in our consolidated statements of income. We also record the related cost of revenue and sales and marketing expense in our consolidated statements of income as these costs are incurred. Payments made to and received from Eisai for its 45.0% share of the co-promotion profits or losses in the U.S. are recognized in collaboration profit (loss) sharing in our consolidated statements of income. For the years ended December 31, 2022 and 2021, we recognized net reductions to our operating expense of approximately $224.7 million and $233.2 million, respectively, to reflect Eisai's 45.0% share of net collaboration losses in the U.S.

For the year ended December 31, 2021, we recognized a net reduction to our operating expense of $45.0 million to reflect Eisai's 45.0% share of the $100.0 million milestone payment made to Neurimmune related to the launch of ADUHELM in the U.S., which was recorded in collaboration profit (loss) sharing in our consolidated statements of income.

For the year ended December 31, 2020, we recognized a net reduction to our operating expense of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone payment made to Neurimmune related to the submission of a Biologics License Application (BLA) to the FDA for the approval of ADUHELM, which was recorded in collaboration profit (loss) sharing in our consolidated statements of income.

During the fourth quarter of 2021 we recorded approximately $164.0 million of charges associated with the write-off of inventory and purchase commitments in excess of forecasted demand related to ADUHELM. 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 years ended December 31, 2022 and 2021, we recorded approximately $111.0 million and $30.0 million, respectively, of aggregate gross idle capacity charges related to ADUHELM. These charges were recorded in cost of sales within our consolidated statements of income for the years ended December 31, 2022 and 2021.

We have recognized approximately $197.0 million and $99.0 million related to Eisai's 45.0% share of inventory, idle capacity charges and contractual commitments in collaboration profit (loss) sharing within our consolidated statements of income for the years ended December 31, 2022 and 2021, respectively.

Amounts receivable from Eisai related to the agreements discussed above were approximately $88.0 million and $285.4 million as of December 31, 2022 and 2021, respectively. Amounts payable to Eisai related to the agreements discussed above were approximately $81.2 million and $46.5 million as of December 31, 2022 and 2021, respectively.

In addition, we and Eisai co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings and Eisai distributes AVONEX, TYSABRI, TECFIDERA and PLEGRIDY in India and other Asia-Pacific markets, excluding China.

UCB

In November 2003 we entered into a collaboration agreement with UCB to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of systemic lupus erythematosus and other future agreed indications. Either we or UCB may propose development of dapirolizumab pegol in additional indications. If the parties do not agree to add an indication as an agreed indication to the collaboration, we or UCB may, at the sole expense of the applicable party, pursue development in such excluded indication(s), subject to an opt-in right of the non-pursuing party after proof of clinical activity.

All costs incurred for agreed indications, including research, development, sales and marketing expense, are shared equally between us and UCB. 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:

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total UCB collaboration development expense	$ 68.0	$ 84.2	$ 58.3
Biogen's share of the UCB collaboration development expense reflected in research and development expense in our consolidated statements of income	34.0	42.1	29.2

Alkermes

In November 2017 we entered into an exclusive license and collaboration agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), for VUMERITY, a novel fumarate for the treatment of RMS. In October 2019 the FDA approved VUMERITY in the U.S. for the treatment of RMS. During the fourth quarter of 2021 VUMERITY was approved for the treatment of relapsing-remitting MS (RRMS) in the E.U., Switzerland and the United Kingdom (U.K.).

Under this agreement, we received an exclusive, worldwide license to develop and commercialize VUMERITY and we pay Alkermes royalties of 15.0% on worldwide net commercial sales of VUMERITY, which are recognized in cost of sales within our consolidated statements of income. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval. Royalty cost of sales related to sales of VUMERITY for the years ended December 31, 2022, 2021 and 2020, totaled approximately $83.0 million, $61.6 million and $12.9 million, respectively.

Alkermes is eligible to receive royalties in the high-single digits to sub-teen double digits of annual net commercial sales upon successful development and commercialization of new product candidates, other than VUMERITY, developed under the exclusive license from Alkermes.

