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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, 2024

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

(State or other jurisdiction of incorporation or organization)

33-0112644

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 \$33,709,755,067.

As of February 11, 2025, the registrant had 146,374,937 shares of common stock, \$0.0005 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for our 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

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**BIOGEN INC.**  
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**For the Year Ended December 31, 2024**  
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## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are being made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995 (the PSLRA) with the intention of obtaining the benefits of the “Safe Harbor” provisions of the PSLRA. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “guidance,” “hope,” “intend,” “may,” “objective,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” or the negative of these words or other words and terms of similar meaning. Given their forward-looking nature, these statements involve substantial risks and uncertainties and may be based on inaccurate assumptions. This report includes, among others, forward-looking statements regarding:

- our expected financial and operating performance;
- our long-term strategy and supporting business plans, including our product pipeline;
- our expectations about continued growth through acquisitions and key collaborative relationships;
- our belief that 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;
- our ability to obtain and maintain adequate coverage, pricing and reimbursement from third-party payors;
- our expectations regarding certain legal and regulatory proceedings and investigations; and
- our belief 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.

These forward-looking statements are based on management's current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to be materially different from those stated or implied in this document, including, among others, factors relating to:

- our substantial dependence on the anticipated amount, timing and accounting of revenue from our products, including from the successful development of new products and approval of additional indications for our existing products, including but not limited to LEQEMBI and SKYCLARYS;
  - the anticipated amount, timing and accounting of 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 product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products all of which is subject to governmental and regulatory oversight, and therefore subject to risks, including but not limited to those related to approvals, unfavorable or delayed reimbursements and coverage determinations, and changes in reimbursement policies or practices of payors and other third-parties;
  - the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other 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, prodrugs or biosimilar versions of our marketed products or competing products, including but not limited to increased competition from TECFIDERA generic entrants in the U.S. market;
  - patent terms, patent term extensions, patent office actions and expected availability and periods of regulatory exclusivity, as well as our ability to adequately enforce existing patents, including our European patent related to TECFIDERA;
  - our ability to effectively implement our corporate strategy which includes significant investment in product and pipeline candidates, including but not limited to felzartamab and nusinersen;
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- the successful execution of our strategic and growth initiatives, including acquisitions, and our ability to realize the anticipated benefits from our acquisitions of Reata and HI-Bio, including future performance of the SKYCLARYS product and further development of the felzartamab product and anticipated synergies;
  - 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, including collaboration agreements, as well as the potential benefits and results of, and the anticipated completion of, certain business development transactions, reorganizations and cost-reduction measures, including our Fit for Growth program;
  - the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, regulatory filing approvals and/or discontinuation, of our products, drug candidates and pipeline programs, including collaborations with third-parties including but not limited to Eisai and Sage, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products, including ZURZUVAE;
  - the timing, outcome and impact of administrative, regulatory, legal and other proceedings, including those related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability, investigations and other matters;
  - our ability to commercialize biosimilars, which is subject to risks such as our reliance on third-parties, competitive challenges, regulatory compliance, adequate supply, intellectual property and regulatory challenges and failure to gain market and patient acceptance;
  - our ability to finance our present and future operations and business initiatives and obtain funding for such activities on favorable terms;
  - our ability to attract, retain and motivate qualified individuals for management and other employee positions in a highly competitive environment, including potential difficulty in retaining talent following acquisitions or following the discontinuation or underperformance of one or more marketed, pre-clinical or clinical programs;
  - adverse safety events involving our marketed or pipeline products, generic, prodrugs or biosimilar versions of our marketed products or any other products from the same class as one of our products;
  - the current and potential impacts of geopolitical tensions, acts of war and other large-scale crises, including impacts to our operations, sales and the possible disruptions or delay in our plans to conduct clinical trial activities in areas of geopolitical tension, including tensions between the U.S. and China, regions affected by Russia's invasion of Ukraine and the military conflict in the Middle East;
  - the direct and indirect impact of global health outbreaks or adverse weather events on our business and operations, including sales, expense, reserves and allowances, the supply chain, manufacturing, research and development costs, clinical trials and employees;
  - our use of information technology systems and data and the potential impacts of any breakdowns, interruptions, invasions, corruptions, data breaches, destructions and/or other cybersecurity incidents of such systems or those of our business partners;
  - our incorporation of technologies using AI into some of our processes;
  - the potential impact of healthcare reform in the U.S., including the IRA and the impact of the IRA Medicare Part D redesign, 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, as well as the potential impact of legislative and regulatory changes and priorities;
  - our manufacturing capacity, including our ability to effectively manufacture biosimilars, reliance on third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities, our ability to adequately address global bulk supply risks, our ability to fully utilize our manufacturing facilities, including our Solothum facility, activities in new or existing manufacturing facilities and the expected timeline for the gene therapy, clinical packaging and other manufacturing facility in RTP, North Carolina to be operational;
  - the impact of the continued uncertainty of the credit and economic conditions in certain countries and our ability to collect accounts receivable in such countries;
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- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- changes in our effective tax rate and obligations in various jurisdictions in which we are subject to taxation; and
- the impact of new laws, regulatory actions, judicial decisions and accounting standards, or tariffs or trade restrictions applicable to our products or operations.

These forward-looking statements involve risks and uncertainties, including those that are described in *Item 1A. Risk Factors* and *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this report and elsewhere in this report, that could cause actual results to differ materially from those reflected in such statements. The factors identified above should not be construed as an exhaustive list of factors that could affect our future results and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. Because some of these risks and uncertainties cannot be predicted or quantified and some are beyond our control, you should not rely on our forward-looking statements as predictions of future events and you should not place undue reliance on these statements. Moreover, we operate in a very competitive and rapidly changing environment, new risks and uncertainties may emerge from time to time and it is not possible for us to predict all risks nor identify all uncertainties. Forward-looking statements speak only as of the date of this report and are based on information and estimates available to us at this time. 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. You should read this report with the understanding that our actual future results, performance, events and circumstances might be materially different from what we expect.

## 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

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

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

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

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## DEFINED TERMS

2023 Form 10-K	Annual Report on Form 10-K for the year ended December 31, 2023
2020 Share Repurchase Program	Board of Directors authorized program to repurchase up to \$5.0 billion of our common stock
2024 Omnibus Equity Plan	Biogen Inc. 2024 Omnibus Equity Plan
2017 Omnibus Equity Plan	Biogen Inc. 2017 Omnibus Equity Plan
2024 ESPP	Biogen Inc. 2024 Employee Stock Purchase Plan
2015 ESPP	Biogen Inc. 2015 Employee Stock Purchase Plan
2023 Term Loan	\$1.5 billion term loan credit agreement
125 Broadway	125 Broadway, Cambridge, MA
300 Binney Street	300 Binney Street, Cambridge, MA
AAC	Alzheimer's Association International Conference
AbbVie	AbbVie Inc.
Acorda	Acorda Therapeutics, Inc.
AI	Artificial Intelligence
Alkermes	Alkermes plc
ALS	Amyotrophic Lateral Sclerosis
AMP	Average Manufacturer Price
AMR	Antibody-Mediated Rejection
AOCI	Accumulated Other Comprehensive Income (Loss)
ASO	Antisense Oligonucleotide
ASU	Accounting Standards Update
ATV	Antibody Transport Vehicle
BLA	Biologics License Application
Blackstone	Blackstone Life Sciences
CCDAA	Climate Corporate Data Accountability Act
CCPA	California Consumer Privacy Act
CEO	Chief Executive Officer
CHMP	Committee for Medicinal Products for Human Use
CISA	Cybersecurity and Infrastructure Security Agency
CISO	Chief Information Security Officer
CJEU	Court of Justice of the European Union
CLE	Cutaneous Lupus Erythematosus
CLL	Chronic Lymphocytic Leukemia
CMS	Centers for Medicare & Medicaid Services
CODM	Chief Operating Decision Maker
Convergence	Convergence Pharmaceuticals Ltd.
CRFRA	Climate-Related Financial Risk Act
CRL	Complete Response Letter
CROs	Contract Research Organizations
CTAD	Clinical Trials on Alzheimer's Disease
DEA	Drug Enforcement Agency
Denali	Denali Therapeutics Inc.
Directors Plan	Biogen Inc. 2015 Non-Employee Directors Equity Plan

## DEFINED TERMS (continued)

District Court	U.S. District Court for the District of Massachusetts
DOJ	U.S. Department of Justice
DPN	Diabetic Painful Neuropathy
EC	European Commission
EHS	Environment, Health and Safety
Eisai	Eisai Co., Ltd.
EMA	European Medicines Agency
EPO	European Patent Office
ERG	Employee Resource Group
ERISA	Employee Retirement Income Security Act of 1974
ERM	Enterprise Risk Management
E.U.	European Union
FA	Friedreich's Ataxia
FASB	Financial Accounting Standards Board
FCPA	Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
Fit for Growth	Cost saving program initiated in 2023
FSS	Federal Supply Schedule
GCP	Good Clinical Practices
GDPR	General Data Privacy Regulation
Genentech	Genentech, Inc.
GILTI	Global Intangible Low Tax Income
GloBE	Global Anti-Base Erosion
GMP	Good Manufacturing Practices
Hi-Bio	Human Immunology Biosciences, Inc.
Humana	Humana Inc.
IgAN	Immunoglobulin A Nephropathy
Ionis	Ionis Pharmaceuticals Inc.
IPR&D	In-process Research and Development
IRA	Inflation Reduction Act of 2022
IT	Information Technology
IV	Intravenous
LHI	Large Hemispheric Infarction
LRRK2	Leucine-Rich Repeat Kinase 2
MAA	Marketing Authorization Application
MDD	Major Depressive Disorder
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Multiple Sclerosis
NCD	National Coverage Decision
NDA	New Drug Application
NDS	New Drug Submission

## DEFINED TERMS (continued)

Neurimmune	Neurimmune SubOne AG
NIST	National Institute of Standards and Technology
NMPA	National Medicinal Products Administration
ODD	Orphan Drug Designation
OECD	Organization for Economic Co-operation and Development
OIE	Other (Income) Expense, Net
PDUFA	Prescription Drug User Fee Act
PFAS	Per- and Polyfluoroalkyl Substances
PHS	Public Health Service
PMDA	Pharmaceuticals and Medical Devices Agency
PMN	Primary Membranous Nephropathy
Polpharma	Polpharma Biologics S.A.
PPACA	Patient Protection and Affordable Care Act
PPD	Postpartum Depression
PPMS	Primary Progressive MS
PRV	Priority Review Voucher
R&D	Research and Development
Reata	Reata Pharmaceuticals, Inc.
REMS	Risk Evaluation and Mitigation Strategies
RMS	Relapsing MS
RRMS	Relapsing-Remitting MS
RTP	Research Triangle Park
SAG	Scientific Advisory Group
Sage	Sage Therapeutics, Inc.
Samsung Bioepis	Samsung Bioepis Co., Ltd.
Samsung BioLogics	Samsung BioLogics Co., Ltd.
Sangamo	Sangamo Therapeutics, Inc.
SEC	U.S. Securities and Exchange Commission
SG&A	Selling, General and Administrative
SLE	Systemic Lupus Erythematosus
SMA	Spinal Muscular Atrophy
SMN	Survival Motor Neuron
SOD1	Superoxide Dismutase 1
SPC	Supplementary Protection Certificate
SSP	Supplemental Savings Plan
SWISSMEDIC	Swiss Agency for Therapeutic Products
TBA	Technical Boards of Appeal
TGN	Trigeminal Neuralgia
TNF	Anti-tumor Necrosis Factor
Transition Toll Tax	A one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings
U.K.	United Kingdom
U.S.	United States
U.S. GAAP	Accounting Principles Generally Accepted in the U.S.
VA	Veterans Administration



## PART I

### 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. We have a broad portfolio of medicines to treat MS, have introduced the first approved treatment for SMA, co-developed treatments to address a defining pathology of Alzheimer's disease and launched the first approved treatment to target a genetic cause of ALS. We market the first and only drug approved in the U.S. and the E.U. for the treatment of FA in adults and adolescents aged 16 years and older. We are focused on advancing our pipeline in neurology, specialized immunology and rare diseases. We support our drug discovery and development efforts through internal research and development programs, external collaborations and acquisitions.

Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY and TYSABRI for the treatment of MS; SPINRAZA for the treatment of SMA; SKYCLARYS for the treatment of FA; QALSODY for the treatment of ALS; and FUMADERM for the treatment of severe plaque psoriasis.

We also have collaborations with Eisai on the commercialization of LEQEMBI for the treatment of Alzheimer's disease and Sage on the commercialization of ZURZUVAE for the treatment of PPD. 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 for the treatment of relapsed or refractory follicular lymphoma; COLUMVI, a bispecific antibody for the 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.

We commercialize a portfolio of biosimilars of advanced biologics including: BENEPALI, an etanercept biosimilar referencing ENBREL; IMRALDI, an adalimumab biosimilar referencing HUMIRA; FLUXABI, an infliximab biosimilar referencing REMICADE; and BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in certain international markets, as well as TOFIDENCE, a tocilizumab biosimilar referencing ACTEMRA, in the U.S. and certain international markets. We also have commercialization rights related to OPUVIZ, an aflibercept biosimilar referencing EYLEA.

On July 2, 2024, we completed the acquisition of HI-Bio. As a result of this transaction we acquired HI-Bio's lead asset, felzartamab, an anti-CD38 antibody currently being evaluated for three leading indications, AMR, PMN and IgAN. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

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 2024.

### ACQUISITIONS AND DIVESTITURES

#### HUMAN IMMUNOLOGY BIOSCIENCES

On July 2, 2024, we completed the acquisition of all of the issued and outstanding shares of HI-Bio, a privately-held clinical-stage biotechnology company focused on targeted therapies for patients with severe immune-mediated diseases. HI-Bio's lead asset, felzartamab, an anti-CD38 antibody, is currently being evaluated for three leading indications, AMR, PMN and IgAN. Felzartamab has received Breakthrough Therapy Designation and ODD from the FDA for development in the treatment of PMN and AMR. Subsequent to our acquisition, felzartamab received ODD in the E.U. in IgAN and solid organ transplantation. The acquisition of HI-Bio is expected to augment our pipeline and build on our expertise in immunology.

Under the terms of this acquisition, we paid shareholders of HI-Bio approximately \$1.15 billion at closing and may pay up to an additional \$650.0 million in potential future development and regulatory milestone payments. We funded this acquisition through available cash on hand and accounted for this acquisition as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*, and recorded assets acquired and liabilities assumed at their respective fair values as of the acquisition date. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

#### SALE OF PRIORITY REVIEW VOUCHER

In April 2024 we completed the sale of our rare pediatric disease PRV, generated by the development associated with SPINRAZA, to a third party. In consideration for the PRV we received a cash payment of \$103.0 million upon the closing of the PRV purchase, of which approximately \$14.4 million was paid to Ionis. Our net portion of approximately \$88.6 million was recognized in gain on sale of priority review voucher, net within our consolidated statements of income for the year ended December 31, 2024. For additional information on the sale of our PRV, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report.

### 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.

#### LEQEMBI (lecanemab)

##### *United States*

Key developments related to LEQEMBI in the U.S. consisted of the following:

- In January 2025 the FDA approved LEQEMBI monthly IV maintenance dosing for the treatment of early Alzheimer's disease.
- In January 2025 the FDA accepted for review the BLA for LEQEMBI subcutaneous autoinjector for weekly maintenance dosing, with a PDUFA action date set for August 31, 2025.
- In July 2024 Eisai presented new clinical data from the CLARITY AD study open-label extension of LEQEMBI, demonstrating that three years of continuous LEQEMBI treatment reduced clinical decline, resulting in a clinically meaningful benefit for early Alzheimer's disease patients.

##### *Rest of World*

Key developments related to LEQEMBI (lecanemab) in rest of world markets consisted of the following:

- In January 2025 we and Eisai announced an update regarding the ongoing regulatory review of the MAA for lecanemab in the E.U., which the CHMP of the EMA previously adopted a positive opinion on in November 2024. The EC has asked the CHMP to consider information on the safety of lecanemab that became available after the adoption of the CHMP opinion in November 2024 and whether this may require an update of the opinion, and to consider whether the wording of the risk minimization measures in the opinion is clear enough to ensure correct implementation. These will be discussed at the CHMP meeting in February 2025.

- In December 2024 LEQEMBI was approved by the Federal Commission for the Protection Against Sanitary Risk in Mexico.
- In November 2024 we and Eisai announced the launch of LEQEMBI in South Korea, which had been approved by the Ministry of Food and Drug Safety in South Korea in May 2024.
- In October 2024 the Therapeutic Goods Administration of Australia issued a public statement about the initial decision not to register lecanemab. In December 2024 Eisai submitted a request for reconsideration of this decision.
- In August 2024 LEQEMBI was approved by the Medicines and Healthcare products Regulatory Agency in Great Britain and by the Ministry of Health and Prevention in the United Arab Emirates.
- In July 2024 LEQEMBI was approved in Hong Kong and Israel.
- In June 2024 we and Eisai announced the launch of LEQEMBI in China, which had been approved by the NMPA in China in January 2024.

## UCB COLLABORATION

In September 2024 we and UCB announced positive topline data from the Phase 3 PHOENYCS GO study of dapirolizumab pegol, a novel Fc-free anti-CD40L drug candidate, in people living with moderate-to-severe SLE. The Phase 3 study met the primary endpoint demonstrating clinical improvement in moderate-to-severe SLE with clinical improvements observed among key secondary endpoints. Based on these results, UCB and Biogen initiated a second Phase 3 study in late 2024.

## MANAGEMENT CHANGES

- In October 2024 we announced that Michael R. McDonnell, Executive Vice President and Chief Financial Officer, plans to retire from Biogen on March 1, 2025. Upon Mr. McDonnell's retirement, Robin C. Kramer, currently Senior Vice President and Chief Accounting Officer at Biogen, will assume the role of Executive Vice President and Chief Financial Officer.
- In January 2025 we announced the appointment of Sean Godbout as Vice President, Chief Accounting Officer and Global Corporate Controller, effective March 1, 2025, upon the transition of Robin C. Kramer, currently Senior Vice President and Chief Accounting Officer at Biogen, to the role of Executive Vice President and Chief Financial Officer.

## BOARD OF DIRECTORS UPDATE

- Effective October 1, 2024, Lloyd B. Minor, M.D. joined our Board of Directors.
- Effective January 1, 2025, Sir Menelas (Mene) Pangalos, Ph.D. 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

### NEUROLOGY

#### ALZHEIMER'S DISEASE

##### LEQEMBI (lecanemab)

- In October 2024 Eisai presented data on benefits of long-term administration of dual-acting LEQEMBI at the 2024 CTAD conference. The data presented additional measures resulting from the three years of continuous LEQEMBI treatment, showing that 46% of patients improved or had no decline and 33% showed improvement from baseline on the CDR-SB. On the ADAS-Cog14 measurement scale, 46% of patients showed improvement or no decline and 43% showed improvement. On the ADCS MCI-ADL measurement scale, 51% of patients showed improvement or no decline and 48% showed improvement.
- In July 2024 Eisai announced the results of a detailed analysis of the Phase 3 CLARITY Alzheimer's disease study of LEQEMBI at the 2024 AAIC conference. The study provided further Phase 3 analysis showing three years of continuous LEQEMBI treatment reduced clinical decline by -0.95 on CDR-SB showing continued clinically and personally meaningful benefit for early Alzheimer's disease patients.

## IMMUNOLOGY

### felzartamab

- Felzartamab was granted ODD in the E.U. in IgAN and solid organ transplantation in November 2024 and December 2024, respectively.
- In October 2024 we presented complete results from the Phase 2 IGNAZ study evaluating felzartamab, an investigational anti-CD38 monoclonal antibody, in people living with IgAN during the American Society of Nephrology Kidney Week 2024. The results from the study showed substantial reductions in proteinuria, stabilization of kidney function and sustained treatment effect more than 18 months after the last dose of felzartamab.
- In October 2024 the FDA granted felzartamab Breakthrough Therapy Designation for the treatment of late AMR without T-cell mediated rejection in kidney transplant patients.

## RARE DISEASE

### SPINRAZA (nusinersen)

- In January 2025 the FDA accepted the supplemental NDA and the EMA validated the application for a higher dose regimen of nusinersen for SMA. The higher dose regimen of nusinersen comprises a more rapid loading regimen, two 50 mg doses 14 days apart, and higher maintenance regimen, 28 mg every four months, compared to the currently approved dose of SPINRAZA.
- In September 2024 we announced positive topline data from the Phase 2/3 DEVOTE study of nusinersen, which evaluated the safety and efficacy of a higher dose regimen of nusinersen in treatment-naïve symptomatic infants with SMA.
- In March 2024 we announced new data from the Phase 4 RESPOND study for SPINRAZA. The study showed that neurofilament levels, an indicator of neurodegeneration, were reduced in nearly all study participants treated with SPINRAZA. The reductions in biomarker complement previously reported RESPOND study efficacy results showing improved motor function in most participants treated with SPINRAZA after gene therapy.

### SKYCLARYS

- In September 2024 SKYCLARYS was approved by SWISSMEDIC for the treatment of FA in adults and adolescents aged 16 years and older.
- In July 2024 the first pediatric patient was treated in the Phase 1 study of SKYCLARYS designed to identify the appropriate dose for the pediatric population living with FA.

### QALSODY

- In December 2024 the Japanese Ministry of Health, Labor and Welfare approved QALSODY in Japan.
- In October 2024 QALSODY was approved in China by the NMPA under the conditional approval pathway for the treatment of adults with ALS associated with a mutation in the SOD1 gene.
- In May 2024 the EC approved QALSODY in the E.U. for the treatment of adults with ALS associated with a mutation in the SOD1 gene. QALSODY is the first treatment approved in the E.U. to target a genetic cause of ALS.

## DISCONTINUED PROGRAMS AND STUDIES

### SAGE COLLABORATION

#### zuranolone

In October 2024 we and Sage agreed to not pursue further development of zuranolone for the potential treatment of MDD. This decision was based on the significant new investment and time we expect would be needed to conduct the additional studies required to support approval of this indication.

#### [BIIB124](#)

In July 2024 we and Sage announced that the Phase 2 KINETIC 2 dose-range study of BIIB124 did not meet its endpoints. Based on these results, we discontinued our further development of BIIB124 and terminated our rights under the collaboration and license agreement specific to BIIB124, effective February 17, 2025.

### **SAMSUNG BIOEPIS 2019 DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

In October 2024 we notified Samsung Bioepis of our decision to terminate our 2019 Development and Commercialization Agreement (the DCA Agreement) solely within the U.S. and Canada. Biogen will transfer commercialization rights for BYOOVIZ and OPUVIZ in the U.S. and Canada back to Samsung Bioepis over a period of up to 18 months. During this transition period, we will continue to commercialize BYOOVIZ. The termination does not impact the other markets in the DCA Agreement.

### **IONIS COLLABORATION**

#### [BIIB105](#)

In May 2024 we and Ionis announced that the Phase 1/2 ALSpire study of BIIB105, an investigational ASO for the potential treatment of ALS, did not meet its endpoints. Based on these results, we discontinued our further development of BIIB105.

#### [BIIB121](#)

In May 2024 we announced that we have elected not to exercise our option to license and lead development of BIIB121, an ASO for the potential treatment of Angelman syndrome.

### **MERZ THERAPEUTICS (PREVIOUSLY ACORDA THERAPEUTICS, INC.)**

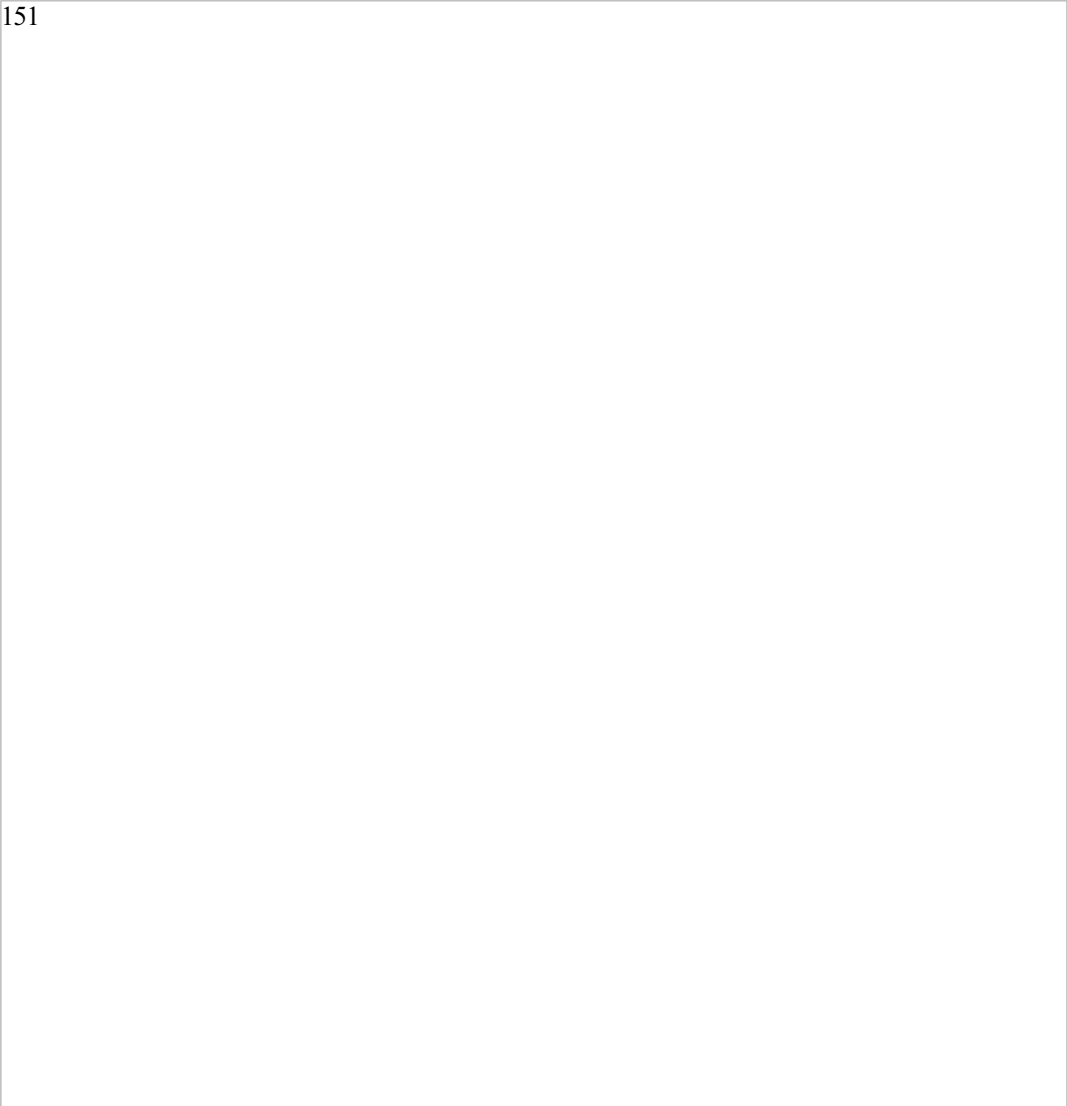
In January 2024 we notified Acorda of our decision to terminate our collaboration and license agreement, effective January 1, 2025, whereby Acorda regained global commercialization rights to FAMPYRA. On April 1, 2024, Acorda filed for bankruptcy protection and announced its intention to sell substantially all of Acorda's assets to a third party. On July 10, 2024, Merz Therapeutics announced that its subsidiary Merz Pharmaceuticals LLC had completed the acquisition of FAMPYRA, and related assets from Acorda. We are now working with Merz Therapeutics on the transition of global commercialization rights of FAMPYRA and we expect to recognize minimal revenue in 2025.

#### **BIIB143 (cemdomespib)**

In early 2025 we discontinued further development of BIIB143 (cemdomespib) for the treatment of diabetic neuropathic pain, as part of our ongoing pipeline prioritization efforts.

MARKETED PRODUCTS

The following graph shows our product revenue, revenue from anti-CD20 therapeutic programs and Alzheimer's collaboration revenue for the years ended December 31, 2024, 2023 and 2022.



<sup>(1)</sup> MS includes TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPHYRA.