Alkermes currently supplies both VUMERITY and FAMPYRA to us pursuant to separate supply agreements. In October 2019 we entered into a new supply agreement and amended our license and collaboration agreement with Alkermes for VUMERITY. We have elected to initiate a technology transfer and, following a transition period, to manufacture VUMERITY or have VUMERITY manufactured by a third party we have engaged in exchange for paying an increased royalty rate to Alkermes on any portion of future worldwide net commercial sales of VUMERITY that is manufactured by us or our designee. In October 2022 we entered into a new supply agreement with Alkermes for FAMPYRA. Acorda previously supplied FAMPYRA to us pursuant to a sublicensing arrangement with Alkermes, which was terminated in October 2022 as a result of an arbitration outcome between Acorda and Alkermes.

Acorda Therapeutics, Inc.

In June 2009 we entered into a collaboration and license agreement with Acorda Therapeutics, Inc. (Acorda) to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S. We are responsible for all regulatory activities and the future clinical development of related products in those markets.

Under this agreement, we pay tiered royalties based on the level of ex-U.S. net sales and we may pay potential milestone payments based on the successful achievement of certain regulatory and commercial milestones, which would be capitalized as intangible assets upon achievement of the milestones and amortized utilizing an economic consumption model. During the third quarter of 2020 we recognized a milestone of $15.0 million, which became due

upon ex-U.S. net sales reaching $100.0 million over a period of four consecutive quarters, and was capitalized within intangible assets, net in our consolidated balance sheets.

In connection with the collaboration and license agreement, we also entered into a supply agreement with Acorda for the commercial supply of FAMPYRA. This agreement was a sublicense arrangement of an existing agreement between Acorda and Alkermes Inc., who acquired Elan Drug Technologies, the original party to the license with Acorda. In October 2022 we learned that, as a result of an arbitration filed by Acorda with the American Arbitration Association in July 2020 after Acorda and Alkermes were unable to resolve a dispute over license and supply royalties, Acorda no longer had to pay Alkermes any royalties on net sales for license and supply of FAMPYRA and Acorda was now free to use alternative sources for supply of FAMPYRA. Acorda notified us that as a result of it no longer obtaining FAMPYRA from Alkermes, that we would need to enter into a supply agreement to obtain FAMPYRA directly with Alkermes.

For the years ending December 31, 2022, 2021 and 2020, total cost of sales related to royalties and commercial supply of FAMPYRA reflected in our consolidated statements of income were approximately $46.1 million, $46.6 million and $44.5 million, respectively.

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage to jointly develop and commercialize zuranolone (BIIB125) 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.

In connection with the closing of this transaction in December 2020 we purchased $650.0 million of Sage common stock, or approximately 6.2 million shares at approximately $104.14 per share, which were initially subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Sage common stock acquired and a charge of approximately $209.0 million to research and development expense in our consolidated statements of income to reflect the premium paid for the Sage common stock. We also made an upfront payment of $875.0 million that was recorded as research and development expense within our consolidated statements of income for the year ended December 31, 2020.

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total Sage collaboration development expense	$ 173.3	$ 167.7	$ —
Biogen's share of the Sage collaboration development expense reflected in research and development expense in our consolidated statements of income	86.7	83.8	—
Total Sage sales and marketing expense incurred by the collaboration	109.9	36.4	—
Biogen's share of the Sage collaboration sales and marketing expense reflected in selling, general and administrative expense in our consolidated statements of income	55.0	18.2	—

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 leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle (ATV): ATV enabled anti-amyloid beta program and a second program utilizing its Transport Vehicle technology. Further, we have a 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.

As part of this collaboration we purchased $465.0 million of Denali common stock in September 2020, or approximately 13 million shares at approximately $34.94 per share, which were initially subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Denali common stock acquired and a charge of approximately $41.3 million to research and development expense in our consolidated statements of income to reflect the premium paid for the Denali common stock. We also made an upfront payment of $560.0 million that was recorded as research and development expense within our consolidated statements of income for the year ended December 31, 2020.

We may also pay Denali development and commercial milestone payments that could total up to approximately $1.1 billion if the milestones related to the LRRK2 program are achieved. Under this collaboration, both companies share responsibility and costs for global development based on specified percentages as well as profits and losses for commercialization in the U.S. and China. Outside the U.S. and China we are responsible for commercialization and may pay Denali potential tiered royalties.

In October 2022 we and Denali announced the initiation of the Phase 3 LIGHTHOUSE study for BIIB122 (DNL151), a small molecule inhibitor of LRRK2 for the potential treatment of Parkinson's disease.

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total Denali collaboration development expense	$ 75.1	$ 42.5	$ 14.6
Biogen's share of the Denali collaboration development expense reflected in research and development expense in our consolidated statements of income	43.8	25.5	8.8

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 connection with the closing of this transaction in April 2020 we purchased $225.0 million of Sangamo common stock, or approximately 24 million shares at approximately $9.21 per share, which were initially subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately $83.0 million to research and development expense in our consolidated statements of income to reflect the premium paid for the Sangamo common stock. We also made an upfront payment of $125.0 million that was recorded as research and development expense within our consolidated statements of income for the year ended December 31, 2020.

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

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

	For the Years Ended December 31,		
(In millions)	2022	2021	2020
Total Sangamo collaboration development expense	$ 19.1	$ 22.7	$ 10.1
Biogen's share of the Sangamo collaboration development expense reflected in research and development expense in our consolidated statements of income	12.1	14.6	6.4

InnoCare Pharma Limited

In July 2021 we entered into a collaboration and license agreement with InnoCare Pharma Limited (InnoCare) for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor for the potential treatment of MS. Orelabrutinib is currently being studied in a multi-country, placebo-controlled Phase 2 trial in RRMS. Under the terms of this collaboration, we have exclusive rights to orelabrutinib in the field of MS worldwide and certain autoimmune diseases outside of China (including Hong Kong, Macau and Taiwan), while InnoCare retains exclusive worldwide rights to orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan).

In connection with the closing of this transaction in August 2021 we made an upfront payment of $125.0 million that was recorded as research and development expense within our consolidated statements of income for the year ended December 31, 2021. We may also pay InnoCare up to approximately $812.5 million in potential development milestones and potential commercial payments should this collaboration achieve certain development, commercial milestones and sales thresholds. In addition, we may pay InnoCare tiered royalties on potential net sales of any products developed under this collaboration in the low to high teen percentages.

In February 2023 we terminated our license and collaboration agreement with InnoCare for orelabrutinib, for the potential treatment of MS.

Other Research and Discovery Arrangements

These arrangements may include the potential for future milestone payments based on the achievement of certain clinical and commercial development payable over a period of several years.

Other

For the years ended December 31, 2022, 2021 and 2020, we recorded approximately $39.2 million, $89.1 million and $92.1 million, respectively, as research and development expense in our consolidated statements of income related to other research and discovery related arrangements.

Samsung Bioepis Co., Ltd.

Joint Venture Agreement

In February 2012 we entered into a joint venture agreement with Samsung BioLogics establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products. Samsung BioLogics contributed 280.5 billion South Korean won (approximately $250.0 million) for an 85.0% ownership interest in Samsung Bioepis and we contributed 49.5 billion South Korean won (approximately $45.0 million) for the remaining 15.0% ownership interest. In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5.0%, which reflected the effect of previous equity financings in which we did not participate, to approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics.

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

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.

Prior to this sale, we recognized our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity became available, which was reflected as equity in (income) loss of investee, net of tax in our consolidated statements of income.

Upon our November 2018 investment, the equity method of accounting required us to identify and allocate differences between the fair value of our investment and the carrying value of our interest in the underlying net assets of the investee. These basis differences were being amortized over their economic life, until the completion of the sale in April 2022, as discussed above. The total basis difference was approximately $675.0 million and related to inventory, developed technology, IPR&D and deferred tax balances. The basis differences related to inventory were amortized, net of tax, over their estimated useful lives of 1.5 years, and the basis differences related to developed technology and IPR&D for marketed products were being amortized, net of tax, over their estimated useful lives of 15 years.

For the year ended December 31, 2022, we recognized net income on our investment of $2.6 million, reflecting our share of Samsung Bioepis' operating profits, net of tax, totaling $17.0 million offset by amortization of basis differences totaling $14.4 million. This amount reflects our share of results prior to the sale of Samsung Bioepis as the results are recognized one quarter in arrears. Following the sale of Samsung Bioepis we no longer recognize gains or losses associated with Samsung Bioepis' results of operations and amortization related to basis differences.

For the year ended December 31, 2021, we recognized net income on our investment of $34.9 million, reflecting our share of Samsung Bioepis' operating profits, net of tax, totaling $64.6 million offset by amortization of basis differences totaling $29.7 million.