<sup>(2)</sup> Rare disease includes SPINRAZA, QALSODY, which became commercially available in the U.S. during the second quarter of 2023 and commercially available in the E.U. during the second quarter of 2024, and SKYCLARYS, which was obtained as part of our acquisition of Reata in September 2023. SKYCLARYS became commercially available in the U.S. during the second quarter of 2023 and we began recognizing revenue from SKYCLARYS in the U.S. during the fourth quarter of 2023, subsequent to our acquisition. SKYCLARYS was approved and became commercially available in the E.U. during the first quarter of 2024.

<sup>(3)</sup> Biosimilars includes BENEPALI, IMRALDI, FLIXABI, BYOOVIZ, which became commercially available in certain international markets in 2023, and TOFIDENCE, which became commercially available in the U.S. during the second quarter of 2024.

<sup>(4)</sup> Alzheimer's collaboration revenue consists of our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties.

<sup>(5)</sup> Anti-CD20 therapeutic programs include RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS and LUNSUMIO, which became commercially available in the U.S. during the first quarter of 2023.

<sup>(6)</sup> Other includes FUMADERM, ADUHELM and ZURZUVAE, which became commercially available in the U.S. during the fourth quarter of 2023.



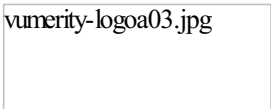


Product sales for TECFIDERA, TYSABRI and SPINRAZA each accounted for more than 10.0% of our total revenue for the years ended December 31, 2024, 2023 and 2022. For additional financial information about our product and other revenue and geographic areas where we operate, please read *Note 5, Revenue* 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.

## NEUROLOGY

### 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
	RMS RRMS in the E.U. Crohn's disease in the U.S.	None	U.S. Brazil France Germany Italy U.K.
	RMS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Japan U.K.
	RMS in the U.S. RRMS in the E.U.	Alkermes Pharma Ireland Limited, a subsidiary of Alkermes	U.S. France Germany Netherlands Spain Switzerland
	RMS	None	U.S. Canada France Germany Italy Spain
	RMS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Spain U.K.


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

## ALZHEIMER'S DISEASE

Alzheimer's disease, the most common form of dementia, is a progressive neurological illness that causes a gradual decline in cognitive abilities, usually during a span of seven to ten years. Nearly all brain functions, including memory, movement, language, judgement, behavior and abstract thinking, are eventually affected. In the U.S., Alzheimer's disease is the seventh-leading cause of death, accounting for over 120,000 deaths each year.

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. Neurofibrillary tangles are bundles of twisted filaments found within neurons. These tangles are largely made up of a protein called tau.


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

Product	Indication	Collaborator	Major Market
	Alzheimer's disease	Eisai	U.S. China Great Britain Israel Japan South Korea United Arab Emirates

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.

## NEUROPSYCHIATRY

Neuropsychiatry includes ZURZUVAE for PPD, which became commercially available in the U.S. during the fourth quarter of 2023. PPD symptoms are estimated to affect approximately one in eight women who have given birth in the U.S. According to the Centers for Disease Control and Prevention, mental health conditions are the leading cause of maternal mortality with PPD among the most common complications during and after pregnancy.

Product	Indication	Collaborator	Major Markets
	PPD in adults	Sage	U.S.

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

## RARE DISEASE

Rare disease includes SPINRAZA for SMA, QALSODY for ALS, which became commercially available in the U.S. during the second quarter of 2023 and commercially available in the E.U. during the second quarter of 2024, and SKYCLARYS for FA, which was obtained as part of our acquisition of Reata in September 2023. SKYCLARYS became commercially available in the U.S. during the second quarter of 2023 and we began recognizing revenue from SKYCLARYS in the U.S. during the fourth quarter of 2023, subsequent to our acquisition. SKYCLARYS was approved and became commercially available in the E.U. during the first quarter of 2024.




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 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.



FA is an inherited, debilitating and degenerative neuromuscular disorder that is typically diagnosed during adolescence and can ultimately lead to premature death. Patients with FA experience progressive loss of coordination, muscle weakness and fatigue, which commonly progresses to motor incapacitation, wheelchair reliance and eventually death.

ALS is a rare, progressive and fatal neurodegenerative disease that results in the loss of motor neurons in the brain and the spinal cord that are responsible for controlling voluntary muscle movement. People with ALS experience muscle weakness and atrophy, causing them to lose independence as they steadily lose the ability to move, speak, eat and eventually breathe. Average life expectancy for people with ALS is three to five years from time of symptom onset. Multiple genes have been implicated in ALS. Genetic testing helps determine if a person's ALS is associated with a genetic mutation, even in individuals without a known family history of the disease. SOD1-ALS is a mutation in the SOD1 gene, and this form of ALS is diagnosed in approximately two percent of all ALS cases.

Our Rare disease products and major markets are as follows:






Product	Indication	Collaborator	Major Markets
	SMA	Ionis	U.S. Brazil France Germany Italy Turkey
	FA in adults and adolescents aged 16 years and older	None	U.S. France Germany
	ALS in adults with mutation in SOD1 gene	Ionis	U.S. Germany

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

Biosimilars are a group of biologic medicines that are highly similar to currently available biologic therapies developed by companies known as "originators". We commercialize a portfolio of biosimilars of advanced biologics including: BENEPALI, an etanercept biosimilar referencing ENBREL; IMRALDI, an adalimumab biosimilar referencing HUMIRA; FLIXABI, an infliximab biosimilar referencing REMICADE; and BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in certain international markets, as well as TOFIDENCE, a tocilizumab biosimilar referencing ACTEMRA, which became commercially available in the U.S. during the second quarter of 2024 and approved in the E.U. during the second quarter of 2024. We also have commercialization rights related to OPUVIZ, an aflibercept biosimilar referencing EYLEA, which was approved in the E.U. during the fourth quarter of 2024.

Our current biosimilar products and major markets are as follows:







Product	Indication	Collaborator	Major Markets
	Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Axial spondyloarthritis Plaque psoriasis Paediatric plaque psoriasis	Samsung Bioepis	France Germany Italy Spain Sweden U.K.
	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	Samsung Bioepis	France Germany Italy Spain Sweden
	Rheumatoid arthritis Crohn's disease Paediatric Crohn's disease Ulcerative colitis Paediatric ulcerative colitis Ankylosing spondylitis Psoriatic arthritis Psoriasis	Samsung Bioepis	France Germany Italy Norway Spain U.K.
	Neovascular (wet) age-related macular degeneration Macular edema following retinal vein occlusion Myopic choroidal neovascularization	Samsung Bioepis	France Germany Switzerland U.K.
	Rheumatoid arthritis Polyarticular juvenile idiopathic arthritis Systemic juvenile idiopathic arthritis Giant cell arteritis COVID-19	Bio-Thera Solutions, Ltd.	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

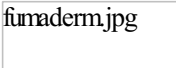
We have agreements with Genentech that entitle us to certain business and financial rights with respect to RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS, LUNSUMIO and COLUMVI, as well as the option to add other potential anti-CD20 therapies.

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

Product	Indication	Major Markets
	Non-Hodgkin's lymphoma CLL Rheumatoid arthritis Two forms of ANCA-associated vasculitis Pemphigus vulgaris	U.S. Canada
	Non-Hodgkin's lymphoma CLL	U.S.
	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.
	RMS PPMS	U.S. E.U.
	Relapsed or refractory follicular lymphoma	U.S.
	Relapsed or refractory diffuse large B-cell lymphoma Large B-cell lymphoma arising from 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
	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 fuller, healthier 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 support 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 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 groups and communities, among others, to determine how best to address requests for access to our investigational therapies in ways that are consistent with our patient-focused values and compliant with regulatory standards and protocols. In appropriate situations, patients may have access to investigational therapies through clinical trials, early access programs, post-trial access programs or compassionate use based on humanitarian 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, LUNSUMIO and COLUMMI are marketed by the Roche Group and its sublicensees.

We commercialize BENEPALI, IMRALDI, FLIXABI and BYOOVIZ pursuant to our agreement with Samsung Bioepis in certain international markets.

We focus our sales and marketing efforts on 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 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.

RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS, LUNSUMIO and COLUMMI 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. We also distribute BYOOVIZ in certain international markets and TOFIDENCE 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, 2024, 2023 and 2022, and on a combined basis, accounted for approximately 39.3%, 36.9% and 37.9%, 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., the E.U. and Japan and in selected other countries 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., additional patent term may be awarded due to U.S. Patent and Trademark Office delays in prosecuting the application. 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 vary, in accordance with local law. For example, in a number of European countries, SPCs can be granted to a product to compensate in part for delays in obtaining marketing approval.

Regulatory exclusivity, which may consist of regulatory data protection and market protection, can also 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 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 utilizing 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 U.S. Patent and Trademark Office and the patent or trademark offices of other countries. We also use trademarks licensed from third parties. 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 may be 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 <sup>(1)</sup>
TECFIDERA	Europe	2,653,873	Methods of use	2028
PLEGRIDY	U.S.	8,017,733	Polymer conjugates of interferon beta-1a	2027
	Europe	1,476,181	Polymer conjugates of interferon-beta-1a and uses thereof	2023 <sup>(2)</sup>
TYSABRI	U.S.	8,124,350	Methods of treatment	2027
	U.S.	8,871,449	Methods of treatment	2026
	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
	U.S.	12,066,442	Methods of treatment	2032
	Europe	1,872,136	Method of treatment	2026
	Europe	2,170,390	Formulation	2028
	Europe	2,645,106	Method of treatment	2026
	Europe	3,264,094	Method of treatment	2026
	Europe	3,339,865	Safety-related assay	2031
	Europe	3,575,792	Safety-related assay	2032
	Europe	4,152,004	Safety-related assay	2031
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
	Europe	3,253,377	Formulation	2035
SPINRAZA	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
	U.S.	12,013,403	Methods for Treating Spinal Muscular Atrophy	2036
	Europe	1,910,395	Compositions and methods for modulation of SMN2 splicing	2026 <sup>(3)</sup>
	Europe	2,548,560	Compositions and methods for modulation of SMN2 splicing	2026 <sup>(4)</sup>
	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 <sup>(6)</sup>
LEQEMBI	U.S.	8,025,878	Protofibril selective antibodies and the use thereof	2027 <sup>(1)(5)</sup>

Product	Territory	Patent No.	General Subject Matter	Patent Expiration <sup>(1)</sup>
QALSODY	U.S.	10,385,341	Compositions for modulating SOD-1 expression	2035 <sup>(1)(5)</sup>
	U.S.	10,669,546	Compositions for modulating SOD-1 expression	2035
	U.S.	10,968,453	Compositions for modulating SOD-1 expression	2035
	Europe	3,126,499	Compositions for modulating SOD-1 expression	2035 <sup>(1)(8)</sup>
	Europe	3,757,214	Compositions for modulating SOD-1 expression	2035
ZURZUAE	U.S.	9,512,165	19-nor C3, 3-disubstituted C21-N-pyrazolyl steroids and methods of use thereof	2034 <sup>(5)</sup>
	U.S.	10,172,871	19-nor C3, 3-disubstituted C21-N-pyrazolyl steroids and methods of use thereof	2034 <sup>(5)</sup>
	U.S.	10,342,810	19-nor C3, 3-disubstituted C21-N-pyrazolyl steroids and methods of use thereof	2034 <sup>(5)</sup>
	U.S.	11,236,121	Crystalline 19-nor C3, 3-disubstituted C21-N-pyrazolyl steroid	2034 <sup>(5)</sup>
	U.S.	8,124,799	Antioxidant Inflammation Modulators: Oleanolic Acid Derivatives with Amino and other Modifications at C-17 (Composition)	2029 <sup>(5)</sup>
SKYCLARYS	U.S.	8,440,854	Antioxidant Inflammation Modulators: Oleanolic Acid Derivatives with Amino and other Modifications at C-17 (Composition)	2029 <sup>(5)</sup>
	U.S.	8,993,640	2,2-Difluoropropionamide Derivatives of Bardoxolone Methyl, Polymorphic Forms and Methods of Use Thereof (Composition)	2033 <sup>(5)</sup>
	U.S.	9,670,147	Antioxidant Inflammation Modulators: Oleanolic Acid Derivatives with Amino and other Modifications at C-17 (Composition)	2029 <sup>(5)</sup>
	U.S.	9,701,709	2,2-Difluoropropionamide Derivatives of Bardoxolone Methyl, Polymorphic Forms and Methods of Use Thereof (Composition)	2033 <sup>(5)</sup>
	U.S.	11,091,430	Antioxidant Inflammation Modulators: Oleanolic Acid Derivatives with Amino and other Modifications at C-17 (Treatment Method)	2029 <sup>(5)</sup>
	Europe	2,276,493	Antioxidant Inflammation Modulators: Oleanolic Acid Derivatives with Amino and other Modifications at C-17 (Composition)	2029
	Europe	2,841,445	2,2-Difluoropropionamide Derivatives of Bardoxolone Methyl, Polymorphic Forms and Methods of Use Thereof (Composition)	2033 <sup>(7)</sup>
	Europe	3,444,261	2,2-Difluoropropionamide Derivatives of Bardoxolone Methyl, Polymorphic Forms and Methods of Use Thereof (Composition)	2033

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
PLEGRIDY	U.S.	2026
SPINRAZA	E.U.	2029
LEQEMBI	U.S.	2035
QALSODY	U.S.	2030
ZURZUAE	U.S.	2028
SKYCLARYS	U.S.	2030

- (2) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2028.
- (3) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2031.
- (4) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2031.
- (5) A patent with this subject matter may be entitled to patent term extension in the U.S.
- (6) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2032.
- (7) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2038.
- (8) This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2039.

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 scientific, 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 regulatory and commercial expertise to effectively advance and 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 could eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. Similarly, developments of new standards of care practices, treatment options or cures for the diseases our products treat could have similar impacts.

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.

## GENERIC AND BIOSIMILARS COMPETITION

Certain of our products already face, or may face in the future, competition 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 some jurisdictions a decrease in reimbursed price is mandated by law. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenue in a short period of time.

Multiple TECFIDERA generic entrants are now in North America, Brazil and certain European countries and have deeply discounted prices compared to TECFIDERA. We are defending the validity of our EP 2 653 873 patent related to TECFIDERA and expiring in 2028 in opposition proceedings in the European Patent Office. We are also engaged in litigation in Europe to defend and enforce national counterparts of our EP 2 653 873 patent, with mixed results. The generic competition for TECFIDERA has significantly reduced our TECFIDERA revenue and we expect that TECFIDERA revenue will continue to decline.

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.

A biosimilar entrant of TYSABRI was approved in the U.S. and the E.U. in 2023. We expect that future sales of TYSABRI may be adversely affected by the entrance of this biosimilar.

## NEUROLOGY

### MULTIPLE SCLEROSIS

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 competing 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. Another competing product that was approved in the U.S. in 2020 and the E.U. in 2021 is KESIMPTA, a treatment for RMS that was developed by Novartis AG. While we have a financial interest in OCREVUS, future sales of our MS products may be adversely affected if OCREVUS and KESIMPTA continue to gain market share, or if other MS products that we or our competitors are developing are commercialized.

### ALZHEIMER'S DISEASE

The market for the treatment of Alzheimer's disease is undeveloped and could be subject to rapid change in the future. Most current treatments are symptomatic or intended to improve quality of life. Along with us, several companies are working to develop additional treatments. We and our collaboration partner Eisai co-commercialize LEQEMBI, an anti-amyloid antibody for the treatment of Alzheimer's disease. In 2024 a competing product, KISUNLA, a treatment for early symptomatic Alzheimer's disease that was developed by Eli Lilly and Company, was approved in the U.S. We are aware of other products now in development that, if approved, may also compete with LEQEMBI.

## RARE DISEASE

### SPINAL MUSCULAR ATROPHY

We face competition from a gene therapy product ZOLGENSMA (onasemnogene abeparvovec-xioi) and an oral product EVRYSDI (risdiplam). We expect that we will experience competition from both products in additional jurisdictions in the future, as well as from the launch of new formulations of those products, which may adversely affect our sales of SPINRAZA.

## RESEARCH AND DEVELOPMENT PROGRAMS

A commitment to research and development 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 capabilities in small molecule, antisense, gene therapy 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) <sup>(1)(2)</sup> - Early Alzheimer's	Approved
	Lecanemab (Aβ mAb) <sup>(1)</sup> - Preclinical Alzheimer's	Phase 3
	Lecanemab (Aβ mAb) <sup>(1)</sup> - Subcutaneous autoinjector maintenance - Early Alzheimer's	Regulatory Review
	Lecanemab (Aβ mAb) <sup>(1)</sup> - Subcutaneous autoinjector initiation - Early Alzheimer's	Phase 3
Neuropsychiatry	BIIB080 (tau ASO) <sup>(1)</sup> - Alzheimer's	Phase 2
	Zuranolone (GABA <sub>A</sub> PAM) <sup>(1)(3)</sup> - PPD	Approved/Regulatory Review
Specialized Immunology	Felzartamab (anti-CD38 mAb) - AMR	Phase 2
	Felzartamab (anti-CD38 mAb) - IgAN	Phase 2
	Felzartamab (anti-CD38 mAb) - PMN	Phase 2
	Felzartamab (anti-CD38 mAb) - Lupus nephritis	Phase 1
	Izastobart (C5aR1 mAb) - complement mediated disease	Phase 1
	Dapirolizumab pegol (anti-CD40L) <sup>(1)</sup> - SLE	Phase 3
	Litifilimab (anti-BDCA2) - SLE	Phase 3
	Litifilimab (anti-BDCA2) - CLE	Phase 3
Neuromuscular Disorders	Omaveloxolone (Nrf2 activator) - FA <sup>(4)</sup>	Approved
	Omaveloxolone (Nrf2 activator) - Pediatric FA	Phase 1
	Tofersen (SOD1 ASO) <sup>(1)(5)</sup> - SOD1 ALS	Approved
	HD Nusinersen (SMN2 splice modulator) - SMA	Regulatory Review
	BIIB115 (SMN ASO) <sup>(1)</sup> - SMA	Phase 1b
Parkinson's and Movement Disorders	BIIB122 (LRRK2 inhibitor) <sup>(1)</sup> - Parkinson's	Phase 2
Multiple Sclerosis	BIIB091 (peripheral BTK inhibitor) - MS	Phase 2

<sup>(1)</sup> Collaboration program

<sup>(2)</sup> Granted accelerated approval in the U.S. in January 2023 and traditional approval in the U.S. in July 2023. Outside the U.S., LEQEMBI is now approved in Japan (September 2023), China (January 2024), South Korea (May 2024), Hong Kong (July 2024), Israel (July 2024), United Arab Emirates (August 2024), Great Britain (August 2024) and Mexico (December 2024).

<sup>(3)</sup> Granted approval in the U.S. in August 2023, pending DEA scheduling, which was completed in October 2023, under the brand name ZURZUVAE.

<sup>(4)</sup> Granted approval in the U.S. in February 2023 and the E.U. in February 2024, under the brand name SKYCLARYS.

<sup>(5)</sup> Granted accelerated approval in the U.S. in April 2023, the E.U. in May 2024 and China in October 2024 under the brand name QALSODY.

# Option agreement

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**

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. We and Eisai 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.

### **SAGE THERAPEUTICS, INC.**

We have a global collaboration and license agreement with Sage to jointly develop and commercialize ZURZUVAE (zuranolone) for the treatment of PPD.

Under this collaboration, both companies will share equal responsibility and costs for development as well as profits and losses for commercialization in the U.S. Outside of the U.S., we are responsible for development and commercialization, excluding Japan, Taiwan and South Korea.

### **IONIS**

We have several exclusive, worldwide option and collaboration agreements with Ionis to develop and commercialize antisense therapeutics, including SPINRAZA for the treatment of SMA and QALSODY for the treatment of ALS with SOD1 mutations, as well as other research programs for a broad range of neurological diseases. Under these agreements, we have the option to license therapies arising out of these collaborations and will be responsible for their development and commercialization. Ionis may receive potential milestones and royalties on net sales if we successfully develop the product candidate after option exercise.

### **GENENTECH**

We have agreements with Genentech that entitle us to certain business and financial rights with respect to RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS, LUNSUMIO and COLUMVI, as well as the option to add other potential anti-CD20 therapies.

### **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 jointly commercialize dapirolizumab pegol and share profits and losses equally.

## DENALI

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 the LRRK2 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.

## SAMSUNG BIOEPIS

We have an agreement with Samsung Bioepis to commercialize three anti-TNF biosimilar product candidates in certain countries in Europe. 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.

We have also secured the exclusive rights to commercialize BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in certain international markets, and OPUVIZ, an aflibercept biosimilar referencing EYLEA, which was approved in the E.U. during the fourth quarter of 2024. 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.

## 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 PRV.

As part of our acquisition of Reata in September 2023 we obtained a rare pediatric disease PRV in connection with the approval of SKYCLARYS, which was approved by the FDA in February 2023.

#### 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 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 and in-vitro diagnostic medical devices entered into force in the E.U. The medical devices regulations became applicable in May 2021 and the in-vitro diagnostic medical devices 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 MAA 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, accelerated assessment and conditional marketing authorization. Priority Medicines Evaluation Scheme 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 GMP 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 GCP). Regulatory agencies enforce current GCP through periodic inspections of trial sponsors, principal investigators and trial sites, CROs and institutional review boards. If our studies fail to comply with applicable current GCP 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 current GCP 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 could be made under the Clinical Trial Directive (the existing regulatory framework) through 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 PPACA amended the PHS Act 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 ODD 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 ODD 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 ODD in the U.S., the E.U. and Japan; QALSODY and SKYCLARYS have been granted ODD in the U.S. and the E.U.; and felzartamab has been granted ODD in the U.S. for development in the treatment of PMN and AMR and in the E.U. in IgAN and solid organ transplantation.

## 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 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 of the drugs. Manufacturers, including us, are required to provide average sales price 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 average sales price, 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, the IRA was signed into law, 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 up to 10.0% of costs up to the \$2,000 cap and up to 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.

- **Federal Agency Discounted Pricing:** Our products are subject to discounted pricing when purchased by federal agencies via the FSS. FSS participation is required for our products to be covered and reimbursed by the VA, Department of Defense, Coast Guard and 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 PHS Act. 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 LAWS AND 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. 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, North Carolina 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. 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.

### Data Privacy

Regulators currently impose data privacy and security requirements, which include monetary fines for privacy violations. For example, the European Parliament and the Council of the E.U. adopted a comprehensive 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. In addition, several U.S. jurisdictions have similar data privacy laws, such as the CCPA and California Privacy Rights Act.

## MANUFACTURING

We seek to ensure an uninterrupted supply of medicines to patients around the world. To that end, we regularly 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 the fourth quarter of 2021 we began construction of a new gene therapy, clinical packaging and other manufacturing facility in RTP, North Carolina to support our gene therapy pipeline across multiple therapeutic areas. We estimate the construction of this manufacturing facility will be completed during 2025. As we continue to advance our research and development prioritization efforts, which includes refocusing our investment in gene therapy, we are evaluating several alternative uses for this facility.

## MANUFACTURING FACILITIES

Our manufacturing facilities include:

Facility	Product Manufactured
RTP, North Carolina	AVONEX PLEGRIDY TYSABRI QALSODY Other*
Solothurn, Switzerland	LEQEMBI TYSABRI

\* 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, North Carolina, 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 have an oligonucleotide synthesis manufacturing facility in RTP, North Carolina. This facility gives us the capability to manufacture both commercial and clinical ASOs, including QALSODY, and beginning in 2025 this facility will manufacture SPINRAZA.

In order to support our future growth and drug development pipeline, we built a large-scale biologics manufacturing facility in Solothurn, Switzerland. In the second quarter of 2021 a portion of the facility (the first manufacturing suite) received a GMP multi-product license from SWISSMEDIC and was placed into service. The second manufacturing suite, which was also licensed to operate by SWISSMEDIC, became operational in the first quarter of 2024. Solothurn has been approved for the manufacture of LEQEMBI.

Genentech is responsible for all worldwide manufacturing activities for bulk RITUXAN, RITUXAN HYCELA and GAZYVA and has sourced the manufacture of certain bulk requirements to a third party.

## THIRD-PARTY SUPPLIERS AND MANUFACTURERS

We principally use third parties to manufacture the active pharmaceutical ingredient and the final product for our small molecule products and product candidates, including TECFIDERA, VUMERITY 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. We endeavor to assure continuity of supply of such raw materials, devices and supplies 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. In addition, one of our contract manufacturers for IMRALDI and BENEPALI was acquired by a third party in December 2024. We have evaluated the impact this will have on our biosimilars business and have mitigation activities in progress designed to ensure supply continuity.

## CORPORATE RESPONSIBILITY

### INTRODUCTION

Our Corporate Responsibility strategy and programs are designed to deliver meaningful results in the areas where we believe we can have the greatest impact. We have bolstered our efforts in access and health equity and refocused our Biogen Foundation efforts in the communities where we operate and to help deliver better health. Our environmental strategy is designed to balance impact in line with investment and to drive sustainability into our core operations.

### GOVERNANCE

Corporate Responsibility oversight is formally embedded into our Board of Directors' corporate governance principles. Our Board of Directors annually reviews our Corporate Responsibility strategy, progress and goals. We also regularly review our environmental commitments within the context of our business performance and external challenges. We remain committed to engaging employees and suppliers.

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 Corporate Responsibility priorities.

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.

### RISK MANAGEMENT

Our Board of Directors believes that a fundamental part of risk management is identifying and understanding the risks we face, monitoring these risks and adopting appropriate controls and mitigation of such risks. Our Board of Directors and its committees are responsible for reviewing our risk framework and governance and management's exercise of its responsibility to assess, monitor and manage our significant risk exposures. Our Board of Directors oversees an enterprise-wide approach to risk management, which is designed to support execution of our strategy and achievement of our objectives to improve long-term operational and financial performance and enhance stockholder value.

We have a company-wide ERM program to identify, mitigate and monitor enterprise-level risks that may affect our ability to achieve our objectives. The ERM program is overseen by our ERM Committee, a cross-functional group of business leaders representing all of our key business functions. On an ongoing basis, we evaluate the greatest risks to our business, their underlying risk drivers and the associated mitigation activities and controls.

## CLIMATE RISK MANAGEMENT

We believe that the areas of risk that are fundamental to the success of our enterprise and rise to enterprise-level risks includes, among other things, environmental matters. Our ERM framework is designed to ensure climate-related risks and opportunities are monitored and integrated into our overall business strategy. Our ERM process includes evaluating identified risks, including any climate-related physical and transition risks, by engaging leaders across the company.

We identify climate risk as the risk of loss arising from climate change which comprises both physical risk and transition risk. Physical risk considers how the physical impacts of climate change (e.g., increased frequency and intensity of 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 biosimilars market and potential shifts in the regulatory environment that disadvantage the use of fossil fuels, PFAS or other materials may make it difficult for us to fulfill business obligations or cause us to incur substantial expense.

Identified climate-related material risks and opportunities are reported to our ERM team, which reports to our ERM Committee with oversight by our Board of Directors. We endeavor to 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.

## CLIMATE-RELATED DISCLOSURES

We monitor global climate-related disclosure requirements to prepare for reporting, progress activities and publish materials designed to ensure our compliance under applicable laws and regulations.

The E.U., California and certain other countries in which we do business have enacted legislation and regulations to enhance disclosures related to the impacts of climate-related matters. The E.U.'s Corporate Sustainability Reporting Directive will require expansive disclosures on various environmental and social matters for companies whose business and assets exceed certain thresholds within E.U. countries. California's environmental disclosure laws will impose additional climate-related reporting requirements on large companies conducting business in the state of California.

## HUMAN CAPITAL

As of December 31, 2024, we had approximately 7,605 employees worldwide. Approximately 4,255 employees were employed in the U.S. and approximately 3,350 employees were employed in foreign countries. As of December 31, 2024, 30.9% of Biogen's U.S. manager-level and above positions were held by ethnic or racial minorities. Globally, 48.3% of Biogen's positions at the director-level and above were held by women as of December 31, 2024.

## CULTURE AND ENGAGEMENT

Our values and merit-based culture guide every action we take, from pioneering new therapies to promoting health access for all patients. To continue to build on our strong culture, we implemented the New Biogen Way, aimed at maintaining our spirit of innovation and patient-centricity while advancing a more entrepreneurial business mindset and results-focused approach.