Net income on our investment for the year ended December 31, 2021, reflects a $31.2 million benefit related to the release of a valuation allowance on deferred tax assets associated with Samsung Bioepis. The valuation allowance was released in the second quarter of 2021 based on a consideration of the positive and negative evidence, including the historic earnings of Samsung Bioepis.

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

For additional information on the sale of our equity interest in Samsung Bioepis, please read *Note 3, Dispositions*, to these consolidated financial statements.

2019 Development and Commercialization Agreement

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

In connection with this transaction, we made an upfront payment of $100.0 million to Samsung Bioepis in January 2020, of which $63.0 million was recorded as research and development expense in our consolidated statements of income in 2019 and $37.0 million was recorded as an intangible assets, net in our consolidated balance sheets in 2019.

During the third quarter of 2020 we paid Samsung Bioepis a $15.0 million development milestone, which was included in research and development expense in our consolidated statements of income. During the third quarter of 2021 we accrued $15.0 million in milestone payments related to the approval of BYOOVIZ in the U.S., the E.U. and the U.K., that were capitalized within intangible assets, net in our consolidated balance sheets. We may also pay Samsung Bioepis up to approximately $180.0 million in additional development, regulatory and sales-based milestones.

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

2013 Commercial Agreement

In December 2013 we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, 3 anti-tumor necrosis factor (TNF) biosimilar product candidates in Europe and in the case of BENEPALI, Japan. As discussed above, we have an option to extend this agreement by an additional five years. Under this agreement, we have made upfront and clinical development milestone payments totaling $46.0 million, which were recorded as research and development expense in our consolidated statements of income as the programs they relate to had not achieved regulatory approval. We also agreed to make additional milestone payments of $25.0 million upon regulatory approval in the E.U. for each of the three anti-TNF biosimilar product candidates. IMRALDI, an adalimumab biosimilar referencing HUMIRA, FLIXABI, an infliximab biosimilar referencing REMICADE, and BENEPALI, an etanercept biosimilar referencing ENBREL, received regulatory approval in the E.U. in August 2017, May 2016 and January 2016, respectively, and we capitalized the related milestone payments totaling $75.0 million as intangible assets, net in our consolidated balance sheets.

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

We share 50.0% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit (loss) sharing in our consolidated statements of income. For the years ended December 31, 2022, 2021 and 2020, we recognized net profit-sharing expense of $217.4 million, $285.4 million and $266.5 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits.

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.

For the years ended December 31, 2022, 2021 and 2020, we recognized $20.6 million, $20.7 million and $20.9 million, respectively, in royalty revenue under the license agreement, as a component of other revenue in our consolidated statements of income.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were $2.0 million and $4.1 million as of December 31, 2022 and 2021, respectively. Amounts payable to Samsung Bioepis related to the agreements discussed above were $40.5 million and $148.7 million as of December 31, 2022 and 2021, respectively.

Note 20: Investments in Variable Interest Entities

Consolidated Variable Interest Entities

Our 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.

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

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

During 2021 we recorded a net deferred tax asset in Switzerland of approximately $100.0 million on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM. 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 this deferred tax asset to zero. These adjustments to our net deferred tax asset are each recorded with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our 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 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.

Research and development costs for which we reimburse Neurimmune are reflected in research and development expense in our consolidated statements of income. During the years ending December 31, 2022, 2021 and 2020, amounts reimbursed were immaterial.

For additional information on our collaboration arrangements with Eisai, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Unconsolidated Variable Interest Entities

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

As of December 31, 2022 and 2021, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $27.8 million and $24.6 million, respectively. Our maximum exposure to loss related to these variable interest entities is limited to the carrying value of our investments.

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

Note 21: Litigation

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

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

We and certain current and former officers are named as defendants in actions filed by shareholders in November 2020 (the November 2020 Securities Action) and February 2022 (the February 2022 Securities Action) and pending in the U.S. District Court for the District of Massachusetts. The actions allege violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and seek declarations of the actions as class actions and monetary relief. In September 2022, the court dismissed the November 2020 Securities Action, and the plaintiff has appealed to the U.S. Court of Appeals for the First Circuit. Our motion to dismiss the February 2022 Securities Action is pending.

Shareholder Derivative Actions

We and members of the Board of Directors are named as defendants in derivative actions filed by shareholders on February 9 and July 21, 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, 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 court has stayed both cases.