These are the essentials that are designed to work together to help us successfully achieve our mission:



<b>Pioneer:</b> We boldly advance rigorous science to drive innovation in medicine.	<b>Think broadly:</b> We are humble and curious, integrating external and internal advancements to successfully compete.	<b>Drive results:</b> We achieve high performance and have a greater impact by being decisive and solution-oriented, while effectively managing risk.
<b>Ethical:</b> We act with the highest integrity with each other and all who place their trust in us.	<b>Inclusive:</b> We are open and embrace and leverage differences, as well as treat everyone with care and dignity.	

We use an employee survey program to understand employee engagement, giving employees an opportunity for feedback. 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 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 those employee perspectives to guide us to take actions that are designed to improve engagement and support and help maintain our reputation as a great place to work for all our employees.

## GLOBAL COMPETENCY

Many factors influence employee success and well-being. We work to foster a workplace to allow employees to deliver on our shared mission. 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 are trained to coach employees for performance, and to engage in employee development discussions to support growth and learning.

Opportunities for ongoing learning can contribute to employee engagement and success. Development occurs through on-the-job learning, challenging new assignments, leadership development programs, instructor-led training, online learning, mentoring and more. With some employees continuing to work from home, virtual learning plays a key role. Virtual learnings are available through Biogen University as well as Coursera.

To create and sustain an inclusive workplace reflective of the patients we serve, we offer programs that invest in our talent pipeline and in our current leaders, including:

- *Global Leadership Summit:* Immersing leaders in topics designed to help them shape culture and build resilience.
- *Advance Your Leadership Potential:* Preparing high-potential individual contributors for first-level leadership roles.
- *Executive Coaching:* Coaching program available to support individuals as they work toward enhancing their impact in the organization.

## 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.

## COMPENSATION AND BENEFITS

Our approach to employee compensation and benefits is designed to deliver merit-based cash, equity and benefit programs that are competitive with those offered by leading companies in the biotechnology industry, and to attract, motivate and retain talent to build a strong, engaged and productive workforce that is equipped to deliver forward-looking business priorities.

We establish components and ranges of compensation based on market and benchmark data. Within this context, we strive to pay all employees fairly within a reasonable range, taking into consideration factors such as role; merit; market data; job location; relevant experience; and individual, business unit and company performance. In addition, we are committed to providing flexible benefits designed to allow our 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 fairness of compensation decisions, for individual employees and our workforce as a whole.

## RECRUITMENT AND RETENTION

We seek to recruit and retain highly qualified employees. A business-wide priority is to strengthen our culture and the employee experience. We believe our wellness initiatives and flexible work arrangements empower employees, increasing workplace satisfaction and allowing us to retain and attract key talent. We examine employee total rewards across four pillars: physical, financial, emotional and social well-being. We regularly assess our global benefits, and we believe we remain competitive with other companies in terms of comprehensive total rewards. We also conduct affordability analyses to benchmark whether our benefits program costs are appropriate and fair.

Our total rewards program is designed to meet the needs of employees in local markets and includes retirement savings plans, financial advising, LTI plans and incentive grants, company-paid life insurance and disability coverage, tuition reimbursement and college-planning services. Our global employee assistance program provides support to all employees and their family members worldwide.

## WORKPLACE HEALTH AND SAFETY

The safety and well-being of our employees is a priority for Biogen, 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 facility. Our EHS policies and practices are intended to protect not only our employees, but also the surrounding communities where we operate.

We maintain an EHS management system, which documents our health and safety management practices, including the following elements:

- risk and opportunity assessments to identify what could cause harm in the workplace;
- prioritization and integration of action plans with quantified targets to address those risks;
- integration of actions to prepare for and respond to emergency situations;
- evaluation of progress in reducing/preventing health issues/risks against targets;
- procedures to investigate work-related injuries, ill health, diseases and incidents; and
- training to employees and contractors to raise awareness and reduce operational health and safety incidents.

We have also introduced safety criteria in our procurement and contractual requirements.

## OUR CULTURE OF INCLUSION

We are committed to merit-based opportunities and believe discrimination is unacceptable. We believe an inclusive workplace fosters innovation and helps us to better support patients. Our strategy outlines steps to build our talent and strengthen our leadership, improve health outcomes for patients in the disease areas we treat and contribute to the communities where we live and work.

Our ERGs are formed by interested employees and sponsored by a senior leader of the company. Membership of each ERG is open to all employees. Our ERGs provide opportunities for employees to build connections, foster leadership development and cultivate a sense of belonging. Our current ERGs include:

- **AccessAbility:** Supports employees with disabilities and employees who are caregivers of individuals with disabilities and their allies.
- **Biogen Veterans Network:** Encourages veterans and allies to connect and support one another.
- **IGNITE:** Brings together early-career professionals and their allies.
- **Mosaic:** Fosters awareness and appreciation of different cultural backgrounds, in addition to promoting networking and development opportunities for employees.
- **ourIMPACT:** Addresses environmental issues at work, in employees' personal lives and in the communities where we live and work.
- **Parenting Network Group:** Provides support, networking and development opportunities to working parents and caregivers, as well as helping employees navigate the challenges of work-life balance.
- **ReachOUT:** Brings together LGBTQ+ employees and their allies.
- **Women's Impact Network:** Creates networking, mentoring and learning opportunities for women and allies worldwide.



## INFORMATION ABOUT OUR EXECUTIVE OFFICERS (as of February 12, 2025)

Officer	Current Position	Age	Year Joined Biogen
<a href="#">Christopher A. Viehbacher</a>	President, Chief Executive Officer	64	2022
<a href="#">Susan H. Alexander</a>	Executive Vice President, Chief Legal Officer	68	2006
<a href="#">Michael R. McDonnell<sup>(1)</sup></a>	Executive Vice President and Chief Financial Officer	61	2020
<a href="#">Nicole Murphy</a>	Executive Vice President, Pharmaceutical Operations and Technology	52	2015
<a href="#">Ginger Gregory, Ph.D.</a>	Executive Vice President and Chief Human Resources Officer	57	2017
<a href="#">Rachid Izzar</a>	Executive Vice President, Global Product Strategy and Commercialization	50	2019
<a href="#">Priya Singhal, M.D., M.P.H.</a>	Executive Vice President, Head of Development	57	2020
<a href="#">Jane Grogan, Ph.D.</a>	Executive Vice President, Head of Research	58	2023
<a href="#">Adam Keeney, Ph.D.</a>	Executive Vice President, Head of Corporate Development	48	2023
<a href="#">Robin C. Kramer<sup>(1)</sup></a>	Senior Vice President, Chief Accounting Officer	59	2018

<sup>(1)</sup> Michael R. McDonnell, Executive Vice President and Chief Financial Officer, plans to retire from Biogen on March 1, 2025. Upon Mr. McDonnell's retirement, Robin C. Kramer, currently Senior Vice President and Chief Accounting Officer at Biogen, will assume the role of Executive Vice President and Chief Financial Officer.

### [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.

#### *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 since April 2018. Prior to that, Ms. Alexander served as our Executive Vice President, Chief Legal and Corporate Services 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.)

## **Jane Grogan, Ph.D.**

### *Experience*

Dr. Grogan has served as our Executive Vice President and Head of Development since October 2023. Dr. Grogan most recently served as the Chief Scientific Officer at Graphite Bio from 2021 to 2023 and ArsenalBio from 2019 to 2021, both cell and gene therapy companies. From 2004 to 2019 Dr. Grogan held several roles in increasing seniority at Genentech across Immunology and Immuno-oncology, covering research strategies and drug development across Rheumatoid Arthritis, Lupus, MS, Inflammatory Bowel Disease and Cancer.

### *Education*

- Leiden University, Ph.D. in Immunology
- University of Melbourne, B.Sc in Biochemistry and Pharmacology

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**Adam Keeney, Ph.D.**

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**Experience**

Dr. Keeney has served as our Executive Vice President and Head of Corporate Development since April 2023. Dr. Keeney brings more than 20 years of experience leading R&D, business development and strategy organizations at industry-leading companies within biotech and large pharma. Dr. Keeney most recently served as the Chief Executive Officer of NodThera, a clinical stage biotech company focused on chronic inflammation from 2018 to 2022. Prior to NodThera, Dr. Keeney was at Sanofi from 2014 to 2018 where he had responsibility for all of Sanofi Gezyme's business development activities, including early- and late-stage deals across therapeutic areas and modalities, successfully completing several significant transactions. From 2004 to 2013 Dr. Keeney worked at Johnson & Johnson where he held a number of business development roles with increasing responsibility and started his career at Lundbeck as a discovery scientist.

**Education**

- University of Nottingham, UK, Ph.D. in Neuropharmacology
- University of Leeds, UK, BSc (Hons)

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**Robin C. Kramer**

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**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 previously served as a Board Member for the Center for Women & Enterprise from August 2020 to November 2024, 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**

- Amata Pharmaceuticals, Inc., a biotechnology company

**Education**

- Salem State University, Bachelor of Science in Business Administration, 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](http://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 SEC. 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.

## USE OF WEBSITE TO PROVIDE INFORMATION

From time to time, we have used, and expect in the future to use, our website as a means of disclosing material information to the public in a broad, non-exclusionary manner, including for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Financial and other material information regarding the Company is routinely posted on our website and accessible at [www.biogen.com](http://www.biogen.com). In order to receive notifications regarding new postings to our website, investors are encouraged to enroll on our website to receive automatic email alerts. None of the information on our website is 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 relating to inflation and those resulting from governmental or regulatory requirements, including those relating to any future potential drug price negotiation under the IRA; 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, geopolitical events, regulatory or legislative developments; or
- our ability to maintain a positive reputation among patients, healthcare providers and others, which may be impacted by our pricing and reimbursement decisions.

LEQEMBI is in the early stages of commercial launch in the U.S. and certain international markets and SKYCLARYS is in the early stages of commercial launch in the U.S. and certain European markets. 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 and our ability to successfully commercialize SKYCLARYS 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;
- requirements such as participation in a registry and the use of imaging or other diagnostics for LEQEMBI;
- our ability to obtain approval in other markets;
- the approval of other new products for the same or similar indications;
- 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 and/or third parties;
- Biogen's ability to obtain and maintain adequate reimbursement for SKYCLARYS; and
- the effectiveness of Biogen's commercial strategy for marketing SKYCLARYS.

#### *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, presents additional challenges and risks, including obtaining approval from regulatory authorities that have limited experience with the development of such therapies. For example, we are currently seeking approval of LEQEMBI in Europe and the approval of a subcutaneous formulation of LEQEMBI in the U.S. and any delays or challenges may impact our ability to realize the anticipated benefits from LEQEMBI.

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 or delay 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 prioritize other opportunities in our pipeline.

Additionally, 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 has in the past and may in the future 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 and maintain appropriate pricing and adequate reimbursement for our products compared to our competitors in key 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 depends upon internal development projects, commercial initiatives and external opportunities, which may include the acquisition and in-licensing of products, technologies, companies, the entry into strategic alliances and collaborations or our Fit for Growth program, as well as our ability to execute on strategic decisions and initiatives.

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 to make any such acquisition if suitable candidates are identified.

We may fail to initiate or complete transactions for many reasons, including failure to obtain regulatory or other approvals as well as a result of disputes or litigation. Furthermore, we may not be able to achieve the full strategic and financial benefits expected to result from transactions or strategic decisions, such as the decision to retain the biosimilars business, 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. For example, we recently acquired Reata and HI-Bio and are in the process of integrating Reata and HI-Bio into our Company. The ultimate success of our acquisitions of Reata and HI-Bio and our ability to realize the anticipated benefits from the acquisitions, including future performance of the SKYCLARYS product and further development of the felzartamab product and anticipated synergies, depends on, among other things, how effective we are in integrating the Biogen, Reata and HI-Bio operations.

We face risks associated with our Fit for Growth program that may impair our ability to achieve anticipated savings and operational efficiencies or that may otherwise harm our business. These risks include delays in implementation of cost optimization actions, loss of workforce capabilities, higher than anticipated separation expenses, litigation and the failure to meet financial and operational targets. In addition, the calculation of the anticipated cost savings and other benefits resulting from our Fit for Growth program are subject to many estimates and assumptions. These estimates and assumptions are subject to significant business, economic, competitive and other uncertainties and contingencies, many of which are beyond our control. If these estimates and assumptions are incorrect or if we experience delays or unforeseen events, our business and financial results could be adversely affected.

*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, diagnosis of the condition it treats and the cost to administer it 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, including the ability for the U.S. government to set prices for certain drugs in Medicare. 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 and result in reductions in revenue. 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, in certain jurisdictions governmental health agencies may adjust, retroactively and/or prospectively, reimbursement rates for our products. Reimbursement for our products by governments, including the timing of any reimbursements, may also be affected by budgetary or political constraints, particularly in challenging economic environments. Government agencies often do not set their own budgets and therefore, have limited control over the amount of money they can spend. In addition, these agencies experience political pressure that may dictate the manner in which they spend money. There can be no assurance that the economic, budgeting or political issues will not worsen and adversely impact sales or reimbursements of 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, and if these relationships fail, our business may be adversely affected.*

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, which may affect our ability to achieve development goals or milestones;
- 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 protect and enforce any intellectual property rights or 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 or reputation 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, require management attention, impact the accuracy and timing of our financial reporting and/or adversely impact our ability to conduct business, our operating results and our reputation.

Given these risks, there is considerable uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed, revenue from products could decline and/or we may not realize the anticipated benefits of these arrangements.

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

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs (including those contained in the IRA) and increasing pressure from social sources could significantly influence the manner in which our products are prescribed, purchased and reimbursed. For example, provisions of the PPACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D and under Section 340B of the Public Health Service Act and similar state legislation. 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 substantial 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. In addition, there have been (including elements of the IRA), and are expected to continue to be, legislative proposals to address prescription drug pricing. We face uncertainties regarding potential healthcare reforms, governmental policy and prioritization, 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, 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 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 biosimilar products. For example, a recently completed acquisition of a contract development and manufacturing organization by a third party may impact its operational, strategic or financial risk. If these third-parties fail to perform successfully, or reduce their third party manufacturing production, 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;
- *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;
- *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 persistent 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. For example, one of our contract manufacturers for IMRALDI and BENEPAU was acquired by a third party in December 2024, which may have an impact on our biosimilars business;
- *Intellectual Property and Regulatory Challenges.* Biosimilar products may face extensive intellectual property clearances and 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; and
- *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.

#### **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, defend 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 have in the past and may not in the future 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 have in the past and may in the future grant marketing approval that is more restricted than anticipated, including limiting indications to narrow patient populations and the imposition of safety monitoring, educational requirements, requiring confirmatory trials and risk evaluation and mitigation strategies. The occurrence of any of these events could result in significant costs and expense, have an adverse effect on our business, financial condition and results of operations and/or cause our stock price to decline or experience periods of volatility.

*Clinical trials and the development of biopharmaceutical products is a lengthy and complex process. If we fail to adequately manage our clinical activities, our clinical trials or potential regulatory approvals may be delayed or denied.*

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete clinical trials in a timely fashion depends on a number of key factors, including protocol design, regulatory and institutional review board approval, patient enrollment rates and compliance with current Good Clinical Practices. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or denied.

We have opened clinical trial sites and are enrolling patients in a number of countries where our experience is limited. In most cases, we use the services of third-parties to carry out our clinical trial related activities and rely on such parties to accurately report their results. Our reliance on third-parties for these activities may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for a substantial portion of our activities and reporting related to our clinical trials and if such CRO does not adequately perform, many of our trials may be affected, including adversely affecting our expenses associated with such trials. We may need to replace our CROs, which may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates.

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

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

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

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

### **Risks Related to Our Operations**

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

We are increasingly dependent upon information systems and data to operate our business. Changes in how we operate have 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 many of our employees now working in hybrid or full-remote positions. As a result, we are increasingly dependent upon our information systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our information 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, which may include impacts such as, but not limited to, comprising the capacity, reliability or security of our information systems or those of our business partners, including our cloud technologies, and/or unauthorized access to our data and information could subject us to significant liability, negatively impact our business operations, and/or require replacement of technology and/or sizeable ransom payments. Our information 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.

Cybersecurity threats and incidents are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect, particularly when they impact vendors, customers or suppliers, and other companies in our supply chain. Cybersecurity threats and incidents are often carried out by motivated, well-resourced, skilled and persistent actors, including nation states, organized crime groups, “hacktivists” and may include or target employees or contractors acting with careless or malicious intent. Recent developments in the threat landscape include use of adversarial AI techniques and machine learning, as well as an increased number of cyber extortion attacks, with higher financial ransom demand amounts and increasing sophistication and variety of ransomware techniques and methodology. Geopolitical instability, including that related to Russia's invasion of Ukraine or the conflict in the Middle East, may increase the risk of cybersecurity threats. Cybersecurity threats or incidents may 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 information systems and data. Cybersecurity threats and incidents 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 proprietary 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 cybersecurity threats or incidents in our systems and any such incidents could materially adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in material 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.

Regulations continue to change as regulators worldwide consider new rules. For example, the SEC has adopted additional disclosure rules regarding cyber security risk management, strategy, governance and incident reporting by public companies. These new regulations or other regulations being considered in Europe and around the world may impact the manner in which we operate.



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

*The increasing use of AI-based software presents new risks and challenges and could adversely affect our business and reputation.*

The use of AI-based software is increasingly being used in the biopharmaceutical industry, including by us, such as for research, marketing, manufacturing and commercialization, and we expect to use technology that uses AI in the future. As with many developing technologies, AI-based software presents risks and challenges. For example, algorithms may be flawed; data sets may be insufficient, of poor quality or contain biased information; and inappropriate or controversial data practices could impair results. If the analyses that AI-based software assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Use of AI-based software may also lead to cybersecurity risks or the release of confidential proprietary information, including personal data, which may impact our ability to realize the benefit of our intellectual property or violate our internal policies, data protection laws or contractual requirements. The use of AI-based software may also result in unauthorized access of personal data or the intellectual property of third parties. Since the use of AI is subject to new or evolving laws and regulations, compliance may impose operational costs and limit our ability to use AI-based software, and failure to comply may result in potential government actions, litigation, fines, penalties or adverse publicity.

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

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

- *Risks of Reliance on Third-Parties and Single Source Providers.* We rely on third-party suppliers and manufacturers for many aspects of our manufacturing process for our products and product candidates. In some cases, due to the unique manner in which our products are manufactured, we rely on single source providers of raw materials and manufacturing supplies. These third-parties are independent entities subject to their own unique operational, strategic and financial risks that are outside of our control. For example, a recently completed acquisition of a contract development and manufacturing organization by a third party may impact its operational, strategic or financial risk. These third-parties may not perform their obligations in a timely and cost-effective manner or in compliance with applicable regulations, and they may be unable or unwilling to increase production capacity commensurate with demand for our existing or future products. Finding alternative providers could take a significant amount of time and involve significant expense due to the specialized nature of the services and the need to obtain regulatory approval of any significant changes to our suppliers or manufacturing methods. We cannot be certain that we could reach agreement with alternative providers or that the FDA or other regulatory authorities would approve our use of such alternatives.
- *Global Bulk Supply Risks.* We rely on our manufacturing facilities for the production of drug substance for our large molecule products and product candidates. Our global bulk supply of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, labor or raw material shortages, geopolitical instability, public health epidemics, natural disasters, adverse weather events, power failures, cyber-attacks and many other factors.
- *Risks Relating to Compliance with current GMP (cGMP).* We and our third-party providers are required to maintain compliance with cGMP and other stringent requirements, as applicable, and are subject to inspections by the FDA and other regulatory authorities to confirm compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or operations or those of third-parties to receive regulatory approval or pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.
- *Risk of Product Loss.* The manufacturing process for our products is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered

in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.

Any adverse developments affecting our manufacturing operations or the operations of our third-party suppliers and manufacturers may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products.

Furthermore, factors such as geopolitical events, global health outbreaks, adverse weather events, labor or raw material shortages, imposition of tariffs or trade restrictions and other supply chain disruptions could result in difficulties and delays in manufacturing our products, which could have an adverse impact on our results in operations or result in product shortages. We may also have to take inventory write-offs and incur other charges and expense for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenue or market share as patients and physicians turn to competing therapeutics, diminish our profitability or damage our reputation.

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

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

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, integration related to the Reata and HI-Bio acquisitions, the underperformance or discontinuation of one or more marketed, pre-clinical or clinical programs, recruitment by competitors or changes in the overall labor market. In addition, changes in our organizational structure or in our flexible working arrangements could impact employees' productivity and morale as well as our ability to attract, retain and motivate employees. We cannot ensure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any personnel will not have a material impact on our financial condition and results of operations.

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

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

Additionally, conditions and regulations governing the health care industry in the U.S. are subject to greater risk of change and uncertainty as a result of changes in legislative and regulatory priorities and personnel.

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 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 or conducting clinical research internationally, including materials manufactured in China or working with CROs in China;
- delays in clinical trials relating to geopolitical instability related to Russia's invasion of Ukraine and the military conflict in the Middle East;
- 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 anti-bribery and anti-corruption legislation across the globe, including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- changes in tax laws; and
- the imposition of tariffs or embargoes and other trade restrictions.

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

*We built a large-scale biologics manufacturing facility and are building a gene therapy, clinical packaging and other 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 have expanded 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.

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

Additionally, we are building a new gene therapy, clinical packaging and other manufacturing facility in RTP, North Carolina with no assurance that this investment will be fully utilized. If we are unable to fully utilize this gene therapy, clinical packaging and other manufacturing facility, charges from excess capacity may occur and would have a negative effect on our financial condition and results of operations.

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.

*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 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;
- the costs associated with decisions to terminate research and development programs;
- impairments with respect to investments, fixed assets and long-lived assets, including IPR&D and other intangible assets;
- inventory write-downs for failed quality specifications, charges for excess capacity, 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, 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.

*We may not be able to access the capital and credit markets on favorable terms, which could increase our financing costs.*

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 which could significantly increase our financing costs. 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.

*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 has in the past and may in the future 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 repurchase shares or that we will repurchase shares at favorable prices, which may negatively affect our stock price.*

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.

*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 in our financial statements.*

As a global biopharmaceutical company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates, including withholding taxes, in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Our effective tax rate may be different than experienced in the past or our current expectations due to many factors, including changes in the mix of our profitability from country to country, the results of examinations and audits of our tax filings, adjustments to the value of our uncertain tax positions, interpretations by tax authorities or other bodies with jurisdiction, the result of tax cases, changes in accounting for income taxes and changes in tax laws, especially in the U.S. and Switzerland, and regulations (including the Global Tax Deal Executive Order issued on January 20, 2025) either prospectively or retrospectively and the effects of the integrations of Reata and HI-Bio.

Our inability to secure or sustain acceptable arrangements with tax authorities and future changes in the tax laws, among other things, may result in tax obligations in excess of amounts accrued in our financial statements.

The enactment of some or all of the recommendations set forth or that may be forthcoming in the OECD's project on "Base Erosion and Profit Shifting" by tax authorities and economic blocs in the countries in which we operate, could unfavorably impact our effective tax rate. These initiatives focus on common international principles for the entitlement to taxation of global corporate profits and minimum global tax rates. Many countries have or are in the process of enacting legislation intended to implement the OECD GloBE Model Rules effective on January 1, 2024. The impact on the Company will depend on the timing of implementation, the exact nature of each country's GloBE legislation, guidance and regulations (including the Global Tax Deal Executive Order issued on January 20, 2025) thereon and their application by tax authorities either prospectively or retrospectively.

*Our business involves environmental and operational 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 which make us subject to changing and evolving rules and interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our business practices. 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 have passed new environmental disclosure rules. For example, the E.U., California and certain other countries we do business in have promulgated new climate disclosure rules that will generally require additional disclosure. Additionally, other regulators are considering environmental disclosure rules. These new rules collectively will impose additional disclosure requirements relating to climate-related risks and emissions disclosures. We expect to be subject to these new laws and regulations if or when they go into effect, which would impose extensive reporting obligations about greenhouse gas emissions and climate-related financial risks. These recently enacted and proposed regulations may require us to incur compliance and disclosure costs and will likely require substantial management attention.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 1C. CYBERSECURITY

### RISK MANAGEMENT AND STRATEGY

We maintain a technology and cybersecurity program, which includes information security, as part of our overall risk management process with the aim that our information systems, including those of our vendors and other third-parties, will be resilient, effective and capable of safeguarding against emerging risks and cybersecurity threats. We endeavor to assure our program is appropriately resourced and to attract and retain expert talent to execute it.

In designing, operating, evaluating and maintaining our program we use internal and external resources and frameworks, including cybersecurity expert consultants, industry working groups, the U.S. NIST Cybersecurity Framework and the U.S. Cybersecurity Agency's National Cyber Incident Scoring System model to benchmark, inform and evaluate the design of our program, our operational capabilities and our program maturity.

Consistent with NIST 800-53, our technology and cybersecurity program and controls include a third party and vendor risk management component. As part of our vendor risk management program, we conduct security assessments prior to engagement of high-risk vendors and other third-party providers and have a monitoring program to evaluate ongoing compliance with our cybersecurity standards.

A key element of our technology and cybersecurity program strategy is fostering training and awareness. Our training and awareness program includes annual cybersecurity awareness training and role-based phishing tests for our employees and for third parties with access to our systems.

Our technology and cybersecurity program focuses on the defense, rapid detection and rapid remediation of cybersecurity threats and incidents. Our program includes systems and processes designed based on defense-in-depth and zero-trust architectural principles and that are intended to provide the control capabilities set forth in NIST's 800-53 Rev 5, Security and Privacy Controls for Information Systems and Organizations. Our program also includes cybersecurity policies and a crisis response and management plan that is intended to allow rapid management and response and appropriate communication of cybersecurity threats and incidents.

We staff a cybersecurity operations center to respond to threats and incidents. Our cybersecurity crisis management plan sets forth the items, procedures and actions we expect to address and follow in the event of a cybersecurity incident, including detection, response, mitigation and remediation. In addition to the cybersecurity operations center and our designated cybersecurity response team, we maintain a cross-functional cybersecurity crisis core team, which includes our CISO and senior representatives from our Legal, Finance, IT and Corporate Security teams.

When a potential threat or incident is identified, our cyber security incident response team will assign a risk level classification and initiate the escalation and other steps called for by our plan. All incidents that are initially assessed by the cybersecurity incident response team as potentially high-risk are escalated promptly to our CISO. Our CISO, Chief Legal Officer and Chief Financial Officer, will determine whether and what elements of our cybersecurity crisis response and management plan should be activated, including escalation to other senior management or our Executive Committee. Our Executive Committee will inform our Board of Directors of cybersecurity incidents, as appropriate, considering a variety of factors, including financial, operational, legal or reputational impact.

Our program's maturity and operational readiness are regularly evaluated by independent experts using the U.S. NIST's CyberSecurity Framework and penetration tests. Our program, and the results of these independent evaluations and testing, are regularly reviewed by our senior management and members of our Board of Directors.

## **CYBERSECURITY RISK GOVERNANCE**

We are committed to appropriate cybersecurity governance and oversight. Our technology and cybersecurity program is the principal responsibility of our Chief Information Officer and CISO, each of whom have over 20 years of experience in information systems, including cybersecurity training and experience. Additionally, we have a Cybersecurity steering committee that includes senior representatives from our Legal, Finance and IT departments, which meets regularly to discuss cybersecurity matters.

Our Board of Directors oversees management's processes for identifying and mitigating risks, including cybersecurity and information security risks. Our Board of Directors regularly reviews our technology and cybersecurity program and effectiveness, internal audits of our program, independent external expert evaluations of our program's maturity and operational readiness and the results of penetration testing. Our Board of Directors also receives cybersecurity updates and education on a broad range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident report and learnings from any cybersecurity events; and

- Compliance with regulatory requirements and industry standards.

We do not believe that any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations or financial condition during the period covered by this filing. For additional information on our cybersecurity risks, please read *Item 1A. Risk Factors - A breakdown or breach of our information systems could subject us to liability or interrupt the operation of our business*, included in this report.

## ITEM 2. PROPERTIES

Below is a summary of our significant properties owned and leased as of December 31, 2024.

Location	Approximate Square Feet	Use	Owned/Leased
<b>U.S.</b>			
Cambridge, Massachusetts	263,000	Research laboratory and cogeneration plant	Owned
Cambridge, Massachusetts	729,000	Corporate headquarters and laboratory	Leased - Expires 2028
Weston, Massachusetts	357,000	Office	Leased - Expires 2025
RTP, North Carolina	1,040,000	Office, laboratory, manufacturing, warehouse	Owned
Durham, North Carolina	65,000	Warehouse	Leased - Expires 2025
Plano, Texas	327,000	Office and laboratory	Leased - Expires 2038
<b>International<sup>(1)</sup></b>			
Solothurn, Switzerland	734,000	Manufacturing facility, warehouse and office	Owned
Baar, Switzerland	81,800	International headquarters	Leased - Expires 2028

<sup>(1)</sup> We also lease office space in other international regions including the U.K.; Germany; France; Japan; Canada and numerous other countries. Our international lease agreements expire at various dates through the year 2034.

In the fourth quarter of 2021 we began construction of a new gene therapy, clinical packaging and other manufacturing facility in RTP, North Carolina to support our gene therapy pipeline across multiple therapeutic areas. The new manufacturing facility will be approximately 197,000 square feet. We estimate the construction of this manufacturing facility will be completed during 2025.

We believe that our existing properties, including both owned and leased sites, are adequate and suitable for the conduct of our business. We believe our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs.

## ITEM 3. LEGAL PROCEEDINGS

For a discussion of legal matters as of December 31, 2024, 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 "BIB." As of February 11, 2025, there were approximately 392 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 2024:

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 1, 2024 - October 31, 2024	—	\$ —	—	\$ 2,050.0
November 1, 2024 - November 30, 2024	—	\$ —	—	\$ 2,050.0
December 1, 2024 - December 31, 2024	—	\$ —	—	\$ 2,050.0
Total <sup>(1)</sup>	—	\$ —	—	—

<sup>(1)</sup> There were no share repurchases during the fourth quarter of 2024.

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 shares repurchased under our 2020 Share Repurchase Program were retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 3.6 million shares of our common stock at a cost of approximately \$750.0 million during the year ended December 31, 2022. There were no share repurchases of our common stock during the years ended December 31, 2024 and 2023. Approximately \$2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2024.

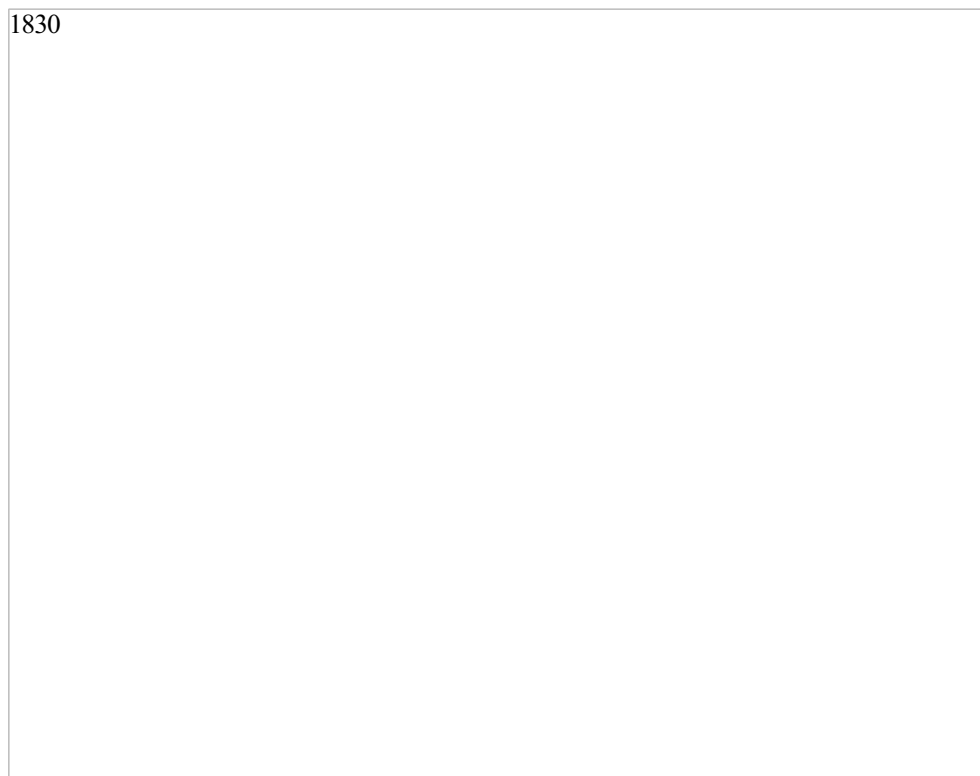
In August 2022 the IRA was signed into law. Among other things, the IRA levies a 1.0% excise tax on net stock repurchases after December 31, 2022. While we have historically made discretionary share repurchases, we had no share repurchases of our common stock during the years ended December 31, 2024 and 2023.



## 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, 2019, 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.



	2019	2020	2021	2022	2023	2024
Biogen Inc.	\$100.00	\$82.52	\$80.85	\$93.31	\$87.19	\$51.52
Nasdaq Pharmaceutical Index	\$100.00	\$110.52	\$137.47	\$153.08	\$159.01	\$172.62
S&P 500 Index	\$100.00	\$118.40	\$152.39	\$124.79	\$157.59	\$197.02
Nasdaq Biotechnology Index	\$100.00	\$126.42	\$126.45	\$113.65	\$118.87	\$118.20

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, 2023, compared to the year ended December 31, 2022, 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, 2023.

### 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. We have a broad portfolio of medicines to treat MS, have introduced the first approved treatment for SMA, co-developed treatments to address a defining pathology of Alzheimer's disease and launched the first approved treatment to target a genetic cause of ALS. We market the first and only drug approved in the U.S. and the E.U. for the treatment of FA in adults and adolescents aged 16 years and older. We are focused on advancing our pipeline in neurology, specialized immunology and rare diseases. We support our drug discovery and development efforts through internal research and development programs, external collaborations and acquisitions.

Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY and TYSABRI for the treatment of MS; SPINRAZA for the treatment of SMA; SKYCLARYS for the treatment of FA; QALSODY for the treatment of ALS; and FUMADERM for the treatment of severe plaque psoriasis.

We also have collaborations with Eisai on the commercialization of LEQEMBI for the treatment of Alzheimer's disease and Sage on the commercialization of ZURZUVAE for the treatment of PPD. 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 for the treatment of relapsed or refractory follicular lymphoma; COLUMVI, a bispecific antibody for the 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.

We commercialize a portfolio of biosimilars of advanced biologics including: BENEPALI, an etanercept biosimilar referencing ENBREL; IMRALDI, an adalimumab biosimilar referencing HUMIRA; FLIXABI, an infliximab biosimilar referencing REMICADE; and BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in certain international markets, as well as TOFIDENCE, a tocilizumab biosimilar referencing ACTEMRA, in the U.S. and certain international markets. We also have commercialization rights related to OPUVIZ, an aflibercept biosimilar referencing EYLEA.

On July 2, 2024, we completed the acquisition of HI-Bio. As a result of this transaction we acquired HI-Bio's lead asset, felzartamab, an anti-CD38 antibody currently being evaluated for three leading indications, AMR, PMN and IgAN. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

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 regularly review our manufacturing capacity, capabilities, processes and facilities. In order to support our future growth and drug development pipeline, we expanded our large molecule production capacity and built a large-scale biologics manufacturing facility in Solothurn, Switzerland. In the second quarter of 2021 a portion of the facility (the first manufacturing suite) received a GMP multi-product license from SWISSMEDIC and was placed into service. The second manufacturing suite, which was also licensed to operate by SWISSMEDIC, became operational in the first quarter of 2024. Solothurn has been approved for the manufacture of LEQEMBI. We believe that the Solothurn facility will support our anticipated near to mid-term needs for the manufacturing of biologic assets. The plant represents a significant increase in our overall manufacturing capacity. If we are unable to fully utilize our manufacturing facilities, we will incur additional excess capacity charges which would have a negative effect on our financial condition and results of operations.

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.

### **TECFIDERA**

Multiple TECFIDERA generic entrants are now in North America, Brazil and certain European 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. We are defending the validity of our EP 2 653 873 patent related to TECFIDERA and expiring in 2028 in opposition proceedings in the European Patent Office. We are also engaged in litigation in Europe to defend and enforce national counterparts of our EP 2 653 873 patent, with mixed results.

### **TYSABRI**

A biosimilar entrant of TYSABRI was approved in the U.S. and the E.U. in 2023. We expect the future sales of TYSABRI may be adversely affected by the entrance of this biosimilar.

## **BUSINESS UPDATE REGARDING MACROECONOMIC CONDITIONS AND OTHER DISRUPTIONS**

Significant portions of our business are conducted in Europe, Asia and other international geographies. Factors such as global health outbreaks, adverse weather events, geopolitical events, tariffs, inflation, labor or raw material shortages and other supply chain disruptions could result in product shortages or other difficulties and delays or increased costs in manufacturing our products.

### **CURRENT ECONOMIC CONDITIONS**

Economic conditions remain vulnerable as markets continue to be impacted in part by elevated inflation, higher interest rates, adverse weather events, global supply chain uncertainties and risks associated with geopolitical conflicts.

### **ADVERSE WEATHER EVENTS**

Adverse weather conditions, including hurricanes, earthquakes, wildfires and natural disaster damage, may affect our ability to do business.

We currently have operations in RTP, North Carolina, which were not impacted by recent hurricanes.

### **GLOBAL SUPPLY CHAIN DISRUPTIONS**

Global supply chain disruptions, such as strikes, work stoppages, port congestion, port closures and other logistical problems, may affect our ability to do business. For example, in 2024 major port strikes on the East and Gulf Coasts of the U.S. resulted in delayed cargo movement for several days. As our primary shipping method for resources and finished goods is through air freight, the recent port strikes did not impact our business; however, we will continue to assess any future port disruptions and if necessary, work to secure alternative transportation.

### **GEOPOLITICAL TENSIONS**

Global disputes and interruptions in international relationships, including tariffs, trade protection measures, import or export licensing requirements and the imposition of trade sanctions or similar restrictions, affect our ability to do business. For example, tensions between China and Taiwan and tensions between the U.S. and China have led to a series of tariffs and sanctions being imposed by the U.S. on imports from China mainland, retaliatory tariffs imposed by China on U.S. imports, as well as other business restrictions, with additional restrictive measures being proposed.

We, and the pharmaceutical industry, utilize China-based partners for certain raw materials, ingredients and components for our pharmaceutical products and their delivery devices. Engaging alternative suppliers may involve seeking additional regulatory approvals and be costly in terms of time and resources needed. For example, certain early processes related to our acquired SKYCLARYS product rely on a single supplier based in China. We are continuing to evaluate SKYCLARYS' supply chain and prioritizing actions to mitigate risks associated with its manufacturing and our ability to supply patients.

The ongoing geopolitical tensions related to Russia's invasion of Ukraine and the military conflict in the Middle East have resulted in global business disruptions and economic volatility. For example, sanctions and other restrictions have been levied on the government and businesses in Russia. Although we do not have affiliates or employees, in either Russia or Ukraine, we do provide various therapies to patients in Russia through a distributor. In addition, new government sanctions on the export of certain manufacturing materials to Russia may delay or limit our ability to get new products approved. The impact of the conflict on our operations and financial performance remains uncertain and will depend on future developments, including the severity and duration of the conflict between Russia and Ukraine, its impact on regional and global economic conditions and whether the conflict spreads or has effects on countries outside Ukraine and Russia.

We will continue to monitor the ongoing conflict between Russia and Ukraine as well as the military conflict in the Middle East 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. Revenue generated from sales in Russia and Ukraine represent less than 2.0% of total revenue for the years ended December 31, 2024, 2023 and 2022. Additionally, revenue generated from sales in the broader Middle East region represents less than 2.0% of total revenue for the years ended December 31, 2024, 2023 and 2022.

## **INFLATION REDUCTION ACT OF 2022**

In August 2022 the IRA was signed into law in the U.S. The IRA introduced new tax provisions, including a 15.0% corporate alternative minimum tax and a 1.0% excise tax on stock repurchases. The provisions of the IRA are effective for periods after December 31, 2022. The IRA did not result in any material adjustments to our income tax provision or other income tax balances as of December 31, 2024 and 2023. Preliminary guidance has been issued by the IRS and we expect additional guidance and regulations to be issued in future periods. We 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 the following:

- (i) allowing CMS to negotiate prices for select high-cost Medicare Part D drugs (beginning in 2026) and Part B drugs (beginning in 2028) to reduce out-of-pocket prescription drug costs for beneficiaries, potentially resulting in higher contributions from plans and manufacturers;
- (ii) drug inflationary rebate requirements to penalize manufacturers from raising the prices of Medicare covered single-source drugs and biologics beyond the inflation-adjusted rate, beginning in 2022 for Part D drugs and 2023 for Part B drugs;
- (iii) 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; and
- (iv) 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 up to 10.0% of costs up to the \$2,000 cap and up to 20.0% after that cap is reached. Manufacturers that qualify as either specified or specified small manufacturers will phase-in the new manufacturer liability for prescription drug costs over a 7-year period from 2025 to 2031 for certain Medicare Part D drugs dispensed to certain beneficiaries.

In April 2024 CMS informed us that we qualified for the specified manufacturer exception pertaining to the Medicare Part D redesign. We expect the IRA's drug pricing controls and Medicare Part D redesign may have an adverse impact on our sales, particularly for our products that are more substantially reliant on Medicare reimbursement. We anticipate the IRA Medicare Part D redesign will have a modest net unfavorable impact to our 2025 revenue, ranging from approximately \$50.0 million to \$100.0 million, concentrated in our SKYCLARYS and MS portfolio product revenue, approximately a third of which could be associated with SKYCLARYS.

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 impacts on our sales and, in turn, our business, remains unclear.

## FINANCIAL HIGHLIGHTS

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, 2024, compared to the year ended December 31, 2023, reflects the following:

TOTAL REVENUE		DILUTED EARNINGS PER SHARE	
6		22	
Decreased \$159.7 million or 1.6%		Increased \$3.21 or 40.3%	
PRODUCT REVENUE, NET			
6		<ul style="list-style-type: none"><li>The decrease in MS product revenue was primarily due to a decrease in Interferon demand due to competition as patients transition to higher efficacy therapies and a decrease in global TYSABRI revenue driven by increased competition.</li><li>The increase in rare disease product revenue in 2024 was primarily due to revenue from new product launches, including global SKYCLARYS revenue of \$382.5 million, \$72.2 million for ZURZUVAE and \$32.4 million for QALSODY. This was partially offset by a decrease in rest of world SPINRAZA revenue driven by the loss of an annual tender in Russia which resulted in an unfavorable impact of approximately \$45.0 million. The decrease was also impacted by the timing of SPINRAZA shipments and the unfavorable impact of foreign currency exchange.</li></ul>	
Decreased \$33.2 million or 0.5%			
<ul style="list-style-type: none"><li>MS revenue decreased \$312.1 million, or 6.7%</li><li>Rare disease revenue increased \$185.1 million, or 10.3%</li></ul>			
TOTAL COST AND EXPENSE			
6		<ul style="list-style-type: none"><li>The decrease in cost of sales was primarily due to favorable product mix from lower contract manufacturing revenue and lower idle capacity charges, partially offset by approximately \$181.5 million in SKYCLARYS amortization costs.</li><li>The decrease in R&amp;D expense was primarily driven by approximately \$197.0 million of equity-based compensation expense recognized in 2023 related to our Reata acquisition, cost-reduction measures realized in 2024 in connection with our portfolio prioritization initiatives and our Fit for Growth program, as well as higher spend on clinical trials and close out costs incurred during 2023, partially offset by approximately \$48.5 million in SKYCLARYS amortization costs and approximately \$42.5 million of equity-based compensation expense recognized in 2024 related to our HI-Bio acquisition.</li><li>The decrease in SG&amp;A expense was primarily due to approximately \$196.4 million of equity-based compensation expense recognized in 2023 related to our Reata acquisition.</li><li>The increase in amortization and impairment of acquired intangible assets was primarily due to amortization for the acquired intangible assets associated with SKYCLARYS, as well as impairment charges of approximately \$60.2 million during 2024.</li></ul>	
Decreased \$768.9 million or 9.0%			
<ul style="list-style-type: none"><li>Cost of sales decreased \$223.0 million, or 8.8%</li><li>R&amp;D expense decreased \$420.2 million, or 17.1%</li><li>SG&amp;A expense decreased \$146.0 million, or 5.7%</li><li>Amortization and impairment of acquired intangible assets increased \$206.1 million, or 85.7%</li></ul>			
FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES			
<ul style="list-style-type: none"><li>Cash and cash equivalents totaled approximately \$2.4 billion as of December 31, 2024, compared to approximately \$1.0 billion as of December 31, 2023.</li><li>We generated approximately \$2,875.5 million of net cash flow from operations for the year ended December 31, 2024.</li><li>We received a net cash payment of \$88.6 million from the sale of our rare pediatric disease PRV in 2024.</li></ul>		<ul style="list-style-type: none"><li>In April 2024 we received \$437.5 million from Samsung BioLogics related to the sale of our equity interest in Samsung Bioepis.</li><li>In July 2024 we completed the acquisition of HI-Bio for \$1.15 billion, which was funded through available cash on hand.</li></ul>	

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## RECENT DEVELOPMENTS

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### ACQUISITIONS AND DIVESTITURES

#### HUMAN IMMUNOLOGY BIOSCIENCES

On July 2, 2024, we completed the acquisition of all of the issued and outstanding shares of HI-Bio, a privately-held clinical-stage biotechnology company focused on targeted therapies for patients with severe immune-mediated diseases. HI-Bio's lead asset, felzartamab, an anti-CD38 antibody, is currently being evaluated for three leading indications, AMR, PMN and IgAN. Felzartamab has received Breakthrough Therapy Designation and ODD from the FDA for development in the treatment of PMN and AMR. Subsequent to our acquisition, felzartamab received ODD in the E.U. in IgAN and solid organ transplantation. The acquisition of HI-Bio is expected to augment our pipeline and build on our expertise in immunology.

Under the terms of this acquisition, we paid shareholders of HI-Bio approximately \$1.15 billion at closing and may pay up to an additional \$650.0 million in potential future development and regulatory milestone payments. We funded this acquisition through available cash on hand and accounted for this acquisition as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*, and recorded assets acquired and liabilities assumed at their respective fair values as of the acquisition date. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

#### SALE OF PRIORITY REVIEW VOUCHER

In April 2024 we completed the sale of our rare pediatric disease PRV, generated by the development associated with SPINRAZA, to a third party. In consideration for the PRV we received a cash payment of \$103.0 million upon the closing of the PRV purchase, of which approximately \$14.4 million was paid to Ionis. Our net portion of approximately \$88.6 million was recognized in gain on sale of priority review voucher, net within our consolidated statements of income for the year ended December 31, 2024. For additional information on the sale of our PRV, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report.

### DEVELOPMENTS IN KEY COLLABORATIVE RELATIONSHIPS

#### LEQEMBI (lecanemab)

##### *United States*

Key developments related to LEQEMBI in the U.S. consisted of the following:

- In January 2025 the FDA approved LEQEMBI monthly IV maintenance dosing for the treatment of early Alzheimer's disease.
- In January 2025 the FDA accepted for review the BLA for LEQEMBI subcutaneous autoinjector for weekly maintenance dosing, with a PDUFA action date set for August 31, 2025.
- In July 2024 Eisai presented new clinical data from the CLARITY AD study open-label extension of LEQEMBI, demonstrating that three years of continuous LEQEMBI treatment reduced clinical decline, resulting in a clinically meaningful benefit for early Alzheimer's disease patients.

##### *Rest of World*

Key developments related to LEQEMBI (lecanemab) in rest of world markets consisted of the following:

- In January 2025 we and Eisai announced an update regarding the ongoing regulatory review of the MAA for lecanemab in the E.U., which the CHMP of the EMA previously adopted a positive opinion on in November 2024. The EC has asked the CHMP to consider information on the safety of lecanemab that became available after the adoption of the CHMP opinion in November 2024 and whether this may require an update of the opinion, and to consider whether the wording of the risk minimization measures in the opinion is clear enough to ensure correct implementation. These will be discussed at the CHMP meeting in February 2025.
- In December 2024 LEQEMBI was approved by the Federal Commission for the Protection Against Sanitary Risk in Mexico.
- In November 2024 we and Eisai announced the launch of LEQEMBI in South Korea, which had been approved by the Ministry of Food and Drug Safety in South Korea in May 2024.

- In October 2024 the Therapeutic Goods Administration of Australia issued a public statement about the initial decision not to register lecanemab. In December 2024 Eisai submitted a request for reconsideration of this decision.
- In August 2024 LEQEMBI was approved by the Medicines and Healthcare products Regulatory Agency in Great Britain and by the Ministry of Health and Prevention in the United Arab Emirates.
- In July 2024 LEQEMBI was approved in Hong Kong and Israel.
- In June 2024 we and Eisai announced the launch of LEQEMBI in China, which had been approved by the NMPA in China in January 2024.

## OTHER KEY DEVELOPMENTS

### felzartamab

In October 2024 the FDA granted felzartamab Breakthrough Therapy Designation for the treatment of late AMR without T-cell mediated rejection in kidney transplant patients. Additionally, felzartamab was granted ODD in the E.U. in IgAN and solid organ transplantation in November 2024 and December 2024, respectively.

### UCB COLLABORATION

In September 2024 we and UCB announced positive topline data from the Phase 3 PHOENYCS GO study of dapirolizumab pegol, a novel Fc-free anti-CD40L drug candidate, in people living with moderate-to-severe SLE. The Phase 3 study met the primary endpoint demonstrating clinical improvement in moderate-to-severe SLE with clinical improvements observed among key secondary endpoints. Based on these results, UCB and Biogen initiated a second Phase 3 study in late 2024.

### SPINRAZA (nusinersen)

In September 2024 we announced positive topline data from the Phase 2/3 DEVOTE study of nusinersen, which evaluated the safety and efficacy of a higher dose regimen of nusinersen in treatment-naïve symptomatic infants with SMA.

In January 2025 the FDA accepted the supplemental NDA and the EMA validated the application for a higher dose regimen of nusinersen for SMA. The higher dose regimen of nusinersen comprises a more rapid loading regimen, two 50 mg-doses 14 days apart, and higher maintenance regimen, 28 mg, every four months, compared to the currently approved dose of SPINRAZA.

## DISCONTINUED PROGRAMS AND STUDIES

### SAGE COLLABORATION

#### *zuranolone*

In October 2024 we and Sage agreed to not pursue further development of zuranolone for the potential treatment of MDD. This decision was based on the significant new investment and time we expect would be needed to conduct the additional studies required to support approval of this indication.

#### *BLIB124*

In July 2024 we and Sage announced that the Phase 2 KINETIC 2 dose-range study of BLIB124 did not meet its endpoints. Based on these results, we discontinued our further development of BLIB124 and terminated our rights under the collaboration and license agreement specific to BLIB124, effective February 17, 2025.

### SAMSUNG BIOEPIS 2019 DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

In October 2024 we notified Samsung Bioepis of our decision to terminate our 2019 Development and Commercialization Agreement (the DCA Agreement) solely within the U.S. and Canada. Biogen will transfer commercialization rights for BYOOVIZ and OPUMIZ in the U.S. and Canada back to Samsung Bioepis over a period of up to 18 months. During this transition period, we will continue to commercialize BYOOVIZ. The termination does not impact the other markets in the DCA Agreement.

## **IONIS COLLABORATION**

### **[BIIB105](#)**

In May 2024 we and Ionis announced that the Phase 1/2 ALSpire study of BIIB105, an investigational ASO for the potential treatment of ALS, did not meet its endpoints. Based on these results, we discontinued our further development of BIIB105.

### **[BIIB121](#)**

In May 2024 we announced that we have elected not to exercise our option to license and lead development of BIIB121, an ASO for the potential treatment of Angelman syndrome.

## **MERZ THERAPEUTICS (PREVIOUSLY ACORDA THERAPEUTICS, INC.)**

In January 2024 we notified Acorda of our decision to terminate our collaboration and license agreement, effective January 1, 2025, whereby Acorda regained global commercialization rights to FAMPYRA. On April 1, 2024, Acorda filed for bankruptcy protection and announced its intention to sell substantially all of Acorda's assets to a third party. On July 10, 2024, Merz Therapeutics announced that its subsidiary Merz Pharmaceuticals LLC had completed the acquisition of FAMPYRA, and related assets from Acorda. We are now working with Merz Therapeutics on the transition of global commercialization rights of FAMPYRA and we expect to recognize minimal revenue in 2025.

### **BIIB143 (cemdomespib)**

In early 2025 we discontinued further development of BIIB143 (cemdomespib) for the treatment of diabetic neuropathic pain, as part of our ongoing pipeline prioritization efforts.

## RESULTS OF OPERATIONS

### REVENUE

The following revenue discussion should be read in conjunction with Note 5, *Revenue*, to our consolidated financial statements included in this report.

Revenue is summarized as follows:

(In millions, except percentages)	For the Years Ended December 31,			% Change		\$ Change	
	2024	2023	2022	2024 vs. 2023	2023 vs. 2022	2024 vs. 2023	2023 vs. 2022
Product revenue, net:							
United States	\$ 3,237.3	\$ 3,141.4	\$ 3,469.3	3.1%	(9.5)%	\$ 95.9	\$ (327.9)
Rest of world	3,976.2	4,105.3	4,518.5	(3.1)	(9.1)	(129.1)	(413.2)
Total product revenue, net	7,213.5	7,246.7	7,987.8	(0.5)	(9.3)	(33.2)	(741.1)
Revenue from anti-CD20 therapeutic programs	1,749.9	1,689.6	1,700.5	3.6	(0.6)	60.3	(10.9)
Alzheimer's collaboration revenue <sup>(1)</sup>	59.9	—	—	nm	—	59.9	—
Contract manufacturing, royalty and other revenue	652.6	899.3	485.1	(27.4)	85.4	(246.7)	414.2
Total revenue	\$ 9,675.9	\$ 9,835.6	\$ 10,173.4	(1.6)%	(3.3)%	\$ (159.7)	\$ (337.8)

nm Not meaningful

<sup>(1)</sup> Alzheimer's collaboration revenue consists of our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties.

### PRODUCT REVENUE

Product revenue is summarized as follows:

(In millions, except percentages)	For the Years Ended December 31,			% Change		\$ Change	
	2024	2023	2022	2024 vs. 2023	2023 vs. 2022	2024 vs. 2023	2023 vs. 2022
Multiple Sclerosis	\$ 4,349.8	\$ 4,661.9	\$ 5,430.2	(6.7)%	(14.1)%	\$ (312.1)	\$ (768.3)
Rare disease	1,988.1	1,803.0	1,793.5	10.3	0.5	185.1	9.5
Biosimilars	793.1	770.0	751.1	3.0	2.5	23.1	18.9
Other <sup>(1)</sup>	82.5	11.8	13.0	599.2	(9.2)	70.7	(1.2)
Total product revenue, net	\$ 7,213.5	\$ 7,246.7	\$ 7,987.8	(0.5)%	(9.3)%	\$ (33.2)	\$ (741.1)

<sup>(1)</sup> Other includes FUMADERM, ADUHELM and ZURZUVAE, which became commercially available in the U.S. during the fourth quarter of 2023.



MULTIPLE SCLEROSIS



- Global TYSABRI revenue decreased \$161.9 million, from \$1,876.9 million in 2023 to \$1,715.0 million in 2024, or 8.6%, primarily due to increased competition and a decrease in pricing in rest of world TYSABRI.
- Global TECFIDERA revenue decreased \$45.4 million, from \$1,012.5 million in 2023 to \$967.1 million in 2024, or 4.5%, driven by a decrease in demand as a result of multiple TECFIDERA generic entrants in North America, Brazil and certain E.U. countries.
- Global Interferon revenue decreased \$137.7 million, from \$1,105.7 million in 2023 to \$968.0 million in 2024, or 12.5%, driven by a decrease in demand as patients transition to higher efficacy therapies.
- Global VUMERITY revenue increased \$51.7 million, from \$576.3 million in 2023 to \$628.0 million in 2024, or 9.0%, primarily due to an increase in global demand.

MS revenue includes sales from TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA. Effective January 1, 2025, our collaboration and license agreement for FAMPYRA global commercialization rights was terminated. We expect to recognize minimal revenue in 2025.

In 2025 we expect total MS revenue will continue to decline as a result of increasing competition for many of our MS products in both the U.S. and rest of world markets. Additionally, a biosimilar entrant of TYSABRI was approved in the U.S. and the E.U. in 2023. We expect that future sales of TYSABRI may be adversely affected by the entrance of this biosimilar.