IMRALDI Patent Litigation

In September 2018 Fresenius Kabi Deutschland GmbH (Fresenius Kabi) commenced proceedings for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris and proceedings against Biogen GmbH in the Düsseldorf Regional Court, alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis that Biogen commercializes in Europe, infringes national counterparts of European Patent No. 3 148 510 (the EP '510 Patent). In June 2022 Fresenius Kabi amended both actions to assert claims under European Patent 3 145 488 (the EP '488 Patent), which expires in May 2035. No hearing has been set in either action.

In June 2022 the Technical Boards of Appeal (TBA) of the European Patent Office (EPO) affirmed the revocation of the EP '510 Patent, which resolves all pending infringement claims under the EP '510 Patent. The EPO upheld the validity of the EP '488 Patent in October 2022.

In June 2020 Fresenius Kabi commenced preliminary injunction proceedings in Denmark's Maritime and Commercial High Court alleging that IMRALDI infringes the Danish counterpart of the EP '488 Patent and a corresponding Danish utility model, DK 2020 00038 Y3. In September 2021 the Court refused Fresenius Kabi's request for a preliminary injunction and Fresenius Kabi has withdrawn its appeal.

In July 2019 Gedeon Richter Nyrt commenced proceedings for damages and injunctive relief against Biogen GmbH in the Düsseldorf Regional Court, alleging infringement of the German counterpart of European Patent No. 3 212 667 (the EP '667 Patent), which expires in October 2035. The case has been stayed pending Gedeon Richter's appeal to the TBA of the revocation of the patent. A hearing has been set by the TBA for July 2023.

In November 2020 Gedeon Richter Nyrt commenced proceedings against Biogen GmbH in the Düsseldorf Regional Court alleging infringement of a German utility model corresponding to EP '667. 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 in which a hearing has been set for March 2023.

Dispute with Former Convergence Shareholders

In 2015 Biogen acquired Convergence, a UK 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 September 2021 Humana Inc. (Humana) filed suit against us in the U.S. District Court for the District of Massachusetts, alleging damages related to our providing MS patients with free medications and making charitable contributions to non-profit organizations that assist MS patients. Humana alleges violation of the federal RICO Act and state laws and seeks statutory treble damages, attorneys' fees and costs. We filed a motion to dismiss, which is pending.

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.

Other Matters

Government Investigations

The company has received subpoenas from the Securities and Exchange Commission seeking information relating to ADUHELM, including healthcare sites and ADUHELM's approval. In 2021 the U.S. House of Representatives Committees on Oversight and Reform and Energy (House Committees) and the Office of Inspector General (OIG) each announced investigations related to ADUHELM. In December 2022 the House Committees issued a report on their investigation.

TYSABRI Patent Matters

In September 2022 we filed an action in the U.S. District Court for the District of Delaware against Sandoz Inc. 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 date has been set.

In December 2022 the TBA affirmed the revocation of our European Patent 2 676 967 (the EP '967 Patent), covering pre-treatment testing of patients using natalizumab (TYSABRI).

In September 2021 Polpharma Biologics S.A., Sandoz AG, Sandoz Limited and Sandoz GmbH filed an action in the English High Court to revoke the U.K. counterpart of the EP ‘967 Patent. No trial date has been set.

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

Pharmaceutical Works Polpharma SA (Polpharma) and Mylan Ireland Ltd. (Mylan Ireland) each filed actions in the General Court of the European Union (Polpharma in October 2018 and Mylan Ireland in November 2020) to annul the European Medicines Agency's (EMA) decision not to validate their applications to market generic versions of TECFIDERA on the grounds that TECFIDERA benefits from regulatory data protection. On May 5, 2021, the European General Court annulled the EMA's non-validation decision with respect to Polpharma. The European Court of Justice will announce its decision in our appeal of this decision on March 16, 2023. The case brought by Mylan Ireland has been stayed.

Product Liability and Other Legal Proceedings

We are also involved in product liability claims and other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe

the ultimate resolution of any of these existing matters would have a material adverse effect on our business or financial condition.

Note 22: Commitments and Contingencies

Royalty Payments

TYSABRI

In 2013 we acquired from Elan full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the acquisition agreement, we are obligated to make contingent payments to Elan of 18.0% on annual worldwide net commercial sales up to $2.0 billion and 25.0% on annual worldwide net commercial sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013 and Perrigo subsequently sold its rights to these payments to a third-party effective January 2017.

SPINRAZA

In 2016 we exercised our option to develop and commercialize SPINRAZA from Ionis. Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net commercial sales of SPINRAZA using a tiered royalty rate between 11.0% and 15.0%, which are recorded as cost of sales in our consolidated statements of income. For additional information on our collaboration arrangements with Ionis, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

VUMERITY

Under our agreement with Alkermes, we make royalty payments to Alkermes on worldwide net commercial sales of VUMERITY using a royalty rate of 15.0%, which are recorded as cost of sales in our consolidated statements of income. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval. For additional information on our collaboration arrangement with Alkermes, please read *Note 19, Collaborative and Other Relationships*, to these consolidated financial statements.

Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2022, we could trigger potential future milestone payments to third parties of up to approximately $9.3 billion, including approximately $2.0 billion in development milestones, approximately $0.5 billion in regulatory milestones and approximately $6.8 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 December 31, 2022, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

If certain clinical and commercial milestones are met, we may pay up to $356.2 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.

During the second quarter of 2020 we paid Neurimmune $75.0 million upon the completed submission of the BLA for the approval of ADUHELM to the FDA, which was recognized as a charge to net income (loss) attributable to noncontrolling interests, net of tax in our consolidated statements of income.

In June 2021 ADUHELM was granted accelerated approval by the FDA. Under the terms of the Neurimmune Agreement, we were required to pay Neurimmune a milestone payment of $100.0 million related to the launch of ADUHELM in the U.S. During the second quarter of 2021 we made this $100.0 million payment, which was recognized as a charge to net income (loss) attributable to noncontrolling interests, net of tax in our consolidated statements of income.

Other Funding Commitments

As of December 31, 2022, 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 $20.4 million in our consolidated balance sheets for expenditures incurred by CROs as of December 31, 2022. We have approximately $929.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2022.

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 December 31, 2022, we have approximately $154.6 million of liabilities associated with uncertain tax positions.

As of December 31, 2022 and 2021, we have accrued income tax liabilities of approximately $558.0 million and $633.0 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of December 31, 2022, approximately $137.8 million is expected to be paid within one year. The Transition Toll Tax will be paid in installments over an eight–year period, which started in 2018, and will not accrue interest. For additional information on the Transition Toll Tax, please read *Note 17, Income Taxes*, to these consolidated financial statements.

Note 23: Guarantees

As of December 31, 2022 and 2021, we did not have significant liabilities recorded for guarantees.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2022 and 2021.

Note 24: Employee Benefit Plans

We sponsor various retirement and pension plans. Our estimates of liabilities and expense for these plans incorporate a number of assumptions, including expected rates of return on plan assets and interest rates used to discount future benefits.

401(k) Savings Plan

We maintain a 401(k) Savings Plan, which is available to substantially all regular employees in the U.S. over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. The 401(k) Savings Plan also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The expense related to our 401(k) Savings Plan primarily consists of our matching contributions.

Expense related to our 401(k) Savings Plan totaled approximately $56.0 million, $58.4 million and $44.3 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Deferred Compensation Plan

We maintain a non-qualified deferred compensation plan, known as the Supplemental Savings Plan (SSP), which allows a select group of management employees in the U.S. to defer a portion of their compensation. The SSP also provides certain credits to highly compensated U.S. employees that are paid by the company. These credits are known as the Restoration Match. The deferred compensation amounts are accrued when earned. Such deferred compensation is distributable in cash in accordance with the rules of the SSP. Deferred compensation amounts under such plan as of December 31, 2022 and 2021, totaled approximately $131.9 million and $131.4 million, respectively, and are included in other long-term liabilities in our consolidated balance sheets. The SSP also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement

Plan. The Restoration Match and participant contributions vest immediately. Distributions to participants can be either in one lump sum payment or annual installments as elected by the participants.

Pension Plans

Our retiree benefit plans include defined benefit plans for employees in our affiliates in Switzerland and Germany as well as other insignificant defined benefit plans in certain other countries where we maintain an operating presence.