## RARE DISEASE

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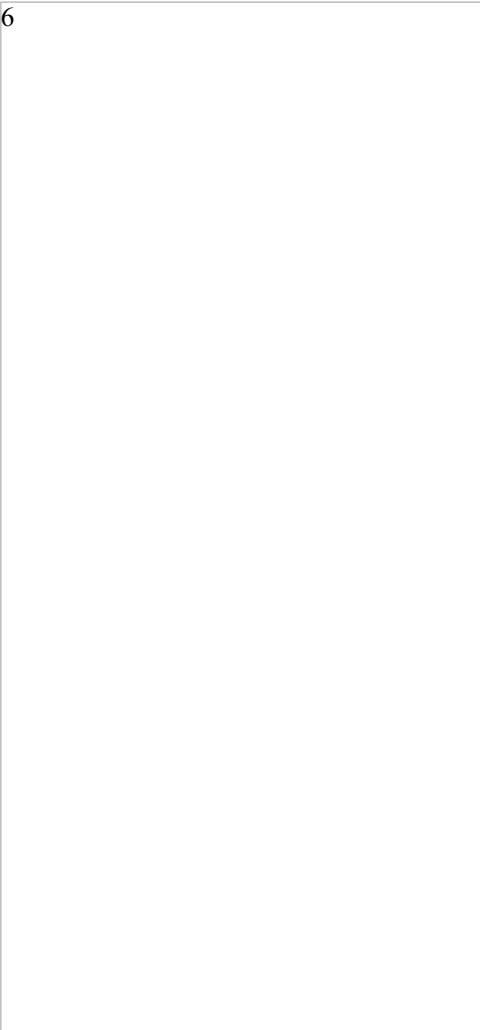
- U.S. SPINRAZA revenue increased \$15.2 million, from \$610.5 million in 2023 to \$625.7 million in 2024, or 2.5%, primarily due to favorable net pricing, offset by a decrease in demand.
- Rest of world SPINRAZA revenue decreased \$183.2 million, from \$1,130.7 million in 2023 to \$947.5 million in 2024, or 16.2%, primarily driven by the loss of an annual tender in Russia which resulted in an unfavorable impact of approximately \$45.0 million. The decrease was also impacted by the timing of shipments and the unfavorable impact of foreign currency exchange.
- Global SKYCLARYS revenue was \$382.5 million in 2024, including \$301.1 million of U.S. SKYCLARYS revenue, which we began recognizing during the fourth quarter of 2023, subsequent to our acquisition of Reata, and \$81.4 million of rest of world SKYCLARYS revenue, which was approved in the E.U. and became commercially available during the first quarter of 2024.
- Global QALSODY revenue was \$32.4 million in 2024.

Rare disease revenue includes sales from SPINRAZA, QALSODY, which became commercially available in the U.S. during the second quarter of 2023 and commercially available in the E.U. during the second quarter of 2024, and SKYCLARYS, which was obtained as part of our acquisition of Reata in September 2023.

SKYCLARYS became commercially available in the U.S. during the second quarter of 2023 and we began recognizing revenue from SKYCLARYS in the U.S. during the fourth quarter of 2023, subsequent to our acquisition of Reata. SKYCLARYS was also approved in the E.U. and became commercially available during the first quarter of 2024.

In 2025 we expect growth in rare disease revenue as we continue to launch SKYCLARYS in the U.S. and the E.U. We anticipate global SPINRAZA revenue to be relatively flat in 2025.

BIOSIMILARS



- For 2024 compared to 2023, the increase in biosimilar revenue was primarily due to an increase in sales volumes related to BENEPALI, partially offset by a decrease in pricing due to competitive pressures.

Biosimilars revenue includes sales from BENEPALI, IMRALDI, FLIXABI, BYOOVIZ and TOFIDENCE. In 2023 BYOOVIZ became commercially available in certain international markets. During the third quarter of 2023 the FDA approved TOFIDENCE, a tocilizumab biosimilar referencing ACTEMRA, which became commercially available in the U.S. during the second quarter of 2024 and approved in the E.U. during the second quarter of 2024.

We continue to work with our third-party contract manufacturers for IMRALDI and BENEPALI to address supply constraints. If not resolved these supply constraints could have an adverse impact on 2025 sales. In addition, one of our contract manufacturers for IMRALDI and BENEPALI was acquired by a third party in December 2024. We have evaluated the impact this will have on our biosimilars business and have mitigation activities in progress designed to ensure supply continuity.

After evaluating our strategic options, we have made the decision to retain our biosimilars business.

## REVENUE FROM ANTI-CD20 THERAPEUTIC PROGRAMS

Our share of RITUXAN, including RITUXAN HYCELA, GAZYVA and LUNSUMIO 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.

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Royalty revenue on sales of OCREVUS	\$ 1,339.5	\$ 1,266.2	\$ 1,136.3
Biogen's share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO <sup>(1)</sup>	392.0	409.4	547.0
Other revenue from anti-CD20 therapeutic programs	18.4	14.0	17.2
Total revenue from anti-CD20 therapeutic programs	\$ 1,749.9	\$ 1,689.6	\$ 1,700.5

<sup>(1)</sup> LUNSUMIO became commercially available in the U.S. during the first quarter of 2023.

## ROYALTY REVENUE ON SALES OF OCREVUS

For 2024 compared to 2023, 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.

## BIOGEN'S SHARE OF PRE-TAX PROFITS IN THE U.S. FOR RITUXAN, GAZYVA AND LUNSUMIO

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Product revenue, net	\$ 1,531.0	\$ 1,581.3	\$ 1,729.2
Cost and expense	404.1	419.9	253.6
Pre-tax profits in the U.S.	\$ 1,126.9	\$ 1,161.4	\$ 1,475.6
Biogen's share of pre-tax profits	\$ 392.0	\$ 409.4	\$ 547.0

For 2024 compared to 2023, the decrease in U.S. product revenue, net was primarily due to a decrease in sales volumes of RITUXAN in the U.S. of 7.9%, resulting from competition from multiple biosimilar products, partially offset by an increase in sales volumes of GAZYVA of 11.8%.

In April 2023 our pre-tax profit share for RITUXAN, GAZYVA and LUNSUMIO decreased from 37.5% to 35.0%.

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

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

## OTHER REVENUE FROM ANTI-CD20 THERAPEUTIC PROGRAMS

Other revenue from anti-CD20 therapeutic programs consists of our share of pre-tax co-promotion profits from RITUXAN in Canada, royalty revenue on sales of LUNSUMIO outside the U.S. and royalty revenue on net sales of COLUMVI in the U.S., which became commercially available during the second quarter of 2023.

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.

## ALZHEIMER'S COLLABORATION REVENUE

Alzheimer's collaboration revenue consists of our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties, as we are not the principal. We began recognizing Alzheimer's collaboration revenue upon the accelerated approval of LEQEMBI in the U.S. during the first quarter of 2023.

For the year ended December 31, 2024, we recognized approximately \$59.9 million of Alzheimer's collaboration revenue within our consolidated statements of income. For the year ended December 31, 2023, our share of LEQEMBI product revenue, net, was fully offset by our share of cost of sales, including royalties, resulting in a zero net impact to Alzheimer's collaboration revenue within our consolidated statements of income.

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.

## CONTRACT MANUFACTURING, ROYALTY AND OTHER REVENUE

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Contract manufacturing revenue	\$ 592.1	\$ 848.2	\$ 417.7
Royalty and other revenue	60.5	51.1	67.4
Total contract manufacturing, royalty and other revenue	\$ 652.6	\$ 899.3	\$ 485.1

## CONTRACT MANUFACTURING REVENUE

Contract manufacturing revenue primarily reflects amounts earned under contract manufacturing agreements with our strategic customers.

For 2024 compared to 2023, the decrease in contract manufacturing revenue was primarily driven by higher volumes in 2023 due to the timing of batch production, which includes batches related to LEQEMBI that we began recognizing in the first quarter of 2023 upon the accelerated approval of LEQEMBI in the U.S.

In addition, as part of the 2020 sale of our Hillerød, Denmark manufacturing operations to FUJIFILM, we provided FUJIFILM with certain minimum batch production commitment guarantees, including batches related to our contract manufacturing arrangements. These batch commitments were satisfied as of December 31, 2023. As a result, we recognized lower contract manufacturing revenue in 2024, compared to 2023, as we are no longer supplying contract manufacturing customers using Hillerød in this manner.

## ROYALTY AND OTHER REVENUE

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

For additional information on our license arrangements with Samsung Bioepis and our collaborative arrangements with Eisai, 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.

In August 2022 the IRA was signed into law in the U.S. and contains substantial drug pricing reforms. We expect the IRA's drug pricing controls and Medicare Part D redesign may have an adverse impact on our sales, particularly for our products that are more substantially reliant on Medicare reimbursement. We anticipate the IRA Medicare Part D redesign will have a modest net unfavorable impact to our 2025 revenue, ranging from approximately \$50.0 million to \$100.0 million, concentrated in our SKYCLARYS and MS portfolio product revenue, approximately a third of which could be associated with SKYCLARYS.

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Contractual adjustments	\$ 2,648.8	\$ 2,681.7	\$ 2,716.9
Discounts	832.2	735.2	663.9
Returns	37.8	38.2	5.1
Total discounts and allowances	<u>\$ 3,518.8</u>	<u>\$ 3,455.1</u>	<u>\$ 3,385.9</u>

For the years ended December 31, 2024, 2023 and 2022, reserves for discounts and allowances as a percentage of gross product revenue were 32.6%, 32.0% and 30.1%, respectively.

## CONTRACTUAL ADJUSTMENTS

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

For 2024 compared to 2023, the decrease in contractual adjustments was primarily due to lower government rebates in rest of world and biosimilars, partially offset by higher government rebates in the U.S.

## DISCOUNTS

Discounts include trade term discounts, wholesaler incentives and volume related discounts.

For 2024 compared to 2023, the increase in discounts was primarily driven by higher purchase and volume discounts for biosimilars and rest of world, as well as higher purchase discounts in the U.S.

## 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 estimated product returns are recognized in the period the related revenue is recognized, resulting in a reduction to product sales.

For 2024 compared to 2023, 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:

(In millions, except percentages)	For the Years Ended December 31,			% Change		\$ Change	
	2024	2023	2022	2024 vs. 2023	2023 vs. 2022	2024 vs. 2023	2023 vs. 2022
Cost of sales, excluding amortization and impairment of acquired intangible assets	\$ 2,310.4	\$ 2,533.4	\$ 2,278.3	(8.8)%	11.2%	\$ (223.0)	\$ 255.1
Research and development	2,041.8	2,462.0	2,231.1	(17.1)	10.3	(420.2)	230.9
Selling, general and administrative	2,403.7	2,549.7	2,403.6	(5.7)	6.1	(146.0)	146.1
Amortization and impairment of acquired intangible assets	446.7	240.6	365.9	85.7	(34.2)	206.1	(125.3)
Collaboration profit sharing/(loss reimbursement)	254.4	218.8	(7.4)	16.3	nm	35.6	226.2
(Gain) loss on fair value remeasurement of contingent consideration	27.7	—	(209.1)	nm	nm	27.7	209.1
Restructuring charges	30.2	218.8	131.1	(86.2)	66.9	(188.6)	87.7
Gain on sale of priority review voucher, net	(88.6)	—	—	nm	—	(88.6)	—
Gain on sale of building, net	—	—	(503.7)	—	nm	—	503.7
Other (income) expense, net	343.6	315.5	(108.2)	8.9	(391.6)	28.1	423.7
Total cost and expense	\$ 7,769.9	\$ 8,538.8	\$ 6,581.6	(9.0)%	29.7%	\$ (768.9)	\$ 1,957.2

nm Not meaningful

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Product	\$ 1,604.2	\$ 1,787.2	\$ 1,504.8
Royalty	706.2	746.2	773.5
Total cost of sales	\$ 2,310.4	\$ 2,533.4	\$ 2,278.3

Cost of sales, as a percentage of total revenue, were 23.9%, 25.8% and 22.4% for the years ended December 31, 2024, 2023 and 2022, respectively.

### PRODUCT COST OF SALES

For 2024 compared to 2023, the decrease in product cost of sales was primarily due to favorable product mix from decreased contract manufacturing revenue and lower idle capacity charges, offset in part by approximately \$181.5 million in SKYCLARYS amortization costs. Contract manufacturing revenue includes LEQEMBI inventory produced for Eisai, beginning in the first quarter of 2023 upon the accelerated approval of LEQEMBI in the U.S. Cost of sales as a percentage of revenue was adversely affected by LEQEMBI batches due to minimal margins.

As a result of our acquisition of Reata in September 2023 we recorded a fair value step-up adjustment related to the acquired inventory of SKYCLARYS of approximately \$1.3 billion. This fair value step-up adjustment is being amortized to cost of sales within our consolidated statements of income as the inventory is sold, which is expected to be sold over a period of approximately 4 years from the acquisition date. For the years ended December 31, 2024 and 2023, amortization from the fair value step-up adjustment was approximately \$181.5 million and \$31.5 million, respectively. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

#### Write Downs and Other Charges

Inventory amounts written down as a result of excess, obsolescence or unmarketability totaled \$101.9 million, \$124.4 million and \$336.2 million for the years ended December 31, 2024, 2023 and 2022, respectively.

For the years ended December 31, 2024, 2023 and 2022, we recorded approximately \$4.8 million, \$165.2 million and \$119.0 million, respectively, of aggregate gross idle capacity charges.

### ROYALTY COST OF SALES

For 2024 compared to 2023, the decrease in royalty cost of sales was primarily due to lower royalties payable associated with lower sales of SPINRAZA and TYSABRI, partially offset by higher royalties payable associated with higher sales of SKYCLARYS.



## RESEARCH AND DEVELOPMENT

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For 2024 compared to 2023, the decrease in research and development was primarily driven by approximately \$197.0 million of equity-based compensation expense recognized in 2023 related to our acquisition of Reata, cost-reduction measures realized in 2024 in connection with our portfolio prioritization initiatives and our Fit for Growth program, as well as higher spend on clinical trials and close out costs incurred during 2023, partially offset by approximately \$48.5 million of step-up amortization related to SKYCLARYS inventory and approximately \$42.5 million of equity based compensation expense recognized in 2024 related to our acquisition of HI-Bio.

### EARLY STAGE PROGRAMS

#### 2024 vs. 2023

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

- advancement of BLIB059 for the treatment of CLE into late stage;
- discontinuation of BLIB121 for the treatment of Angelman syndrome; and
- discontinuation of BLIB131 for the treatment of acute ischemic stroke.

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

- development of BLIB080 for the treatment of Alzheimer's disease;
- development of cemdomespib for the treatment of diabetic neuropathic pain; and
- development of BLIB091 for the treatment of MS.

### LATE STAGE PROGRAMS

#### 2024 vs. 2023

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

- advancement of ZURZUAE from late stage to marketed upon the approval of ZURZUAE for PPD in the U.S.;
- advancement of QALSODY from late stage to marketed upon the accelerated approval of QALSODY in the U.S.;
- advancement of TOFIDENCE from late stage to marketed upon the approval of TOFIDENCE in the U.S.; and
- discontinuation of BLIB093 for LHI.

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

- advancement of BLIB059 for the treatment of CLE into late stage; and
- development of BLIB059 for the treatment of SLE.

### MARKETED PROGRAMS

#### 2024 vs. 2023

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

- discontinuation of ADUHELM for the treatment of Alzheimer's disease;
- decreased spend on LEQEMBI for the treatment of Alzheimer's disease; and
- decreased spend on ZURZUAE for MDD.

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

- increased spend in SKYCLARYS as a result of our acquisition of Reata in 2023;
- advancement of QALSODY from late stage to marketed upon the accelerated approval of QALSODY in the U.S.; and
- advancement of TOFIDENCE from late stage to marketed upon the approval of TOFIDENCE in the U.S.

Research and development expense, as a percentage of total revenue, was 21.1%, 25.0% and 21.9% for the years ended December 31, 2024, 2023 and 2022, respectively.

## MILESTONE AND UPFRONT EXPENSE

Research and development expense for 2024 includes:

- \$20.0 million in charges to research and development expense in connection with the upfront payment associated with entering into our collaboration with Neomorph in the fourth quarter of 2024;
- \$16.0 million in charges to research and development expense in connection with milestone payments to C4;
- \$12.0 million in charges to research and development expense in connection with milestone payments to Alcyone; and
- \$7.5 million in charges to research and development expense in connection with a milestone payment to Ionis.

Research and development expense for 2023 includes:

- \$7.5 million charge to research and development expense in connection with a milestone payment to Ionis; and
- \$5.0 million charge to research and development expense in connection with exercising our option with Denali to license the ATV-enabled anti-amyloid beta program.

Research and development expense is reported above based on the following classifications. The development stage reported is 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.

- **Research and discovery:** represents costs incurred to support our discovery research and translational science efforts.
- **Early stage programs:** are programs in Phase 1 or Phase 2 development.
- **Late stage programs:** are programs in Phase 3 development or in registration stage.
- **Marketed products:** includes costs associated with product lifecycle management activities including, if applicable, costs associated with the development of new indications for existing products.
- **Other research and development costs:** 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. For 2023 other research and development costs also includes approximately \$197.0 million of equity-based compensation expense incurred as a result of our acquisition of Reata in 2023.

Excluding any milestone and upfront payments, we expect our core research and development expense to decrease in 2025, while continuing to invest in our pipeline, such as our acquisition of HI-Bio in July 2024. This is primarily due to the continued realization of our cost savings initiatives. 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.

For additional information on our acquisitions of Reata and HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## SELLING, GENERAL AND ADMINISTRATIVE

For 2024 compared to 2023, selling, general and administrative expense decreased by approximately 5.7% primarily due to equity-based compensation expense recognized in 2023 of approximately \$196.4 million related to our acquisition of Reata. Selling, general and administrative expense for 2024 also includes higher operational spending on sales and marketing activities in support of LEQEMBI and SKYCLARYS as we continue to expand our U.S. and international product launches, which was partially offset by cost-reduction measures realized in connection with our Fit for Growth program.

In 2024, selling, general and administrative expense included the recognition of approximately \$13.9 million in equity-based compensation expense related to our acquisition of HI-Bio that was associated with the accelerated vesting of stock options and RSUs previously granted to HI-Bio employees and required no future services to vest. Additionally, we incurred transaction and integration-related expense of approximately \$3.6 million related to our acquisition of HI-Bio.

In 2023, selling, general and administrative expense included the recognition of approximately \$196.4 million in equity-based compensation expense related to our acquisition of Reata that was associated with the accelerated vesting of stock options and RSUs previously granted to Reata employees and required no future services to vest. Additionally, we incurred transaction and integration-related expense of approximately \$34.6 million related to our acquisition of Reata. In 2023, selling, general and administrative expense also included a \$31.0 million obligation to Eisai related to the termination of the co-promotion agreement for our MS products in Japan and approximately \$11.5 million of accelerated depreciation.

### GENERAL AND ADMINISTRATIVE EXPENSE

In 2024 compared to 2023, general and administrative expense decreased by approximately \$173.2 million, or 19.6%, due to the recognition of approximately \$196.4 million in equity-based compensation expense in 2023 related to our acquisition of Reata.

We expect selling, general and administrative costs to continue to decline in 2025 due to the continued realization of our cost-reduction measures in connection with our Fit for Growth program.

For additional information on our acquisitions of Reata and HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## AMORTIZATION AND IMPAIRMENT OF ACQUIRED INTANGIBLE ASSETS

Our amortization expense is based on the economic consumption and impairment of intangible assets. Our most significant amortizable intangible assets are related to TYSABRI, AVONEX, SPINRAZA, VUMERITY and SKYCLARYS, which was obtained as part of our acquisition of Reata in September 2023. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

For the year ended December 31, 2024, amortization and impairment of acquired intangible assets reflects the impact of a \$40.0 million impairment charge related to intangible assets from other clinical programs we acquired from Reata, reducing the remaining book value of these IPR&D intangible assets to zero, and a \$20.2 million impairment charge related to intangible assets associated with Samsung Bioepis commercialization rights terminated during the third quarter of 2024. For the year ended December 31, 2023, we had no impairment charges.

Amortization of acquired intangible assets, excluding impairment charges, totaled \$386.5 million, \$240.6 million and \$246.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. For 2024 compared to 2023, the increase in amortization of acquired intangible assets, excluding impairment charges, was primarily due to amortization for the Reata acquisition acquired intangible assets associated with SKYCLARYS.

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. For additional information on our 2019 Development and Commercialization Agreement with Samsung Bioepis, please read *Note 19, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

## COLLABORATION PROFIT SHARING/(LOSS REIMBURSEMENT)

Collaboration profit sharing/(loss reimbursement) 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 third quarter of 2023, collaboration profit sharing/(loss reimbursement) related to Sage's 50.0% share of the profit or loss in the U.S. related to ZURZUAE for PPD.

For the years ended December 31, 2024, 2023 and 2022, we recognized net profit-sharing expense of approximately \$227.4 million, \$223.5 million and \$217.4 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits.

For the years ended December 31, 2024 and 2023, we recognized net profit-sharing expense of approximately \$27.0 million and net loss reimbursement of approximately \$4.7 million, respectively, to reflect Sage's 50.0% share of net collaboration results in the U.S. for ZURZUAE for PPD.

For additional information on our collaboration and license arrangements with Samsung Bioepis and Sage, 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

Consideration payable for certain of our business combinations include future payments that are contingent upon the occurrence of a particular event or events. We record an obligation for such contingent consideration payments at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in our condensed consolidated statements of income. In connection with our acquisition of HI-Bio in July 2024 we recorded contingent consideration obligations related to potential milestone payments.

For the year ended December 31, 2024, the changes in the fair value of our contingent consideration obligations were primarily due to changes in interest rates used to revalue our contingent consideration liabilities, the passage of time and updates to the expected timing of achieving certain milestones which will trigger contingent consideration payments.

For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## RESTRUCTURING CHARGES

### 2023 FIT FOR GROWTH RESTRUCTURING PROGRAM

In 2023 we initiated additional cost saving measures as part of our Fit for Growth program to reduce operating costs, while improving operating efficiency and effectiveness. The Fit for Growth program is expected to generate approximately \$1.0 billion in gross operating expense savings by the end of 2025, some of which will be reinvested in various initiatives. The Fit for Growth program is currently estimated to include net headcount reductions of approximately 1,000 employees and we expect to incur restructuring charges ranging from approximately \$260.0 million to \$280.0 million.

Total charges incurred from our 2023 Fit for Growth program are summarized as follows:

	For the Years Ended December 31,					
	2024			2023		
(In millions)	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accelerated Depreciation and Other Costs	Total
Selling, general and administrative	\$ —	\$ 13.8	\$ 13.8	\$ —	\$ 23.3	\$ 23.3
Research and development	—	11.7	11.7	—	1.2	1.2
Restructuring charges	24.2	—	24.2	153.4	34.6	188.0
Total charges	\$ 24.2	\$ 25.5	\$ 49.7	\$ 153.4	\$ 59.1	\$ 212.5

*Other Costs:* includes costs associated with items such as asset abandonment and write-offs, facility closure costs, pretax gains and losses resulting from the termination of certain leases, employee non-severance expense, consulting fees and other costs.

## REATA INTEGRATION

Following the close of our Reata acquisition in September 2023, we implemented an integration plan designed to realize operating synergies through cost savings and avoidance. Under this initiative, we estimate we will incur total integration charges of approximately \$35.0 million, related to severance and employment costs. These severance and employment costs were substantially incurred during 2023.

Total charges incurred from our Reata integration are summarized as follows:

(In millions)	For the Years Ended December 31,					
	2024			2023		
	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accelerated Depreciation and Other Costs	Total
Selling, general and administrative	\$ —	\$ 6.3	\$ 6.3	\$ —	\$ —	\$ —
Research and development	—	11.9	11.9	—	—	—
Restructuring charges	3.4	—	3.4	30.4	—	30.4
Total charges	\$ 3.4	\$ 18.2	\$ 21.6	\$ 30.4	\$ —	\$ 30.4

In connection with our acquisition of Reata we assumed responsibility for a single-tenant, build-to-suit building of approximately 327,400 square feet of office and laboratory space located in Plano, Texas, with an initial lease term of 16 years. We do not intend to occupy this building and are evaluating opportunities to sublease the property. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## HI-BIO INTEGRATION

Following the close of our HI-Bio acquisition in July 2024, we implemented an integration plan designed to realize operating synergies through cost savings and avoidance. Under this initiative, we incurred approximately \$2.6 million of severance and employment costs, which are reflected in restructuring charges within our consolidated statements of income for the year ended December 31, 2024. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, 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 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, deprioritization of certain research and development programs, the consolidation of certain real estate locations and operating efficiencies across our selling, general and administrative and research and development functions. Charges related to our 2022 cost saving initiatives were substantially incurred during 2022 with remaining payments expected to be made through 2026.

Total charges incurred from our 2022 cost saving initiatives are summarized as follows:

(In millions)	For the Years Ended December 31,					
	2023			2022		
	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accumulated Depreciation and Other Costs <sup>(1)</sup>	Total
Restructuring charges	\$ (2.2)	\$ 2.6	\$ 0.4	\$ 112.6	\$ 18.5	\$ 131.1
Total charges	\$ (2.2)	\$ 2.6	\$ 0.4	\$ 112.6	\$ 18.5	\$ 131.1

<sup>(1)</sup> Amounts reflect a gain recorded during the third quarter of 2022 of approximately \$5.3 million related to the partial termination of a portion of our lease located at 300 Binney Street. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to our consolidated financial statements included in this report.

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

## OTHER (INCOME) EXPENSE, NET

For 2024 compared to 2023, the change in other (income) expense, net primarily reflects lower interest income driven by lower cash balances in 2024, compared to 2023, partially offset by higher net losses on our holdings in equity securities in 2023.

## NET (GAINS) LOSSES IN EQUITY SECURITIES

For the year ended December 31, 2024, net unrealized losses and realized gains on our holdings in equity securities were approximately \$102.4 million and \$2.0 million, respectively, compared to net unrealized and realized losses of approximately \$270.0 million and \$5.2 million, respectively, in 2023.

- The net unrealized losses recognized during the year ended December 31, 2024, primarily reflect a decrease in the aggregate fair value of our investments in Sage common stock of approximately \$101.4 million, partially offset by an increase in the fair value of Denali and Sangamo common stock of approximately \$7.5 million.
- The net unrealized losses recognized during the year ended December 31, 2023, primarily reflect a decrease in the aggregate fair value of our investments in Sage, Denali, Sangamo and Ionis common stock of approximately \$248.5 million.

## INTEREST INCOME AND EXPENSE

For the year ended December 31, 2024, net interest expense was approximately \$182.7 million, compared to net interest income of \$29.6 million in 2023. The change was primarily due to lower interest income driven by lower cash balances in 2024, compared to 2023, due to use of cash on hand for business development transactions.

For 2025 compared to 2024, we anticipate lower net interest expense as a result of higher cash balances, somewhat offset by lower interest rates, leading to more interest income.

## INCOME TAX PROVISION

(In millions, except percentages)

	For the Years Ended December 31,		
	2024	2023	2022
Income before income tax (benefit) expense	\$ 1,906.0	\$ 1,296.8	\$ 3,591.8
Income tax (benefit) expense	273.8	135.3	632.8
Effective tax rate	14.4%	10.4%	17.6%

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 2024 compared to 2023, the increase in our effective tax rate was partially driven by the relative deferred tax effects of the changes in the value of our equity investments and amortization of purchased intangible assets and inventory. Further, 2023 benefited from the combined impacts of Reata acquisition-related expenses and the resolution of an uncertain tax matter related to tax credits. This was partially offset by a 2024 benefit related to a decrease in our valuation allowance related to projected future foreign taxable income.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

As a result of decreases in our stock price between the grant date of certain share-based compensation awards and the vesting date in 2025, we expect that we will record an income tax expense of approximately \$15.0 million during the first quarter of 2025, upon the vesting of these awards. The exact amount of the income tax expense will depend on our stock price at the time of vesting.

## PILLAR TWO

The OECD has issued model rules, which generally provide for a jurisdictional minimum effective tax rate of 15.0% as defined in those rules. Various countries have or are in the process of enacting legislation intended to implement the principles effective January 1, 2024. Our income tax provision for the year ended December 31, 2024, reflects currently enacted legislation and guidance related to the OECD model rules. This enacted legislation and guidance related to the OECD model rules did not result in any material adjustments to our income tax provision or income tax balances as of December 31, 2024. On January 20, 2025, the Global Tax Deal Executive Order was issued. At this stage, we do not believe this Executive Order impacts our financial results as of December 31, 2024.

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.

## NONCONTROLLING INTERESTS, NET OF TAX

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

In November 2023 we notified Neurimmune of our decision to terminate the Neurimmune Agreement. Subsequent to the termination, we reconsidered our relationship with Neurimmune and determined that we were no longer the primary beneficiary of the variable interest entity. As a result, we recorded a net gain on the deconsolidation of Neurimmune of approximately \$3.0 million, which was recorded in other (income) expense, net within our consolidated statements of income for the year ended December 31, 2023.

For additional information on the deconsolidation and our collaboration agreement with Neurimmune, please read *Note 20, Investments in Variable Interest Entities*, 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,		% Change	\$ Change
	2024	2023		
Financial assets:				
Cash and cash equivalents	\$ 2,375.0	\$ 1,049.9	126.2 %	\$ 1,325.1
Total cash and cash equivalents	\$ 2,375.0	\$ 1,049.9	126.2 %	\$ 1,325.1
Borrowings:				
Current portion of notes payable and term loan	\$ 1,748.6	\$ 150.0	nm	\$ 1,598.6
Notes payable and term loan	4,547.2	6,788.2	(33.0)	(2,241.0)
Total borrowings	\$ 6,295.8	\$ 6,938.2	(9.3)%	\$ (642.4)
Working Capital:				
Current assets	\$ 7,456.8	\$ 6,859.3	8.7 %	\$ 597.5
Current liabilities	(5,528.8)	(3,434.3)	61.0	(2,094.5)
Total working capital	\$ 1,928.0	\$ 3,425.0	(43.7)%	\$ (1,497.0)

<sup>nm</sup> 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 that generic and biosimilar competition for many of our key products, the continued overall decline of our MS business and our investments in the launch of key new products and the development of our pipeline will have a significant adverse impact on our future cash flow from operations.

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

On July 2, 2024, we completed the acquisition of all of the issued and outstanding shares of HI-Bio. Under the terms of this acquisition, we paid shareholders of HI-Bio approximately \$1.15 billion as well as an additional \$43.7 million related to working capital adjustments as of the transaction close date. These amounts were funded through available cash on hand. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, 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.



## LIQUIDITY

### WORKING CAPITAL

Working capital is defined as current assets less current liabilities. Our working capital was \$1.9 billion as of December 31, 2024, compared to \$3.4 billion as of December 31, 2023. The change in working capital reflects an increase in total current assets of approximately \$597.5 million and an increase in total current liabilities of approximately \$2.1 billion. The changes in total current assets and total current liabilities were primarily driven by the following:

#### CURRENT ASSETS

- \$1.3 billion increase in cash and cash equivalents;
- \$259.3 million decrease in accounts receivable, net related to our ongoing operations; and
- \$429.5 million decrease in other current assets primarily due to the receipt of \$437.5 million from Samsung BioLogics related to the sale of our 49.9% equity interest in Samsung Bioepis.

#### CURRENT LIABILITIES

- \$184.1 million increase in accrued expense and other primarily due to \$279.3 million of short-term contingent consideration recognized from our acquisition of HI-Bio, offset in part by the timing of our annual incentive compensation payment and other benefits-related payments; and
- \$1.6 billion increase in current portion of debt primarily due to the reclassification of our \$1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025, from long-term to short-term and the repayment of our 2023 Term Loan.

For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report. For additional information on the sale of our equity interest in Samsung Bioepis and the sale of our PRV, please read *Note 3, Dispositions*, to our consolidated financial statements included in this report. For additional information on our 2023 Term Loan, please read *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

### CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

As of December 31, 2024, we had cash and cash equivalents totaling approximately \$2.4 billion compared to approximately \$1.0 billion as of December 31, 2023. The increase in the balance was primarily due to cash generated by our operations, the receipt of \$437.5 million in April 2024 from Samsung BioLogics related to the sale of our 49.9% equity interest in Samsung Bioepis, the net cash receipt of \$88.6 million from the sale of one of our two PRVs and proceeds from the sale of a portion of our Denali common stock and our remaining Sangamo common stock during 2024. The increase was offset in part by \$1.15 billion of cash and cash equivalents used to fund our acquisition of HI-Bio in July 2024 and \$650.0 million of cash used for the repayment of our 2023 Term Loan.

Until required for another use in our business, we typically invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments, overnight reverse repurchase agreements and other interest-bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type. We have experienced no significant limitations in our liquidity resulting from uncertainties in the banking sector.

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

(In millions)	As of December 31,	
	2024	2023
Denali <sup>(1)</sup>	\$ 145.8	\$ 273.6
Sage	33.9	135.3
Sangamo <sup>(1)</sup>	—	7.9
Total	\$ 179.7	\$ 416.8

<sup>(1)</sup> During 2024 we sold a portion of our Denali common stock and the remaining shares of our Sangamo common stock.

Our ability to liquidate our investments in Denali and Sage 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.

## CASH FLOW

The following table summarizes our cash flow activity:

(In millions, except percentages)	For the Years Ended December 31,			% Change	
	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Net cash flow provided by (used in) operating activities	\$ 2,875.5	\$ 1,547.2	\$ 1,384.3	85.9%	11.8%
Net cash flow provided by (used in) investing activities	(799.2)	(4,101.0)	1,576.6	(80.5)	(360.1)
Net cash flow provided by (used in) financing activities	(683.5)	149.3	(1,747.3)	(557.8)	108.5

## OPERATING ACTIVITIES

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

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

For 2024 compared to 2023, the increase in net cash flow provided by operating activities was primarily due to higher net income, lower employee-benefit payments made during the first quarter of 2024, as compared to the same period in 2023, lower estimated federal tax payments made during 2024, as compared to 2023, and changes in non-cash adjustments to net income. The increase was partially offset by the timing of working capital, which includes higher inventory levels, primarily associated with our contract manufacturing for LEQEMBI.

## INVESTING ACTIVITIES

For 2024 compared to 2023, the change in net cash flow in investing activities was primarily due to cash payments made associated with our acquisition of HI-Bio in 2024 and with our acquisition of Reata in 2023. Additionally, cash outlay in 2023 was partially offset by net proceeds received from the sale of our marketable securities.

## FINANCING ACTIVITIES

For 2024 compared to 2023, the change in net cash flow in financing activities was primarily due to the repayment of our 2023 Term Loan for \$650.0 million during 2024 compared to the issuance of term loans totaling \$1.0 billion under our 2023 Term Loan which were used to partially fund our acquisition of Reata in 2023, partially offset by repayments of borrowings and debt premiums paid in 2023 totaling \$809.9 million.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## CAPITAL RESOURCES

### DEBT AND CREDIT FACILITIES

#### LONG-TERM DEBT AND TERM LOAN CREDIT AGREEMENTS

Our long-term obligations primarily consist of long-term debt related to our Senior Notes with final maturity dates ranging between 2030 and 2051. As of December 31, 2024, our outstanding balance related to long-term debt was \$4,547.2 million.

In connection with our acquisition of Reata in September 2023 we entered into a \$1.5 billion term loan credit agreement. On the closing date of the Reata acquisition we drew \$1.0 billion from the 2023 Term Loan, comprised of a \$500.0 million floating rate 364-day tranche and a \$500.0 million floating rate three-year tranche. The remaining unused commitment of \$500.0 million was terminated. As of December 31, 2023, we repaid \$350.0 million of the 364-day tranche. The remaining \$150.0 million portion of the 364-day tranche was repaid during the first quarter of 2024.

Additionally, during the first quarter of 2024 we repaid \$250.0 million of the three-year tranche, with the remaining \$250.0 million portion being subsequently repaid in full during the second quarter of 2024.

#### 2024 REVOLVING CREDIT FACILITY

In August 2024 we entered into a \$1.5 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 January 2020. As of December 31, 2024, we had no outstanding borrowings and were in compliance with all covenants under this facility.

For a summary of the fair values of our outstanding borrowings as of December 31, 2024 and 2023, please read *Note 8, Fair Value Measurements*, to our consolidated financial statements included in this report.

For additional information on our Senior Notes, 2023 Term Loan and credit facility please read, *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

### 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 shares repurchased under our 2020 Share Repurchase Program were retired. There were no share repurchases of our common stock during the years ended December 31, 2024 and 2023. Approximately \$2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2024.

### CAPITAL EXPENDITURES

In the fourth quarter of 2021 we began construction of a new gene therapy, clinical packaging and other manufacturing facility in RTP, North Carolina to support our gene therapy pipeline across multiple therapeutic areas. The new manufacturing facility will be approximately 197,000 square feet with an estimated total investment of approximately \$195.0 million. We estimate the construction of this manufacturing facility will be completed during 2025. As we continue to advance our research and development prioritization efforts, which includes refocusing our investment in gene therapy, we are evaluating several alternative uses for this facility.

## CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

### CONTRACTUAL OBLIGATIONS

The following table summarizes our contractual obligations as of December 31, 2024, 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.

(In millions)	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Non-cancelable operating leases <sup>(1)(2)(3)</sup>	\$ 459.6	\$ 88.7	\$ 152.5	\$ 66.0	\$ 152.4
Long-term debt obligations <sup>(4)</sup>	9,797.0	1,965.0	323.7	323.7	7,184.6
Purchase and other obligations <sup>(5)</sup>	566.7	406.2	135.3	20.7	4.5
Defined benefit obligation	107.1	—	—	—	107.1
Total contractual obligations	\$ 10,930.4	\$ 2,459.9	\$ 611.5	\$ 410.4	\$ 7,448.6

<sup>(1)</sup> 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 expense.

<sup>(2)</sup> Obligations are presented net of sublease income expected to be received for our vacated portions of our Weston, Massachusetts facility and other facilities throughout the world.

<sup>(3)</sup> In connection with our acquisition of Reata in September 2023 we assumed operating lease commitments, including the responsibility for a single-tenant, built-to-suit building with a total net present value of rental expense of approximately \$154.4 million over the next 15 years. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

<sup>(4)</sup> Long-term debt obligations are related to our 2021 Exchange Offer Senior Notes, our 2020 Senior Notes and our 2015 Senior Notes, including principal and interest payments. For additional information on our long-term debt obligations, please read *Note 13, Indebtedness*, to our consolidated financial statements included in this report.

<sup>(5)</sup> Purchase and other obligations include \$234.0 million related to the remaining payments on the Transition Toll Tax and \$11.7 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 to Ionis 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.

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.

#### QALSODY

We make royalty payments to Ionis on annual worldwide net sales of QALSODY using a tiered royalty rate between 11.0% and 15.0%, which are recognized 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 our consolidated financial statements included in this report.

#### VUMERITY

We make royalty payments to Alkermes on worldwide net sales of VUMERITY using a royalty rate of 15.0%, which are recognized as cost of sales in our consolidated statements of income. Royalties payable on net sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval.

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.

## SKYCLARYS

In connection with our acquisition of Reata in September 2023 we assumed additional contractual obligations related to royalty payments. Reata entered into agreements to pay royalties on future sales of SKYCLARYS, which will cumulatively range in the low- to mid-single digits.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

## CONTINGENT CONSIDERATION RELATED TO BUSINESS COMBINATIONS

In connection with our acquisition of HI-Bio in July 2024 we may make additional payments based upon the achievement of certain milestone events. We recognized the contingent consideration obligations associated with this acquisition at its fair value on the acquisition date and we revalue this obligation each reporting period. We may pay up to an additional \$650.0 million in potential future development and regulatory milestone payments. The acquisition-date fair value of these milestones was approximately \$485.1 million. We anticipate that we may trigger the first and second milestone payments of approximately \$150.0 million each in 2025.

For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to our condensed consolidated financial statements included in this report.

## CONTINGENT DEVELOPMENT, REGULATORY AND COMMERCIAL MILESTONE PAYMENTS

Based on our development plans as of December 31, 2024, we could trigger potential future milestone payments to third parties of up to approximately \$3.8 billion, including approximately \$0.5 billion in development milestones, approximately \$0.5 billion in regulatory milestones and approximately \$2.8 billion in commercial milestones, as part of our various collaborations, including licensing and development programs and HI-Bio's pre-existing commitments, as discussed below. 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, 2024, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

If certain clinical and commercial milestones are met, we may pay up to approximately \$73.6 million in milestones in 2025 under our current agreements, excluding opt-in payments.

We acquired HI-Bio's pre-existing in-license commitments under third-party agreements, which include tiered royalties on potential future sales of felzartamab and izastobart/HIB210, ranging from high-single digit to mid-teen percentages, as well as potential future development, regulatory and commercial milestone payments related to felzartamab and izastobart/HIB210 of up to \$130.0 million, \$230.0 million and \$640.0 million, respectively. This amount includes potential milestone payments due upon the first patient dosed in a phase 3 clinical trial of felzartamab in a first and second indication of \$35.0 million and \$30.0 million, respectively, which we anticipate will be triggered in 2025.

## OTHER FUNDING COMMITMENTS

As of December 31, 2024, 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 \$21.7 million in our consolidated balance sheets for expenditures incurred by CROs as of December 31, 2024. We have approximately \$509.2 million in cancellable future commitments based on existing CRO contracts as of December 31, 2024.

## 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, 2024, we have approximately \$173.8 million of liabilities associated with uncertain tax positions.

As of December 31, 2024 and 2023, we have accrued income tax liabilities of approximately \$234.0 million and \$419.5 million, respectively, under the Transition Toll Tax. The amount accrued as of December 31, 2024, is expected to be paid within one year. The Transition Toll Tax is being paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

## 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, 2024, 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 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 FASB 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. 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, 2024 and 2023, a 10.0% change in our discounts, contractual adjustments and reserves would have resulted in a decrease of our pre-tax earnings by approximately \$351.9 million and \$345.5 million, respectively.

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.

## 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, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense within our consolidated statements of income 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, IPR&D product candidates and priority review vouchers. 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.



## 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.

## 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 \$60.2 million for the year ended December 31, 2024, related to the impairment of other clinical programs we acquired from Reata and Samsung Bioepis commercialization rights terminated during the third quarter of 2024. For the year ended December 31, 2023, we had no impairment charges. For additional information on our impairments, please read *Note 7, Intangible Assets and Goodwill*, to our consolidated financial statements included in this report.

Our most significant intangible assets relate to SKYCLARYS and TYSABRI. We amortize the intangible assets related to our marketed products using the economic consumption method, which is 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 2024, 2023 and 2022, 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 changes in the fair value as an adjustment to (gain) loss on fair value remeasurement of contingent consideration 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. These fair value measurements represent Level 3 measurements as they are based on significant inputs that are 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 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 (benefit) expense in our consolidated statements of income.

## **BUSINESS COMBINATIONS**

Business combinations are recorded using the acquisition method of accounting. The results of operations of the acquired company are included in our results of operations beginning on the acquisition date, and assets acquired and liabilities assumed are recognized on the acquisition date at their respective fair values. Any excess of consideration transferred over the net carrying value of the assets acquired and liabilities assumed as of the acquisition date is recognized as goodwill.

We use the multi-period excess earnings method, which is a form of the income approach, utilizing post-tax cash flow and discount rates in estimating the fair value of identifiable intangible assets acquired when allocating the purchase consideration paid for the acquisition. The estimates of the fair value of identifiable intangible assets involve significant judgment by management and include assumptions with measurement uncertainty, such as the amount and timing of projected cash flow, long-term sales forecasts, discount rates and additionally for IPR&D intangible assets, the timing and probability of regulatory and commercial success.

We use the net realizable value method in estimating the fair value of acquired finished goods and work-in-process inventory. Raw materials acquired are valued using the replacement cost method.

Transaction and restructuring costs related to business combinations are expensed as incurred. The fair value of assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. If we determine the assets acquired do not meet the definition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination.

## **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 conflict between Russia and Ukraine and the military conflict in the Middle East. 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, foreign currency options, 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 and Swiss franc.

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, 2024, and is not expected to have a material impact on our results of operations or financial position in the future. In December 2023 the Argentinian Peso experienced a substantial devaluation following a presidential election. The devaluation resulted in a \$16.0 million charge recorded during the fourth quarter of 2023 in other (income) expense, net within our consolidated statements of income for the year ended December 31, 2023.

## REVENUE AND OPERATING EXPENSE HEDGING PROGRAM

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenue and operating expense. We use foreign currency forward contracts and foreign currency options to manage foreign currency risk, with the majority of our forward contracts and options used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 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, 2024 and 2023, 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 \$191.7 million and \$249.4 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.

## **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 conflict between Russia and Ukraine and the military conflict in the Middle East, 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, 2024 and 2023.

## **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, 2024 and 2023, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately \$18.0 million and \$41.7 million, respectively.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this Item 8 is contained on pages F-1 through F-83 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, 2024. 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, 2024, 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, 2024. 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, 2024, 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, 2024, 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

### RULE 10b5-1 TRADING ARRANGEMENTS

From time to time, our officers (as defined in Rule 16a-1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the fourth quarter of 2024 our officers and directors took the following actions with respect to 10b5-1 trading arrangements:

Name and Position	Action	Date	Trading Arrangement		Total Shares to be Sold	Expiration Date
			Rule 10b5-1	Non-Rule 10b5-1		
Stephen A. Sherwin, Director	Adopt	11/7/2024	X	—	8,760	05/08/2025

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not Applicable.

## PART III

### 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.

**Code of Business Conduct and Ethics:** 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](http://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.

**Insider Trading Policy:** We have adopted an insider trading policy governing the purchase, sale and/or other dispositions of our securities and those of public companies in which we do business with by our directors, executive officers, employees and temporary staff, that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable NASDAQ listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

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*” and “*Miscellaneous - Stockholder Proposals*” contained in the proxy statement for our 2025 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 Tables*,” “*Compensation Discussion and Analysis*” and “*Corporate Governance*” contained in the proxy statement for our 2025 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 2025 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*” contained in the proxy statement for our 2025 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 2025 annual meeting of stockholders.



## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### *a. (1) Consolidated Financial Statements:*

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

<b>Financial Statements</b>	<b>Page Number</b>
Consolidated Statements of Income	F-2
Consolidated Statements of Comprehensive Income	F-3
Consolidated Balance Sheets	F-4
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Certain totals may not sum due to rounding.

#### *(2) Exhibits*

The exhibits listed on the Exhibit Index beginning on page 95, 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	<a href="#">Agreement and Plan of Merger by and among Reata Pharmaceuticals, Inc., Biogen Inc. and River Acquisition, Inc. dated as of July 28, 2023. Filed as Exhibit 2.1 to our current report on Form 8-K filed July 31, 2023.</a>
3.1	<a href="#">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.</a>
3.2	<a href="#">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.</a>
3.3	<a href="#">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.</a>
3.4	<a href="#">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 25, 2024.</a>
3.5	<a href="#">Fifth Amended and Restated Bylaws of Biogen Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on December 12, 2023.</a>
4.1	<a href="#">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.</a>
4.2	<a href="#">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.</a>
4.3	<a href="#">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.</a>
4.4	<a href="#">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.</a>
4.5	<a href="#">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.</a>
4.6+	<a href="#">Description of Securities. Filed as Exhibit 4.6 to our Annual Report on Form 10-K for the year ended December 31, 2023.</a>
10.1	<a href="#">Credit Agreement, dated as of August 12, 2024, 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 August 14, 2024.</a>
10.2	<a href="#">Credit Agreement, dated as of August 28, 2023, among Biogen Inc., JPMorgan Chase Bank N.S., as administrative agent and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2023.</a>
10.3†	<a href="#">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.</a>
10.4†	<a href="#">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.</a>
10.5	<a href="#">Form of performance share award agreement under the Biogen Inc. 2024 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.</a>
10.6	<a href="#">Form of restricted stock award agreement under the Biogen Inc. 2024 Omnibus Equity Plan. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.</a>
10.7	<a href="#">Form of non-employee director restricted stock unit award agreement under the Biogen Inc. 2024 Omnibus Equity Plan. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.</a>
10.8*	<a href="#">Biogen Inc. 2017 Omnibus Equity Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2017.</a>
10.9*	<a href="#">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.</a>
10.10*	<a href="#">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.</a>
10.11*	<a href="#">Form of nonqualified stock option award agreement under Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.20 to our Annual Report on Form 10-K for the year ended December 31, 2022.</a>
10.12*	<a href="#">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.</a>
10.13*	<a href="#">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.</a>
10.14+	<a href="#">Voluntary Board of Directors Savings Plan.</a>
10.15+	<a href="#">Biogen Inc. Supplemental Savings Plan.</a>
10.16*	<a href="#">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.</a>

<b>Exhibit No.</b>	<b>Description</b>
10.17*	<a href="#">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.</a>
10.18*	<a href="#">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.</a>
10.19*	<a href="#">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.</a>
10.20*	<a href="#">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.</a>
10.21*	<a href="#">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.</a>
10.22*	<a href="#">Letter amending employment arrangement of Susan Alexander dated February 28, 2020. Filed as Exhibit 10.32 to our Annual Report on Form 10-K for the year ended December 31, 2023.</a>
10.23*	<a href="#">Letter regarding employment arrangement of Rachid Izzar dated August 1, 2019. Filed as Exhibit 10.33 to our Annual Report on Form 10-K for the year ended December 31, 2023.</a>
10.24*	<a href="#">Letter regarding employment arrangement of Nicole Murphy dated January 28, 2022. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.</a>
10.25*	<a href="#">Letter regarding employment arrangement of Robin Kramer dated October 28, 2024. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on October 30, 2024.</a>
10.26	<a href="#">Amended and Restated Collaboration Agreement, dated October 22, 2017, between Biogen MA Inc. and Eisai Co., LTD. Filed as Exhibit 10.45 to our Annual Report on Form 10-K for the year ended December 31, 2022.</a>
10.27	<a href="#">First Amendment to Amended and Restated Collaboration Agreement, dated March 13, 2022, between Biogen MA Inc. and Eisai Co., LTD. Filed as Exhibit 10.46 to our Annual Report on Form 10-K for the year ended December 31, 2022.</a>
19.1+	<a href="#">Policy relating to insider trading.</a>
21+	<a href="#">Subsidiaries.</a>
23+	<a href="#">Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm.</a>
31.1+	<a href="#">Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2+	<a href="#">Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1++	<a href="#">Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
97.1	<a href="#">Policy relating to recovery of erroneously awarded compensation. Filed as Exhibit 97.1 to our Annual Report on Form 10-K for the year ended December 31, 2023.</a>
101++	The following materials from Biogen Inc.'s Annual Report on Form 10-K for the year ended December 31, 2024, 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.
104	Cover Page Interactive Data File (contained in Exhibit 101)
*	Management contract or compensatory plan or arrangement.
†	Confidential treatment has been granted or requested with respect to portions of this exhibit.
+	Filed herewith.
++	Furnished herewith.

## 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 12, 2025

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.

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/S/ CHRISTOPHER A. VIEHBACHER</u> Christopher A. Viehbacher	Director and Chief Executive Officer (principal executive officer)	February 12, 2025
<u>/S/ MICHAEL R. McDONNELL</u> Michael R. McDonnell	Executive Vice President and Chief Financial Officer (principal financial officer)	February 12, 2025
<u>/S/ ROBIN C. KRAMER</u> Robin C. Kramer	Senior Vice President, Chief Accounting Officer (principal accounting officer)	February 12, 2025
<u>/S/ CAROLINE D. DORSA</u> Caroline D. Dorsa	Director and Chair of the Board of Directors	February 12, 2025
<u>/S/ MARIA C. FREIRE</u> Maria C. Freire	Director	February 12, 2025
<u>/S/ WILLIAM A. HAWKINS</u> William A. Hawkins	Director	February 12, 2025
<u>/S/ SUSAN LANGER</u> Susan Langer	Director	February 12, 2025
<u>/S/ JESUS B. MANTAS</u> Jesus B. Mantas	Director	February 12, 2025
<u>/S/ LLOYD B. MINOR</u> Lloyd B. Minor	Director	February 12, 2025
<u>/S/ SIR MENELAS PANGALOS</u> Sir Menelas Pangalos	Director	February 12, 2025
<u>/S/ MONISH PATOLAWALA</u> Monish Patolawala	Director	February 12, 2025
<u>/S/ ERIC K. ROWINSKY</u> Eric K. Rowinsky	Director	February 12, 2025
<u>/S/ STEPHEN A. SHERWIN</u> Stephen A. Sherwin	Director	February 12, 2025

## BIOGEN INC. AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS

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

	For the Years Ended December 31,		
	2024	2023	2022
Revenue:			
Product revenue, net	\$ 7,213.5	\$ 7,246.7	\$ 7,987.8
Revenue from anti-CD20 therapeutic programs	1,749.9	1,689.6	1,700.5
Alzheimer's collaboration revenue	59.9	—	—
Contract manufacturing, royalty and other revenue	652.6	899.3	485.1
Total revenue	9,675.9	9,835.6	10,173.4
Cost and expense:			
Cost of sales, excluding amortization and impairment of acquired intangible assets	2,310.4	2,533.4	2,278.3
Research and development	2,041.8	2,462.0	2,231.1
Selling, general and administrative	2,403.7	2,549.7	2,403.6
Amortization and impairment of acquired intangible assets	446.7	240.6	365.9
Collaboration profit sharing/(loss reimbursement)	254.4	218.8	(7.4)
(Gain) loss on fair value remeasurement of contingent consideration	27.7	—	(209.1)
Restructuring charges	30.2	218.8	131.1
Gain on sale of priority review voucher, net	(88.6)	—	—
Gain on sale of building, net	—	—	(503.7)
Other (income) expense, net	343.6	315.5	(108.2)
Total cost and expense	7,769.9	8,538.8	6,581.6
Income before income tax (benefit) expense and equity in (income) loss of investee, net of tax	1,906.0	1,296.8	3,591.8
Income tax (benefit) expense	273.8	135.3	632.8
Equity in (income) loss of investee, net of tax	—	—	(2.6)
Net income	1,632.2	1,161.5	2,961.6
Net income (loss) attributable to noncontrolling interests, net of tax	—	0.4	(85.3)
Net income attributable to Biogen Inc.	\$ 1,632.2	\$ 1,161.1	\$ 3,046.9
Net income per share:			
Basic earnings per share attributable to Biogen Inc.	\$ 11.21	\$ 8.02	\$ 20.96
Diluted earnings per share attributable to Biogen Inc.	\$ 11.18	\$ 7.97	\$ 20.87
Weighted-average shares used in calculating:			
Basic earnings per share attributable to Biogen Inc.	145.6	144.7	145.3
Diluted earnings per share attributable to Biogen Inc.	145.9	145.6	146.0

See accompanying notes to these consolidated financial statements.

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

	For the Years Ended December 31,		
	2024	2023	2022
Net income attributable to Biogen Inc.	\$ 1,632.2	\$ 1,161.1	\$ 3,046.9
Other comprehensive income (loss):			
Unrealized gains (losses) on securities available for sale, net of tax	—	15.7	(13.5)
Unrealized gains (losses) on cash flow hedges, net of tax	76.6	(40.1)	(38.7)
Gains (losses) on net investment hedges, net of tax	—	—	(25.5)
Unrealized gains (losses) on pension benefit obligation, net of tax	(14.0)	(1.5)	43.7
Currency translation adjustments, net of tax	(45.1)	37.1	(24.2)
Total other comprehensive income (loss), net of tax	17.5	11.2	(58.2)
Comprehensive income (loss) attributable to Biogen Inc.	1,649.7	1,172.3	2,988.7
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	—	0.4	(85.3)
Comprehensive income (loss)	\$ 1,649.7	\$ 1,172.7	\$ 2,903.4

See accompanying notes to these consolidated financial statements.