Our Swiss plan is a government-mandated retirement fund that provides employees with a minimum investment return. The minimum investment return is determined annually by the Swiss government and was 2.00% in 2022 and 1.00% in both 2021 and 2020. Under the Swiss plan, both we and certain of our employees with annual earnings in excess of government determined amounts are required to make contributions into a fund managed by an independent investment fiduciary. Employer contributions must be in an amount at least equal to the employee's contribution. Minimum employee contributions are based on the respective employee's age, salary and gender. As of December 31, 2022 and 2021, the Swiss plan had an unfunded net pension obligation of $49.9 million and $64.1 million, respectively, and plan assets that totaled $193.7 million and $200.1 million, respectively. In 2022, 2021 and 2020 we recognized net expense totaling $20.0 million, $21.5 million and $15.5 million, respectively, related to our Swiss plan, of which $5.3 million, $3.5 million and $2.6 million, respectively, was included in other (income) expense, net in our consolidated statements of income.

The obligations under the German plans are unfunded and totaled $40.9 million and $68.4 million as of December 31, 2022 and 2021, respectively. Net periodic pension cost related to the German plans totaled $5.9 million, $7.6 million and $6.2 million for the years ended December 31, 2022, 2021 and 2020, respectively, of which $1.8 million, $2.1 million and $2.0 million, respectively, was included in other (income) expense, net in our consolidated statements of income.

Note 25: Segment Information

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. Our CEO, as the chief operating decision-maker, manages and allocates resources to the operations of our company on a total company basis. Our research and development organization is responsible for the research and discovery of new product candidates and supports development and registration efforts for potential future products. Our pharmaceutical, operations and technology organization manages the development of the manufacturing processes, clinical trial supply, commercial product supply, distribution, buildings and facilities. Our commercial organization is responsible for U.S. and international development of our commercial products. The company is also supported by corporate staff functions. Managing and allocating resources on a total company basis enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

Enterprise-wide disclosures about product revenue, other revenue and long-lived assets by geographic area are presented below. Revenue is primarily attributed to individual countries based on location of the customer or licensee.

Geographic Information

The following tables contain certain financial information by geographic area:

	December 31, 2022					
(In millions)	U.S.	Europe[1]	Germany	Asia	Other	Total
Product revenue from external customers	$ 3,469.3	$ 2,401.3	$ 926.2	$ 672.1	$ 518.9	$ 7,987.8
Revenue from anti-CD20 therapeutic programs	1,636.4	0.1	—	—	64.0	1,700.5
Other revenue from external customers	425.8	11.7	—	47.6	—	485.1
Long-lived assets	1,369.4	2,275.8	21.0	13.7	22.6	3,702.5

	December 31, 2021					
(In millions)	U.S.	Europe[1]	Germany	Asia	Other	Total
Product revenue from external customers	$ 3,805.7	$ 2,626.0	$ 1,162.4	$ 688.0	$ 564.8	$ 8,846.9
Revenue from anti-CD20 therapeutic programs	1,596.7	—	—	—	61.8	1,658.5
Other revenue from external customers	429.9	9.7	—	36.7	—	476.3
Long-lived assets	1,390.5	2,337.8	25.4	16.4	21.7	3,791.8

	December 31, 2020					
(In millions)	U.S.	Europe[1]	Germany	Asia	Other	Total
Product revenue from external customers	$ 5,900.1	$ 2,495.3	$ 1,161.1	$ 596.7	$ 539.0	$ 10,692.2
Revenue from anti-CD20 therapeutic programs	1,897.4	0.1	—	—	80.3	1,977.8
Other revenue from external customers	733.6	8.0	0.1	32.9	—	774.6
Long-lived assets	1,496.3	2,290.2	31.2	16.2	10.9	3,844.8

[1] Represents amounts related to Europe less those attributable to Germany.

Long-Lived Assets

As of December 31, 2022, 2021 and 2020, approximately $2,198.5 million, $2,237.0 million and $2,180.6 million, respectively, of our long-lived assets were related to the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland.

For additional information on our Solothurn manufacturing facility, please read *Note 11, Property, Plant and Equipment,* to these consolidated financial statements.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Biogen Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Biogen Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of income, of comprehensive income, of equity and of cash flow for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Reserves for Medicaid and Managed Care Rebates

As described in Notes 1 and 5 to the consolidated financial statements, the Company recognized revenue from product sales net of reserves, including Medicaid and managed care rebates. Within accrued expense and other, total contractual adjustments amounted to $868.1 million as of December 31, 2022. A portion of this balance includes provisions for Medicaid and managed care rebates in the US. Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end. Managed care rebates represent the Company's estimated obligations to third-parties, primarily pharmacy benefit managers. These rebates result from performance-based goals, formulary position and price increase limit allowances (price protection). The calculation of the accrual for these rebates is based on an estimate of the coverage patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period. Rebate accruals for Medicaid and managed care are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expense and other current liabilities. The Medicaid and managed care estimates reflect historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

The principal considerations for our determination that performing procedures relating to reserves for Medicaid and managed care rebates is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves, as the reserves are based on assumptions developed using historical experience, current contractual requirements, specific known market events and payment patterns, which in turn led to a high degree of auditor judgment, subjectivity, and effort in applying procedures and evaluating audit evidence related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the reserves for Medicaid and managed care rebates, including controls over the assumptions used to estimate these Medicaid and managed care rebate reserves. These procedures also included, among others (i) developing an independent estimate of the Medicaid and managed care rebate reserves by utilizing third-party data related to product demand, data related to price changes, the terms of the specific rebate programs, the historical trend of actual rebate claims paid and consideration of contractual requirement changes and market events; (ii) comparing the independent estimate to management's estimate; and (iii) testing rebate claims paid by the Company, including evaluating the claims for consistency with the contractual terms of the Company's rebate agreements.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
February 15, 2023

We have served as the Company's auditor since 2003.

Corporate information

Board of Directors (as of April 21, 2023)

Stelios Papadopoulos, Ph.D.
Chairman, Biogen Inc., Chairman, Exelixis, Inc.; Chairman, Regulus Therapeutics Inc.; Chairman, Eucrates Biomedical Acquisition Corp.

Alexander J. Denner, Ph.D.
Founding Partner and Chief Investment Officer, Sarissa Capital Management LP

Caroline D. Dorsa
Retired Executive Vice President and Chief Financial Officer, Public Service Enterprise Group Incorporated

Maria C. Freire, Ph.D.
Retired President and Executive Director, Foundation for the National Institutes of Health

William A. Hawkins
Retired Chairman and CEO, Medtronic, Inc.; Senior Advisor, EW Healthcare Partners

William D. Jones
Managing Member, CityLink LLC

Jesus Mantas
Global Managing Partner for IBM Business Transformation Services

Richard C. Mulligan, Ph.D.
Mallinckrodt Professor of Genetics, Emeritus, Harvard Medical School and Head of SanaX; Vice Chairman, Sana Biotechnology, Inc.

Eric K. Rowinsky, M.D.
President and Executive Chairman, RGenix, Inc.

Stephen A. Sherwin, M.D.
Clinical Professor of Medicine, University of California, San Francisco

Christopher A. Viehbacher
President and Chief Executive Officer, Biogen Inc.

Stockholder Information

Corporate headquarters
Biogen Inc.
225 Binney Street
Cambridge, MA 02142
Phone: (617) 679-2000

SEC Form 10-K
A copy of Biogen's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission is available at sec.gov and upon request to:

Investor Relations Department
Biogen Inc.
225 Binney Street
Cambridge, MA 02142
Phone: (781) 464-2442

Transfer agent
To keep your contact information current and for stockholder questions regarding lost stock certificates, address changes and changes of ownership or names in which the shares are held, direct inquiries to:

Computershare
Phone: (781) 575-2879
Toll Free Phone: (877) 282-1168
computershare.com

By regular mail:
P.O. Box 505000
Louisville, KY 40233-5000

By overnight delivery:
462 South 4th Street
Suite 1600
Louisville, KY 40202

Independent accountant
PricewaterhouseCoopers LLP
101 Seaport Boulevard
Boston, MA 02210

News releases
As a service to our stockholders and prospective investors, Biogen's news releases are usually posted within one hour of being issued and are available at no cost at investors.biogen.com.

Market information
Our common stock trades on the Nasdaq Global Select Market under the symbol "BIIB."

ADDITIONAL RESOURCES
Access and Health Equity: **www.biogen.com/responsibility/access-and-health-equity.html**
Diversity, Equity & Inclusion: **www.biogen.com/responsibility/diversity-inclusion.html**
Environment: **www.biogen.com/responsibility/environment.html**
Global Community Lab: **www.biogen.com/responsibility/global-community-lab.html**
2022 ESG Report: **www.biogen.com/esgreport**
Reporting & Principles: **www.biogen.com/responsibility/reporting-and-principles.html**

We include our website addresses in this report only as inactive textual references and do not intend them to be active links to our website. The contents of our website are not incorporated into this report.

Biogen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