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

		As of December 31,	
		2024	2023
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents		\$ 2,375.0	\$ 1,049.9
Accounts receivable, net of allowance for doubtful accounts of \$2.2 and \$2.4, respectively		1,404.8	1,664.1
Due from anti-CD20 therapeutic programs		464.0	435.9
Inventory		2,460.5	2,527.4
Other current assets		752.5	1,182.0
Total current assets		7,456.8	6,859.3
Property, plant and equipment, net		3,181.3	3,309.7
Operating lease assets		356.4	420.0
Intangible assets, net		9,691.2	8,363.0
Goodwill		6,478.9	6,219.2
Deferred tax asset		324.2	928.6
Investments and other assets		560.5	745.0
Total assets		<u>\$ 28,049.3</u>	<u>\$ 26,844.8</u>
<b>LIABILITIES AND EQUITY</b>			
Current liabilities:			
Current portion of notes payable and term loan		\$ 1,748.6	\$ 150.0
Taxes payable		548.3	257.4
Accounts payable		424.2	403.3
Accrued expense and other		2,807.7	2,623.6
Total current liabilities		5,528.8	3,434.3
Notes payable and term loan		4,547.2	6,788.2
Deferred tax liability		190.5	641.8
Long-term operating lease liabilities		334.5	400.0
Other long-term liabilities		732.3	781.1
Total liabilities		11,333.3	12,045.4
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		569.4	302.5
Accumulated other comprehensive income (loss)		(136.2)	(153.7)
Retained earnings		19,259.8	17,627.6
Treasury stock, at cost; 23.8 million and 23.8 million shares, respectively		(2,977.1)	(2,977.1)
Total equity		16,716.0	14,799.4
Total liabilities and equity		<u>\$ 28,049.3</u>	<u>\$ 26,844.8</u>

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,		
	2024	2023	2022
<b>Cash flow from operating activities:</b>			
Net income	\$ 1,632.2	\$ 1,161.5	\$ 2,961.6
Adjustments to reconcile net income to net cash flow from operating activities:			
Depreciation and amortization	673.2	494.8	518.4
Impairment of intangible assets	60.2	—	119.6
Excess and obsolescence charges related to inventory	101.9	124.4	336.2
Amortization of acquired inventory step-up	230.0	31.5	—
Share-based compensation	291.2	264.2	254.1
Contingent consideration	27.7	—	(209.1)
Deferred income taxes	(158.1)	(305.8)	(168.6)
(Gain) loss on strategic investments	101.4	277.1	265.9
(Gain) loss on equity method investment	—	—	(2.6)
Gain on sale of equity interest in Samsung Bioepis	—	—	(1,505.4)
Gain on sale of building, net	—	—	(503.7)
Gain on sale of priority review voucher, net	(88.6)	—	—
Other	159.6	148.2	208.2
Changes in operating assets and liabilities, net of effects of business acquired:			
Accounts receivable	222.3	61.3	(203.4)
Due from anti-CD20 therapeutic programs	(28.1)	(4.6)	(19.0)
Inventory	(273.8)	(130.9)	(320.2)
Accrued expense and other current liabilities	24.6	(201.6)	(113.4)
Income tax assets and liabilities	78.5	(299.0)	(142.3)
Other changes in operating assets and liabilities, net	(178.7)	(73.9)	(92.0)
Net cash flow provided by (used in) operating activities	2,875.5	1,547.2	1,384.3
<b>Cash flow from investing activities:</b>			
Purchases of property, plant and equipment	(153.7)	(277.0)	(240.3)
Proceeds from sales and maturities of marketable securities	—	7,380.8	3,671.0
Purchases of marketable securities	—	(5,140.7)	(3,448.5)
Acquisition of Reata, net of cash acquired	—	(6,926.1)	—
Acquisition of Hl-Bio, net of cash acquired	(1,074.8)	—	—
Proceeds from sale of equity interest in Samsung Bioepis	406.8	788.1	990.3
Proceeds from sale of building	—	—	582.6
Proceeds from sale of priority review voucher, net	88.6	—	—
Acquisitions of intangible assets	(206.1)	(34.4)	(2.9)
Proceeds from sales of strategic investments	144.7	119.6	—
Other	(4.7)	(11.3)	24.4
Net cash flow provided by (used in) investing activities	(799.2)	(4,101.0)	1,576.6
<b>Cash flow from financing activities:</b>			
Purchase of treasury stock	—	—	(750.0)
Payments related to issuance of stock for share-based compensation arrangements, net	(31.3)	(44.3)	(1.9)
Repayments of borrowings and premiums paid	(650.0)	(809.9)	(1,002.2)
Proceeds from borrowings	—	997.2	—
Net (distribution) contribution to noncontrolling interest	—	12.3	12.4
Other	(2.2)	(6.0)	(5.6)
Net cash flow provided by (used in) financing activities	(683.5)	149.3	(1,747.3)
Net increase (decrease) in cash and cash equivalents	1,392.8	(2,404.5)	1,213.6
Effect of exchange rate changes on cash and cash equivalents	(67.7)	35.1	(55.7)
Cash and cash equivalents, beginning of the year	1,049.9	3,419.3	2,261.4
Cash and cash equivalents, end of the year	\$ 2,375.0	\$ 1,049.9	\$ 3,419.3

See accompanying notes to these consolidated financial statements.

# **BIAGEN INC. AND SUBSIDIARIES** **CONSOLIDATED STATEMENTS OF EQUITY** (In millions)

For the Year Ended December 31, 2024										
	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings	Treasury stock		Total equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2023	—	\$ —	168.7	\$ 0.1	\$ 302.5	\$ (153.7)	\$ 17,627.6	(23.8)	\$ (2,977.1)	\$ 14,799.4
Net income	—	—	—	—	—	—	1,632.2	—	—	1,632.2
Other comprehensive income (loss), net of tax	—	—	—	—	—	17.5	—	—	—	17.5
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	36.3	—	—	—	—	36.3
Issuance of common stock under stock award plan	—	—	0.6	—	(67.7)	—	—	—	—	(67.7)
Compensation related to share-based payments	—	—	—	—	301.5	—	—	—	—	301.5
Other	—	—	—	—	(3.2)	—	—	—	—	(3.2)
Balance, December 31, 2024	—	\$ —	169.5	\$ 0.1	\$ 569.4	\$ (136.2)	\$ 19,259.8	(23.8)	\$ (2,977.1)	\$ 16,716.0

	For the Year Ended December 31, 2023											
	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2022	—	\$ —	167.9	\$ 0.1	\$ 73.3	\$ (164.9)	\$16,466.5	(23.8)	\$(2,977.1)	\$ 13,397.9	\$ (9.5)	\$13,388.4
Net income	—	—	—	—	—	—	1,161.1	—	—	1,161.1	0.4	1,161.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	11.2	—	—	—	11.2	—	11.2
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	12.3	12.3
Deconsolidation of noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(3.2)	(3.2)
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	45.1	—	—	—	—	45.1	—	45.1
Issuance of common stock under stock award plan	—	—	0.6	—	(89.5)	—	—	—	—	(89.5)	—	(89.5)
Compensation related to share-based payments	—	—	—	—	274.4	—	—	—	—	274.4	—	274.4
Other	—	—	—	—	(0.8)	—	—	—	—	(0.8)	—	(0.8)
Balance, December 31, 2023	—	\$ —	168.7	\$ 0.1	\$ 302.5	\$ (153.7)	\$17,627.6	(23.8)	\$(2,977.1)	\$ 14,799.4	\$ —	\$14,799.4

See accompanying notes to these consolidated financial statements.

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

	For the Year Ended December 31, 2022											
	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (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)
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 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

### NOTES TO 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. We have a broad portfolio of medicines to treat MS, have introduced the first approved treatment for SMA, co-developed treatments to address a defining pathology of Alzheimer's disease and launched the first approved treatment to target a genetic cause of ALS. We market the first and only drug approved in the U.S. and the E.U. for the treatment of FA in adults and adolescents aged 16 years and older. We are focused on advancing our pipeline in neurology, specialized immunology and rare diseases. We support our drug discovery and development efforts through internal research and development programs, external collaborations and acquisitions.

Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY and TYSABRI for the treatment of MS; SPINRAZA for the treatment of SMA; SKYCLARYS for the treatment of FA; QALSODY for the treatment of ALS; and FUMADERM for the treatment of severe plaque psoriasis.

We also have collaborations with Eisai on the commercialization of LEQEMBI for the treatment of Alzheimer's disease and Sage on the commercialization of ZURZUVAE for the treatment of PPD. 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 for the treatment of relapsed or refractory follicular lymphoma; COLUMVI, a bispecific antibody for the 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.

We commercialize a portfolio of biosimilars of advanced biologics including: BENEPALI, an etanercept biosimilar referencing ENBREL; IMRALDI, an adalimumab biosimilar referencing HUMIRA; FLIXABI, an infliximab biosimilar referencing REMICADE; and BYOOVIZ, a ranibizumab biosimilar referencing LUCENTIS, in certain international markets, as well as TOFIDENCE, a tocilizumab biosimilar referencing ACTEMRA, in the U.S. and certain international markets. We also have commercialization rights related to OPUVIZ, an aflibercept biosimilar referencing EYLEA.

On July 2, 2024, we completed the acquisition of HI-Bio. As a result of this transaction we acquired HI-Bio's lead asset, felzartamab, an anti-CD38 antibody currently being evaluated for three leading indications, AMR, PMN and IgAN. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to these consolidated financial statements.

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

##### 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. In November 2023 we terminated the Neurimmune Agreement, which resulted in the deconsolidation of our variable interest entity, Neurimmune.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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.

#### 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 FASB 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, wholesaler incentives and volume related discounts. 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. Volume related discounts primarily relate to incentives offered to downstream customers who earn discounts based upon the quarterly or annual volume of units purchased.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Contractual adjustments primarily relate to Medicaid and managed care rebates in the U.S., pharmacy rebates, co-payment (copay) assistance, VA and 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



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, GAZYVA and LUNSUMIO and royalty revenue on sales 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, GAZYVA and LUNSUMIO;
- (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, royalties on net sales of COLUMVI in the U.S. and royalties on sales of LUNSUMIO outside the U.S.

Pre-tax co-promotion profits on RITUXAN, GAZYVA and LUNSUMIO 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, GAZYVA and LUNSUMIO 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.

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 pre-tax profits and losses in the U.S. for LUNSUMIO was 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.

#### *Alzheimer's Collaboration Revenue*

Alzheimer's collaboration revenue consists of our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties, as we are not the principal. We began recognizing Alzheimer's collaboration revenue upon the accelerated approval of LEQEMBI in the U.S. during the first quarter of 2023.

#### *Contract Manufacturing, Royalty and Other Revenue*

##### *Contract Manufacturing Revenue*

We record contract manufacturing revenue primarily from amounts earned under contract manufacturing agreements with our strategic customers. 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. During the first quarter of 2023 we began recognizing contract manufacturing revenue

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

for LEQEMBI, upon accelerated approval of LEQEMBI in the U.S. Prior to accelerated approval, our share of contract manufacturing amounts related to LEQEMBI were recognized in research and development expense within our consolidated statements of income.

#### *Royalty and Other Revenue*

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

As the royalties we receive relate to arrangements that resulted from an exchange of a license and utilize the sales and usage based royalty exception, the royalties 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 on a net basis as a component of other revenue in our consolidated statements of income.

Our development and commercialization arrangements with Genentech, Eisai, Sage 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, Sage 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, and 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, 2024 and 2023.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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, 2024 and 2023, cash equivalents were comprised of money market funds 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, which resulted in a receivable of approximately \$1.3 billion in cash to be deferred over two payments. The first deferred payment of \$812.5 million was received in April 2023 and the second deferred payment of \$437.5 million was received in April 2024. The payments due to us from Samsung BioLogics were 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, 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 AOCI 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.

During the third quarter of 2023 we sold all of our marketable debt securities and used the proceeds to partially fund our acquisition of Reata. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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*

When we hold marketable debt securities, 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 AOCI.

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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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:

<u>Asset Category</u>	<u>Useful Lives</u>
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 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 primarily consist of completed technology (comprising of acquired and in-licensed rights and patents, and developed technology), IPR&D acquired after January 1, 2009, acquired priority review vouchers and 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 completed technology 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.

The economic consumption method is 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

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, IPR&D prior to commercialization and priority review vouchers 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*

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 within 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.



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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 AOCI, 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 AOCI 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

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 AOCI, 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 MSUs, time-vested RSUs, performance-vested stock units that settle in stock or cash (PSUs) and shares issued under our 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 and PSUs that settle in stock and have market-based metrics 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 these awards. 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 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 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 and do not have market-based metrics 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

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 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, LUNSUMIO 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.

#### 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, 2024, 2023 and 2022, advertising costs totaled \$66.8 million, \$71.4 million and \$54.1 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 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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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.

#### Business Combinations

Business combinations are recorded using the acquisition method of accounting. The results of operations of the acquired company are included in our results of operations beginning on the acquisition date, and assets acquired and liabilities assumed are recognized on the acquisition date at their respective fair values. Any excess of consideration transferred over the net carrying value of the assets acquired and liabilities assumed as of the acquisition date is recognized as goodwill.

We use the multi-period excess earnings method, which is a form of the income approach, utilizing post-tax cash flow and discount rates in estimating the fair value of identifiable intangible assets acquired when allocating the purchase consideration paid for the acquisition. The estimates of the fair value of identifiable intangible assets involve significant judgment by management and include assumptions with measurement uncertainty, such as the amount and timing of projected cash flow, long-term sales forecasts, discount rates and additionally for IPR&D intangible assets, the timing and probability of regulatory and commercial success.

We use the net realizable value method in estimating the fair value of acquired finished goods and work-in-process inventory. Raw materials acquired are valued using the replacement cost method.

Transaction and restructuring costs related to business combinations are expensed as incurred. The fair value of assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. If we determine the assets acquired do not meet the definition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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.

Standard	Description	Effective Date	Effects on the financial statements
ASU No. 2023-07, <i>Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure</i>	This standard requires disclosure of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss and the title and position of the entity's CODM. The amendments in this update also expand the interim segment disclosure requirements. All disclosure requirements under this standard are also required for public entities with a single reportable segment. The amendments in this update are required to be applied on a retrospective basis.	Annual reporting for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted.	This standard became effective for us for our annual reporting period ended December 31, 2024, using the retrospective method. The adoption of this standard resulted in additional disclosure on the significant expenses reviewed by our CODM. The adoption did not have a material impact on our consolidated financial position or results of operations. Refer to Note 25, <i>Segment Information</i> , for our updated segment presentation.
ASU No. 2023-09, <i>Income Taxes (Topic 740): Improvements to Income Tax Disclosures</i>	This standard establishes incremental disaggregation of income tax disclosures pertaining to the effective tax rate reconciliation and income taxes paid. The amendments in this update are required to be applied on a prospective basis with the option to apply it retrospectively.	Annual reporting for fiscal years beginning after December 15, 2024. Early adoption is permitted.	We are currently evaluating the potential impact that this new standard will have on our consolidated financial statements and related disclosures.
ASU No. 2024-03, <i>Income Statement (Subtopic 220-40): Reporting Comprehensive Income - Expense Disaggregation Disclosures</i>	This standard requires disclosure in the notes to the financial statements, at each interim and annual reporting period, of specified information about certain costs and expense including purchases of inventory, employee compensation, depreciation and intangible asset amortization included in each relevant expense caption. This standard also requires a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated, as well as disclosure of the total amount of selling expenses, and, in annual reporting periods, an entity's definition of selling expenses.	Annual reporting for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted.	We are currently evaluating the potential impact that this new standard will have on our consolidated financial statements and related disclosures.
SEC Release No. 33-11275, <i>The Enhancement and Standardization of Climate-Related Disclosures for Investors</i>	This new rule will require large accelerated filers to disclose material climate-related risks that are reasonably likely to have a material impact on their business, results of operations or financial condition. The required information about climate-related risks will also include disclosure of material direct greenhouse gas emissions from operations owned or controlled (Scope 1) and/or material indirect greenhouse gas emissions from purchased energy consumed in owned or controlled operations (Scope 2). Additionally, the new rules will require disclosure within the notes to the financial statements of the effects of severe weather events and other natural conditions and information on any climate-related targets or goals, subject to certain materiality thresholds.	Phased-in compliance period beginning with annual reporting for fiscal years as of December 31, 2025.  In April 2024 the SEC voluntarily stayed implementation of the new climate-related disclosure requirements pending judicial review. Once the litigation is resolved, and if the rule remains in effect, the SEC will announce a new effective date.	We are currently evaluating the potential impact that this new rule may have on our company's disclosures.

# **BIOGEN INC. AND SUBSIDIARIES** **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

## **Note 2: Acquisitions**

### **Human Immunology Biosciences**

On July 2, 2024, we completed the acquisition of all of the issued and outstanding shares of HI-Bio, a privately-held clinical-stage biotechnology company focused on targeted therapies for patients with severe immune-mediated diseases. HI-Bio's lead asset, felzartamab, an anti-CD38 antibody, is currently being evaluated for three leading indications, AMR, PMN and IgAN. Felzartamab has received Breakthrough Therapy Designation and ODD from the FDA for development in the treatment of PMN and AMR. Subsequent to our acquisition, felzartamab received ODD in the E.U. in IgAN and solid organ transplantation. The acquisition of HI-Bio is expected to augment our pipeline and build on our expertise in immunology.

Under the terms of this acquisition, we paid shareholders of HI-Bio approximately \$1.15 billion at closing and may pay up to an additional \$650.0 million in potential future development and regulatory milestone payments. The \$1.15 billion paid includes approximately \$74.5 million related to HI-Bio's outstanding non-vested equity awards, inclusive of employer taxes, of which \$56.4 million was recognized as share-based compensation payments to settle non-vested equity awards attributable to the post-acquisition service period and therefore not reflected as a component of total purchase price paid. Of the total \$56.4 million, we recognized approximately \$42.5 million as a charge to research and development expense with the remaining \$13.9 million as a charge to selling, general and administrative expense within our consolidated statements of income for the year ended December 31, 2024. These amounts were associated with the accelerated vesting of stock options and RSUs previously granted to HI-Bio employees and required no future services to vest.

Upon closing we also paid an additional \$43.7 million related to working capital adjustments as of the transaction close date, which was included as a component of total purchase price paid.

We funded this acquisition through available cash on hand and accounted for this acquisition as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*, and recorded assets acquired and liabilities assumed at their respective fair values as of the acquisition date.

In addition to the lead program felzartamab, the HI-Bio pipeline acquired includes izastobart/HIB210, an anti-C5aR1 antibody currently in a Phase 1 trial, and the potential for continued development in a range of complement-mediated diseases.

### **Purchase Price Consideration**

Total consideration transferred for the acquisition of HI-Bio is summarized as follows:

(In millions)	As of July 2, 2024
Cash consideration paid to HI-Bio shareholders <sup>(1)</sup>	\$ 1,137.3
Contingent consideration	485.1
Total consideration	\$ 1,622.4

<sup>(1)</sup> Represents total consideration paid to shareholders of HI-Bio of \$1.15 billion, plus an additional \$43.7 million related to working capital adjustments as of the transaction close date, less \$56.4 million of cash paid for HI-Bio's outstanding, non-vested equity awards, inclusive of employer taxes, which were recognized as compensation attributable to the post-acquisition service period and therefore not reflected as a component of total consideration.

**Contingent Consideration:** We may make certain contingent payments to the former shareholders of HI-Bio upon the achievement of certain development and regulatory milestones. As of the acquisition date, the maximum aggregate amount payable for these potential milestones was \$650.0 million. The acquisition-date fair value of these milestones was approximately \$485.1 million and was estimated utilizing a probability-adjusted discounted cash flow calculation using an appropriate discount rate dependent on the nature and timing of the milestone payments, which ranged from 6.2% to 7.0%, and probabilities of technological and regulatory success ranging from 67.0% to near-certain probability. Of the total contingent consideration, approximately \$279.3 million related to milestones classified as short-term and reflected as a component of accrued expense and other with the remaining \$205.8 million reflected as a component of other long-term liabilities within our consolidated balance sheets. The short-term liability relates to the fourth patient dosed in a phase 3 clinical trial of felzartamab in a first and second indication, which would trigger milestone payments of \$150.0 million each.



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Subsequent changes in the fair value of the contingent consideration obligation will be recognized as (gain) loss on fair value remeasurement of contingent consideration within our consolidated statements of income. This fair value measurement was based on significant inputs that are not observable in the market and thus represent Level 3 fair value measurements. For additional information related to the fair value of this obligation, please read *Note 8, Fair Value Measurements*, to these consolidated financial statements.

**Other Contractual Commitments:** We acquired HI-Bio's pre-existing in-license commitments under third-party agreements, which include tiered royalties on potential future sales of felzartamab and izastobart/HIB210, ranging from high-single digit to mid-teen percentages, as well as potential future development, regulatory and commercial milestone payments related to felzartamab and izastobart/HIB210 of up to \$130.0 million, \$230.0 million and \$640.0 million, respectively. Because the achievement of these milestones was not considered probable as of the transaction close date, such contingencies have not been recorded in our financial statements.

#### Preliminary Purchase Price Allocation

The following table summarizes the preliminary purchase price allocation of the separately identifiable assets acquired and liabilities assumed as of July 2, 2024:

(In millions)	Estimated Fair Value as of July 2, 2024
Cash and cash equivalents	\$ 62.5
Intangible assets:	
IPR&D - felzartamab (IgAN)	920.0
IPR&D - felzartamab (AMR)	450.0
IPR&D - felzartamab (PMN)	265.0
Other clinical programs	7.9
Prepaid expense and other assets	1.0
Operating lease assets	1.2
Accounts payable	(1.1)
Accrued liabilities	(35.0)
Deferred tax liability	(304.4)
Operating lease liabilities	(1.2)
Total identifiable net assets	1,365.9
Goodwill	256.5
Total assets acquired and liabilities assumed	\$ 1,622.4

There were no material purchase price allocation adjustments for the year ended December 31, 2024.

**Intangible assets:** Intangible assets comprised of \$1.6 billion of IPR&D related to HI-Bio's lead asset felzartamab. This includes \$920.0 million of IPR&D related to felzartamab indication for IgAN, \$450.0 million of IPR&D related to felzartamab indication for AMR and \$265.0 million of IPR&D related to felzartamab indication for PMN. The estimated fair values of the program related intangible assets were determined using a multi-period excess earnings method, a form of the income approach, utilizing cash flow analyses and a discount rate of 14.5%. These fair value measurements were based on significant inputs that are not observable in the market and thus represent Level 3 fair value measurements.

**Goodwill:** Goodwill was calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from the other assets acquired that could not be individually identified and separately recognized. We recognized goodwill of approximately \$256.5 million, which is not deductible for tax purposes. The goodwill recognized from our acquisition of HI-Bio is primarily the result of the deferred tax consequences from the transaction recorded for financial statement purposes.

**Acquisition-related expense:** Acquisition-related expense, primarily comprised of advisory and legal fees, and other transaction costs, totaled approximately \$2.8 million and were recorded within selling, general and administrative expense within our consolidated statements of income for the year ended December 31, 2024.



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Assumptions in the Allocations of Purchase Price

The results of operations of HI-Bio, along with the estimated fair values of the assets acquired and liabilities assumed in the HI-Bio acquisition, have been included in our consolidated financial statements since the closing of the HI-Bio acquisition on July 2, 2024.

Our preliminary estimate of the fair value of the specifically identifiable assets acquired and liabilities assumed as of the date of acquisition is subject to the finalization of management's analysis related to certain matters, such as finalizing our assessment of income taxes. The final determination of these fair values will be completed as additional information becomes available but no later than one year from the acquisition date. The final determination may result in asset and liability fair values that are different than the preliminary estimates.

Subsequent to the acquisition date, our results of operations include the results of operations of HI-Bio. HI-Bio operations had an immaterial impact on our results of operations for the year ended December 31, 2024. Due to the immateriality of HI-Bio's historic revenue and expenses, additional pro forma information combining the results of operations of Biogen and HI-Bio have not been included.

#### Reata Pharmaceuticals, Inc.

On September 26, 2023, we completed the acquisition of all of the issued and outstanding shares of Reata, a biopharmaceutical company focused on developing therapeutics that regulate cellular metabolism and inflammation in serious neurologic diseases. As a result of this transaction we acquired SKYCLARYS (ornaveloxolone), the first and only drug approved in the U.S. and the E.U. for the treatment of FA in adults and adolescents aged 16 years and older, as well as other clinical and preclinical pipeline programs. The acquisition of Reata is expected to complement our global portfolio of neuromuscular and rare disease therapies. The addition of SKYCLARYS is anticipated to provide potential operating synergies with SPINRAZA and QALSODY.

Under the terms of this acquisition, we paid Reata shareholders \$172.50 in cash for each issued and outstanding Reata share, which totaled approximately \$6.6 billion. In addition, we agreed to pay approximately \$983.9 million in cash for Reata's outstanding equity awards, inclusive of employer taxes, of which approximately \$590.5 million was attributable to pre-acquisition services and is therefore reflected as a component of total purchase price paid. Of the \$983.9 million paid to Reata's equity award holders, we recognized approximately \$393.4 million as compensation attributable to the post-acquisition service period, of which \$196.4 million was recognized as a charge to selling, general and administrative expense with the remaining \$197.0 million as a charge to research and development expense within our consolidated statements of income for the year ended December 31, 2023. These amounts were associated with the accelerated vesting of stock options and RSUs previously granted to Reata employees that required no future services to vest.

We funded this acquisition through available cash, cash equivalents and marketable securities, supplemented by the issuance of a \$1.0 billion term loan under our 2023 Term Loan. For additional information on our 2023 Term Loan, please read *Note 13, Indebtedness*, to these consolidated financial statements.

We accounted for this acquisition as a business combination using the acquisition method of accounting in accordance with *ASC Topic 805, Business Combinations*, and recorded assets acquired and liabilities assumed at their respective fair values as of the acquisition date.

#### Purchase Price Consideration

Total consideration transferred for the acquisition of Reata is summarized as follows:

(In millions)	As of September 26, 2023
Cash consideration paid to Reata shareholders <sup>(1)</sup>	\$ 6,602.9
Fair value of Reata equity compensation pre-acquisition services and related taxes <sup>(2)</sup>	590.5
Total consideration	\$ 7,193.4

<sup>(1)</sup> Represents cash consideration transferred of \$172.50 per outstanding Reata ordinary share based on 38.3 million Reata shares outstanding at closing.

<sup>(2)</sup> Represents the fair value of Reata stock options and stock units issued to Reata equity award holders and the related taxes attributable to pre-acquisition vesting services.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Purchase Price Allocation**

We finalized purchase accounting for this acquisition in the third quarter of 2024. The following table summarizes the amounts recognized for assets acquired and liabilities assumed as of the acquisition date, and reflects measurement period adjustments made to the amounts initially recorded as of the acquisition date on September 26, 2023. The measurement period adjustments summarized below resulted from updates to our valuation assumptions related to the estimated amounts and timing of future cash flows associated with certain intangible assets, updates of our assumptions related to the quantities, selling location and remaining manufacturing and selling costs of acquired inventory, and other assets and liabilities. The related impact to our consolidated statements of income that would have been recognized in previous periods if the adjustments were recognized as of the acquisition date is immaterial.

(In millions)	Amounts Recognized as of Acquisition Date (as adjusted)
Cash and cash equivalents	\$ 267.3
Accounts receivable	15.9
Inventory	1,259.0
Other current assets <sup>(1)</sup>	54.6
Intangible assets:	
Completed technology for SKYCLARYS (U.S.)	4,200.0
In-process research and development (omaveloxolone)	2,300.0
Priority review voucher	100.0
Other clinical programs	40.0
Operating lease assets	121.2
Accrued expense and other <sup>(1)</sup>	(110.3)
Debt payable	(159.9)
Contingent payable to Blackstone	(300.0)
Deferred tax liability <sup>(1)</sup>	(909.3)
Operating lease liabilities	(151.8)
Other assets and liabilities, net	(2.5)
Total identifiable net assets	6,724.2
Goodwill <sup>(1)</sup>	469.2
Total assets acquired and liabilities assumed	\$ 7,193.4

<sup>(1)</sup> Includes measurement period adjustments recorded in 2024 that increased other current assets by \$1.0 million, accrued expense and other by \$8.8 million and goodwill by \$4.7 million, and decreased deferred tax liability by \$3.1 million.

**Inventory:** Total inventory acquired was approximately \$1.3 billion, which reflects a step-up in the fair value of finished goods and work-in-process inventory for SKYCLARYS. The fair value was determined based on the estimated selling price of the inventory, less the remaining manufacturing and selling costs and a normal profit margin on those manufacturing and selling efforts. This fair value step-up adjustment is being amortized to cost of sales within our consolidated statements of income as the inventory is sold, which is expected to be sold over a period of approximately 4 years from the acquisition date. For the years ended December 31, 2024 and 2023, amortization from the fair value step-up adjustment was approximately \$230.0 million and \$31.5 million, respectively. For the year ended December 31, 2024, amortization from the fair value step-up adjustment includes approximately \$48.5 million of inventory used for clinical purposes, which is reflected within research and development expense within our consolidated statements of income.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**Intangible assets:** Intangible assets are comprised of \$4.2 billion related to SKYCLARYS commercialization rights in the U.S., \$2.3 billion of IPR&D related to the omaveloxolone program outside the U.S., which had not yet received regulatory approval in the E.U. as of the acquisition date, \$100.0 million related to a rare pediatric disease PRV which may be used to obtain priority review by the FDA for a future regulatory submission or sold to a third party and \$40.0 million related to other clinical programs. The estimated fair values of the program related intangible assets were determined using a multi-period excess earnings method, a form of the income approach, utilizing a discount rate of 14.3% and the estimated fair value of the PRV was based on recent external purchase and sale transactions of similar vouchers.

Our valuation of the SKYCLARYS commercialization rights reflects the assumption that, using an economic consumption model, the related \$4.2 billion intangible asset will be amortized over its expected economic life. Upon SKYCLARYS receiving regulatory approval in the E.U. in February 2024, we began selling the product in certain countries in Europe, and began amortizing the \$2.3 billion IPR&D asset related to the program outside the U.S. over its expected economic life using an economic consumption model.

These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

**Leases:** We assumed responsibility for a single-tenant, build-to-suit building of approximately 327,400 square feet of office and laboratory space located in Plano, Texas, with an initial lease term of 16 years. We recorded a lease liability of approximately \$151.8 million, which represents the net present value of rental expense over the remaining lease term of approximately 15 years, with a corresponding right-of-use asset of approximately \$121.2 million, which represents our estimate of the fair value for a market participant of the current rental market in the Dallas, Texas area. Included in our estimate of the market rental rate is the value of any leasehold improvements or tenant allowances related to the building. We do not intend to occupy this building and are evaluating opportunities to sublease the property.

**Goodwill:** Goodwill was calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from the other assets acquired that could not be individually identified and separately recognized. We recognized goodwill of approximately \$469.2 million, which includes measurement period adjustments, and is not deductible for tax purposes. The goodwill recognized from our acquisition of Reata is primarily the result of the deferred tax consequences from the transaction recorded for financial statement purposes.

**Acquisition-related expense:** Acquisition-related expense, primarily comprised of regulatory, advisory and legal fees, and other transaction costs, totaled approximately \$28.4 million and were recorded in selling, general and administrative expense within our consolidated statements of income for the year ended December 31, 2023.

#### 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 in exchange for total consideration of approximately \$2.3 billion. Under the terms of this transaction, we received approximately \$1.0 billion in cash at closing, with approximately \$1.3 billion in cash to be deferred over two payments. The first deferred payment of \$812.5 million was received in April 2023 and the second deferred payment of \$437.5 million was received in April 2024.

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 AOCI to net income of approximately \$58.9 million in cumulative translation losses, partially offset by approximately \$57.0 million in gains resulting from the termination of our net investment hedge.

We concluded that the divestment of Samsung Bioepis did not meet the criteria to be reported as discontinued operations in our consolidated financial statements, as our decision to divest this business did not represent a strategic shift that would 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, 2023, the estimated fair value of the remaining second deferred payment using a risk-adjusted discount rate of 5.8% was approximately \$430.0 million. This payment has been classified as a Level 3 fair value

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

measurement and is reflected in other current assets within our consolidated balance sheets as of December 31, 2023.

For the year ended December 31, 2024, we recognized a gain of approximately \$7.5 million to reflect the change in fair value associated with the passage of time related to the second deferred payment due to us, which was received in April 2024. For the year ended December 31, 2023, we recognized gains of approximately \$13.7 million and \$24.6 million to reflect the changes in fair value associated with changes in interest rates and the passage of time related to the first and second deferred payments due to us, respectively, which were received in April 2023 and April 2024, respectively. 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 associated with changes in interest rates and the passage of time related to the first and second deferred payments due to us, respectively, which were received in April 2023 and April 2024, respectively. These changes were recorded in other (income) expense, net within 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 the payments become realizable, which is generally the same period in which the payments are earned.

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.

#### Sale of Priority Review Voucher

In April 2024 we completed the sale of our rare pediatric disease PRV, generated by the development associated with SPINRAZA, to a third party. In consideration for the PRV we received a cash payment of \$103.0 million upon the closing of the PRV purchase, of which approximately \$14.4 million was paid to Ionis. Our net portion of approximately \$88.6 million was recognized in gain on sale of priority review voucher, net within our consolidated statements of income for the year ended December 31, 2024.

## Note 4: Restructuring

### 2023 Fit for Growth Restructuring Program

In 2023 we initiated additional cost saving measures as part of our Fit for Growth program to reduce operating costs, while improving operating efficiency and effectiveness. The Fit for Growth program is expected to generate approximately \$1.0 billion in gross operating expense savings by the end of 2025, some of which will be reinvested in various initiatives. The Fit for Growth program is currently estimated to include net headcount reductions of approximately 1,000 employees and we expect to incur restructuring charges ranging from approximately \$260.0 million to \$280.0 million.

Total charges incurred from our 2023 Fit for Growth program are summarized as follows:

	For the Years Ended December 31,					
	2024			2023		
(In millions)	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accelerated Depreciation and Other Costs	Total
Selling, general and administrative	\$ —	\$ 13.8	\$ 13.8	\$ —	\$ 23.3	\$ 23.3
Research and development	—	11.7	11.7	—	1.2	1.2
Restructuring charges	24.2	—	24.2	153.4	34.6	188.0
Total charges	\$ 24.2	\$ 25.5	\$ 49.7	\$ 153.4	\$ 59.1	\$ 212.5

**Other Costs:** includes costs associated with items such as asset abandonment and write-offs, facility closure costs, pretax gains and losses resulting from the termination of certain leases, employee non-severance expense, consulting fees and other costs.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Reata Integration

Following the close of our Reata acquisition in September 2023, we implemented an integration plan designed to realize operating synergies through cost savings and avoidance. Under this initiative, we estimate we will incur total integration charges of approximately \$35.0 million, related to severance and employment costs. These severance and employment costs were substantially incurred during 2023.

Total charges incurred from our Reata integration are summarized as follows:

	For the Years Ended December 31,					
	2024			2023		
(In millions)	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accelerated Depreciation and Other Costs	Total
Selling, general and administrative	\$ —	\$ 6.3	\$ 6.3	\$ —	\$ —	\$ —
Research and development	—	11.9	11.9	—	—	—
Restructuring charges	3.4	—	3.4	30.4	—	30.4
Total charges	\$ 3.4	\$ 18.2	\$ 21.6	\$ 30.4	\$ —	\$ 30.4

In connection with our acquisition of Reata we assumed responsibility for a single-tenant, build-to-suit building of approximately 327,400 square feet of office and laboratory space located in Plano, Texas, with an initial lease term of 16 years. We do not intend to occupy this building and are evaluating opportunities to sublease the property. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

#### HI-Bio Integration

Following the close of our HI-Bio acquisition in July 2024, we implemented an integration plan designed to realize operating synergies through cost savings and avoidance. Under this initiative, we incurred approximately \$2.6 million of severance and employment costs, which are reflected in restructuring charges within our consolidated statements of income for the year ended December 31, 2024. For additional information on our acquisition of HI-Bio, please read *Note 2, Acquisitions*, to these consolidated financial statements.

#### 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, deprioritization of certain research and development programs, the consolidation of certain real estate locations and operating efficiencies across our selling, general and administrative and research and development functions. Charges related to our 2022 cost saving initiatives were substantially incurred during 2022 with remaining payments expected to be made through 2026.

Total charges incurred from our 2022 cost saving initiatives are summarized as follows:

	For the Years Ended December 31,					
	2023			2022		
(In millions)	Severance Costs	Accelerated Depreciation and Other Costs	Total	Severance Costs	Accumulated Depreciation and Other Costs <sup>(1)</sup>	Total
Restructuring charges	\$ (2.2)	\$ 2.6	\$ 0.4	\$ 112.6	\$ 18.5	\$ 131.1
Total charges	\$ (2.2)	\$ 2.6	\$ 0.4	\$ 112.6	\$ 18.5	\$ 131.1

<sup>(1)</sup> Amounts reflect a gain recorded during the third quarter of 2022 of approximately \$5.3 million related to the partial termination of a portion of our lease located at 300 Binney Street. For additional information on our 300 Binney Street lease modification, please read *Note 12, Leases*, to these consolidated financial statements.

**BIOPEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Charges and spending related to workforce reductions are summarized as follows:

<b>(In millions)</b>	<b>Workforce Reductions</b>
Restructuring reserve, December 31, 2022	\$ 35.9
Expense	181.6
Payment	(140.5)
Foreign currency and other adjustments	(1.6)
Restructuring reserve, December 31, 2023	75.4
Expense	30.2
Payment	(73.8)
Foreign currency and other adjustments	0.1
Restructuring reserve, December 31, 2024	\$ 31.9

**BIAGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 5: Revenue**

**Product Revenue**

Revenue by product are summarized as follows:

In millions)	For the Years Ended December 31,								
	2024			2023			2022		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis:									
TECFIDERA	\$ 169.2	\$ 797.9	\$ 967.1	\$ 263.1	\$ 749.4	\$ 1,012.5	\$ 417.7	\$ 1,026.2	\$ 1,443.9
VUMERITY	538.6	89.4	628.0	512.1	64.2	576.3	521.3	32.1	553.4
Total Fumarate	707.8	887.3	1,595.1	775.2	813.6	1,588.8	939.0	1,058.3	1,997.3
AVONEX	451.3	256.2	707.5	536.7	274.3	811.0	649.2	324.3	973.5
PLEGRIDY	111.4	149.1	260.5	126.2	168.5	294.7	148.4	183.5	331.9
Total Interferon	562.7	405.3	968.0	662.9	442.8	1,105.7	797.6	507.8	1,305.4
TYSABRI	920.0	795.0	1,715.0	997.9	879.0	1,876.9	1,123.4	907.5	2,030.9
FAMPYRA	—	71.7	71.7	—	90.5	90.5	—	96.6	96.6
Subtotal: Multiple Sclerosis	2,190.5	2,159.3	4,349.8	2,436.0	2,225.9	4,661.9	2,860.0	2,570.2	5,430.2
Rare Disease:									
SPINRAZA	625.7	947.5	1,573.2	610.5	1,130.7	1,741.2	600.2	1,193.3	1,793.5
SKYCLARYS <sup>(1)</sup>	301.1	81.4	382.5	55.9	—	55.9	—	—	—
QALSODY <sup>(2)</sup>	20.9	11.5	32.4	5.8	0.1	5.9	—	—	—
Subtotal: Rare Disease	947.7	1,040.4	1,988.1	672.2	1,130.8	1,803.0	600.2	1,193.3	1,793.5
Biosimilars:									
BENEPALI	—	479.1	479.1	—	438.8	438.8	—	441.0	441.0
IMIRALDI	—	213.1	213.1	—	222.1	222.1	—	224.5	224.5
FLUXABI	—	63.2	63.2	—	77.4	77.4	—	81.3	81.3
BYOOVIZ <sup>(3)</sup>	23.0	13.6	36.6	29.2	2.5	31.7	4.3	—	4.3
TOFIDENCE <sup>(4)</sup>	1.1	—	1.1	—	—	—	—	—	—
Subtotal: Biosimilars	24.1	769.0	793.1	29.2	740.8	770.0	4.3	746.8	751.1
Other:									
ZURZUVAE <sup>(5)</sup>	72.2	—	72.2	1.6	—	1.6	—	—	—
Other <sup>(6)</sup>	2.8	7.5	10.3	2.4	7.8	10.2	4.8	8.2	13.0
Subtotal: Other	75.0	7.5	82.5	4.0	7.8	11.8	4.8	8.2	13.0
Total product revenue, net	\$ 3,237.3	\$ 3,976.2	\$ 7,213.5	\$ 3,141.4	\$ 4,105.3	\$ 7,246.7	\$ 3,469.3	\$ 4,518.5	\$ 7,987.8

<sup>(1)</sup> SKYCLARYS was obtained as part of our acquisition of Reata in September 2023. SKYCLARYS became commercially available in the U.S. during the second quarter of 2023 and we began recognizing revenue from SKYCLARYS in the U.S. during the fourth quarter of 2023, subsequent to our acquisition. SKYCLARYS was approved and became commercially available in the E.U. during the first quarter of 2024.

<sup>(2)</sup> QALSODY became commercially available in the U.S. during the second quarter of 2023 and commercially available in the E.U. during the second quarter of 2024.

<sup>(3)</sup> BYOOVIZ became commercially available in certain international markets in 2023.

<sup>(4)</sup> TOFIDENCE became commercially available in the U.S. during the second quarter of 2024.

<sup>(5)</sup> ZURZUVAE became commercially available in the U.S. during the fourth quarter of 2023.

<sup>(6)</sup> Other includes FUMADERM and ADUHELM.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

We recognized revenue from two wholesalers accounting for 25.9% and 13.4% of gross product revenue in 2024, 27.0% and 9.9% of gross product revenue in 2023 and 26.8% and 11.1% of gross product revenue in 2022, respectively.

As of December 31, 2024, two wholesale distributors individually accounted for approximately 27.2% and 11.7% of net accounts receivable associated with our product sales, as compared to 24.6% and 11.6% as of December 31, 2023, respectively.

An analysis of the change in reserves for discounts and allowances is summarized as follows:

December 31, 2024				
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Balance, December 31, 2023	\$ 173.3	\$ 857.1	\$ 31.6	\$ 1,062.0
Current provisions relating to sales in current year	824.2	2,687.5	23.6	3,535.3
Adjustments relating to prior years	8.0	(38.7)	14.2	(16.5)
Payments/credits relating to sales in current year	(670.9)	(1,989.7)	(0.6)	(2,661.2)
Payments/credits relating to sales in prior years	(171.9)	(635.4)	(20.7)	(828.0)
Balance, December 31, 2024	\$ 162.7	\$ 880.8	\$ 48.1	\$ 1,091.6

December 31, 2023				
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Balance, December 31, 2022	\$ 153.8	\$ 857.7	\$ 23.5	\$ 1,035.0
Current provisions relating to sales in current year	735.6	2,720.1	19.0	3,474.7
Adjustments relating to prior years	(0.4)	(38.4)	19.2	(19.6)
Payments/credits relating to sales in current year	(572.9)	(1,944.8)	(2.1)	(2,519.8)
Payments/credits relating to sales in prior years	(142.8)	(737.5)	(28.0)	(908.3)
Balance, December 31, 2023	\$ 173.3	\$ 857.1	\$ 31.6	\$ 1,062.0

December 31, 2022				
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Balance, December 31, 2021	\$ 137.7	\$ 759.6	\$ 38.0	\$ 935.3
Current provisions relating to sales in current year	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)
Balance, December 31, 2022	\$ 153.8	\$ 857.7	\$ 23.5	\$ 1,035.0

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

As of December 31,		
(In millions)	2024	2023
Reduction of accounts receivable	\$ 154.1	\$ 135.5
Component of accrued expense and other	937.5	926.5
Total revenue-related reserves	\$ 1,091.6	\$ 1,062.0



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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.

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Royalty revenue on sales of OCREVUS	\$ 1,339.5	\$ 1,266.2	\$ 1,136.3
Biogen's share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO <sup>(1)</sup>	392.0	409.4	547.0
Other revenue from anti-CD20 therapeutic programs	18.4	14.0	17.2
Total revenue from anti-CD20 therapeutic programs	\$ 1,749.9	\$ 1,689.6	\$ 1,700.5

<sup>(1)</sup> LUNSUMIO became commercially available in the U.S. during the first quarter of 2023.

Approximately 18.1%, 17.2% and 16.7% of our total revenue in 2024, 2023 and 2022, 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.

#### Alzheimer's Collaboration Revenue

Alzheimer's collaboration revenue consists of our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties, as we are not the principal. We began recognizing Alzheimer's collaboration revenue upon the accelerated approval of LEQEMBI in the U.S. during the first quarter of 2023.

For the year ended December 31, 2024, we recognized approximately \$59.9 million of Alzheimer's collaboration revenue within our consolidated statements of income. For the year ended December 31, 2023, our share of LEQEMBI product revenue, net, was fully offset by our share of cost of sales, including royalties, resulting in a zero net impact to Alzheimer's collaboration revenue within our consolidated statements of income.

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

#### Contract Manufacturing, Royalty and Other Revenue

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Contract manufacturing revenue	\$ 592.1	\$ 848.2	\$ 417.7
Royalty and other revenue	60.5	51.1	67.4
Total contract manufacturing, royalty and other revenue	\$ 652.6	\$ 899.3	\$ 485.1

#### Contract Manufacturing Revenue

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

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 third and final payment became due upon the second anniversary of the regulatory approval and was received during the second quarter of 2022.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Royalty and Other Revenue

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

For additional information on our license arrangements with Samsung Bioepis and our collaboration arrangements with Eisai, 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,	
	2024	2023
Raw materials	\$ 317.8	\$ 426.9
Work in process	1,882.8	1,926.8
Finished goods	353.8	255.4
Total inventory	<u>\$ 2,554.4</u>	<u>\$ 2,609.1</u>
<i>Balance Sheet Classification:</i>		
Inventory	\$ 2,460.5	\$ 2,527.4
Investments and other assets	93.9	81.7
Total inventory	<u>\$ 2,554.4</u>	<u>\$ 2,609.1</u>

Long-term inventory is included in investments and other assets within our consolidated balance sheets.

We recorded approximately \$1.3 billion of acquired inventory, which includes measurement period adjustments, related to SKYCLARYS as a result of our acquisition of Reata in September 2023. The fair value was determined based on the estimated selling price of the inventory, less the remaining manufacturing and selling costs and a normal profit margin on those manufacturing and selling efforts. This fair value step-up adjustment is being amortized to cost of sales within our consolidated statements of income as the inventory is sold, which is expected to be sold over a period of approximately 4 years from the acquisition date. For the years ended December 31, 2024 and 2023, amortization from the fair value step-up adjustment was approximately \$230.0 million and \$31.5 million, respectively. For the year ended December 31, 2024, amortization from the fair value step-up adjustment includes approximately \$48.5 million of inventory used for clinical purposes, which is reflected within research and development expense within our consolidated statements of income. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

#### Write Downs and Other Charges

Inventory amounts written down as a result of excess, obsolescence or unmarketability are charged to cost of sales, and totaled \$101.9 million, \$124.4 million and \$336.2 million for the years ended December 31, 2024, 2023 and 2022, respectively.

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

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

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 7: Intangible Assets and Goodwill**

**Intangible Assets**

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

(In millions)	Estimated Life	As of December 31, 2024			As of December 31, 2023		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	1-31 years	\$ 14,138.4	\$ (6,254.1)	\$ 7,884.3	\$ 11,728.8	\$ (5,869.8)	\$ 5,859.0
In-process research and development	Indefinite until commercialization	1,642.9	—	1,642.9	2,340.0	—	2,340.0
Priority review voucher	Indefinite	100.0	—	100.0	100.0	—	100.0
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		\$ 15,945.3	\$ (6,254.1)	\$ 9,691.2	\$ 14,232.8	\$ (5,869.8)	\$ 8,363.0

*Amortization and Impairments*

Amortization and impairment of acquired intangible assets totaled \$446.7 million, \$240.6 million and \$365.9 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Amortization of acquired intangible assets, excluding impairment charges, totaled \$386.5 million, \$240.6 million and \$246.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. The increase in amortization of acquired intangible assets, excluding impairment charges, was primarily due to amortization for the Reata acquisition acquired intangible assets associated with SKYCLARYS.

For the year ended December 31, 2024, amortization and impairment of acquired intangible assets reflects the impact of a \$40.0 million impairment charge related to intangible assets from other clinical programs we acquired from Reata, reducing the remaining book value of these IPR&D intangible assets to zero, and a \$20.2 million impairment charge related to intangible assets associated with Samsung Bioepis commercialization rights terminated during the third quarter of 2024. For the year ended December 31, 2023, we had no impairment charges.

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 (BIB074) for the potential treatment of DPN, which was discontinued during the fourth quarter of 2022 based on regulatory, development and commercialization challenges, 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 for the year ended December 31, 2022.

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.

*Completed Technology*

Completed technology primarily relates to our other marketed products and programs acquired through asset acquisitions, licenses and business combinations. Completed technology intangible assets are amortized over their estimated useful lives, which range between 1 to 31 years, with a remaining weighted average useful life of 1.3 years. In connection with our acquisition of Reata in September 2023 we acquired SKYCLARYS, a commercially-approved product in the U.S., with an estimated fair value of approximately \$4.2 billion, which includes measurement period adjustments. During the first quarter of 2024 SKYCLARYS was approved in the E.U. and became commercially available, which resulted in the reclassification of the related intangible asset, with an estimated fair value of approximately \$2.3 billion, from IPR&D to completed technology.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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, 2024, relates to the IPR&D programs we acquired in connection with our acquisition of HI-Bio in July 2024, with an estimated fair value of approximately \$1.6 billion.

The carrying value associated with our IPR&D assets as of December 31, 2023, relates to the IPR&D programs we acquired in connection with our acquisition of Reata in September 2023 with an estimated fair value of approximately \$2.3 billion, which includes measurement period adjustments. During the first quarter of 2024 SKYCLARYS was approved in the E.U. and became commercially available, which resulted in the reclassification of the related intangible asset from IPR&D to completed technology.

#### Priority Review Voucher

In connection with our acquisition of Reata in September 2023 we acquired a rare pediatric disease PRV which may be used to obtain priority review by the FDA for a future regulatory submission or sold to a third party. We recorded the PRV based on its estimated fair value of \$100.0 million as an intangible asset. The estimated fair value of the PRV was based on recent external purchase and sale transactions of similar vouchers.

For additional information on our acquisitions of Reata and HI-Bio, please read *Note 2, Acquisitions*, to these consolidated financial statements.

#### 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, 2024
2025	\$ 525.0
2026	560.0
2027	600.0
2028	630.0
2029	665.0

#### Goodwill

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

(In millions)	As of December 31,	
	2024	2023
Goodwill, January 1	\$ 6,219.2	\$ 5,749.0
Goodwill resulting from HI-Bio acquisition	256.5	—
Goodwill resulting from Reata acquisition <sup>(1)</sup>	4.7	464.5
Other	(1.5)	5.7
Goodwill, December 31	<u>\$ 6,478.9</u>	<u>\$ 6,219.2</u>

<sup>(1)</sup> Goodwill resulting from Reata acquisition for the year ended December 31, 2024, relates to Reata measurement period adjustments recognized during 2024.

For additional information on our acquisitions of Reata and HI-Bio, please read *Note 2, Acquisitions*, to these consolidated financial statements.

As of December 31, 2024 and 2023, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**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:

Fair Value Measurements on a Recurring Basis				
As of December 31, 2024				
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 1,664.9	\$ —	\$ 1,664.9	\$ —
Marketable equity securities	179.7	179.7	—	—
Other current assets:				
Derivative contracts	62.5	—	62.5	—
Other non-current assets:				
Plan assets for deferred compensation	42.8	—	42.8	—
<b>Total</b>	<b>\$ 1,949.9</b>	<b>\$ 179.7</b>	<b>\$ 1,770.2</b>	<b>\$ —</b>
<b>Liabilities:</b>				
Other current liabilities:				
Derivative contracts	\$ 11.7	\$ —	\$ 11.7	\$ —
Contingent consideration obligations	291.2	—	—	291.2
Other non-current liabilities:				
Contingent consideration obligations	221.6	—	—	221.6
<b>Total</b>	<b>\$ 524.5</b>	<b>\$ —</b>	<b>\$ 11.7</b>	<b>\$ 512.8</b>

Fair Value Measurements on a Recurring Basis				
As of December 31, 2023				
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 610.7	\$ —	\$ 610.7	\$ —
Marketable equity securities	416.8	416.8	—	—
Other current assets:				
Receivable from Samsung BioLogics <sup>(1)</sup>	430.0	—	—	430.0
Derivative contracts	11.9	—	11.9	—
Other non-current assets:				
Plan assets for deferred compensation	37.5	—	37.5	—
<b>Total</b>	<b>\$ 1,506.9</b>	<b>\$ 416.8</b>	<b>\$ 660.1</b>	<b>\$ 430.0</b>
<b>Liabilities:</b>				
Derivative contracts	\$ 31.6	\$ —	\$ 31.6	\$ —
<b>Total</b>	<b>\$ 31.6</b>	<b>\$ —</b>	<b>\$ 31.6</b>	<b>\$ —</b>

<sup>(1)</sup> Represents the fair value of the second deferred payment 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.

Our marketable equity securities represent investments in publicly traded equity securities. Our ability to liquidate our investments in Denali and Sage may be limited by the size of our interest, the volume of market related activity, our

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2024 and 2023. In addition, there have been no changes to our valuation techniques as of December 31, 2024 and 2023.

For a description of our validation procedures related to prices provided by third-party pricing services and our option pricing valuation model, please read *Note 1, Summary of Significant Accounting Policies - Fair Value Measurements*, to 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:

(In millions)	Quantitative Information about Level 3 Fair Value Measurements				
	As of December 31, 2024				
	Fair Value	Valuation Technique	Significant Unobservable Input(s)	Range	Weighted Average
<i>Liabilities:</i>					
Contingent consideration obligations	\$ 512.8	Discounted cash flow	Discount rate Expected timing of achievement of development milestones	6.2% - 6.3% 2025 - 2030	6.2% —

The weighted average discount rates were calculated based on the relative fair values of each distinct contingent consideration obligation related to our acquisition of HI-Bio in July 2024. In addition, we apply various probabilities of technological and regulatory success to the valuation models to estimate the fair values of these contingent consideration obligations, which ranged from 68.3% to near certain probability as of December 31, 2024.

There were no transfers of assets or liabilities into or out of Level 3 as of December 31, 2024 and 2023.

#### Contingent Consideration Obligations

In connection with our acquisition of HI-Bio in July 2024 we agreed to make additional payments based upon the achievement of certain milestone events. The following table provides a roll forward of the fair value of our contingent consideration obligations, which were classified as Level 3 measurements:

(In millions)	As of December 31, 2024
Fair value, beginning of year	\$ —
Contingent consideration resulting from HI-Bio acquisition	485.1
Changes in fair value	27.7
Fair value, end of year	\$ 512.8

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. 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.

As of December 31, 2024, approximately \$291.2 million of the fair value of the total contingent consideration obligation was classified as short-term and reflected as a component of accrued expense and other within our consolidated balance sheets with the remaining \$221.6 million reflected as a component of other long-term liabilities in our consolidated balance sheets.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

For the year ended December 31, 2024, the changes in the fair value of our contingent consideration obligations were primarily due to changes in interest rates used to revalue our contingent consideration liabilities, the passage of time and updates to the expected timing of achieving certain milestones which will trigger contingent consideration payments.

#### 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:

(In millions)	Fair Value As of December 31,	
	2024	2023
<i>Current portion:</i>		
2023 Term Loan 364-day tranche	\$ —	\$ 150.0
4.050% Senior Notes due September 15, 2025	1,741.0	—
Current portion of notes payable and term loan	1,741.0	150.0
<i>Non-current portion:</i>		
2023 Term Loan three-year tranche	—	500.0
4.050% Senior Notes due September 15, 2025	—	1,721.5
2.250% Senior Notes due May 1, 2030	1,295.6	1,279.3
5.200% Senior Notes due September 15, 2045	1,008.0	1,089.7
3.150% Senior Notes due May 1, 2050	943.7	1,049.0
3.250% Senior Notes due February 15, 2051	448.9	498.2
Non-current portion of notes payable and term loan	3,696.2	6,137.7
Total notes payable and term loan	\$ 5,437.2	\$ 6,287.7

In connection with our acquisition of Reata we drew \$1.0 billion from our 2023 Term Loan, comprised of a \$500.0 million floating rate 364-day tranche and a \$500.0 million floating rate three-year tranche. As of December 31, 2024, our 2023 Term Loan was repaid in full. For additional information on our 2023 Term Loan, 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, 2024, compared to 2023, are primarily related to increases in U.S. treasury yields partially offset by a decrease in credit spreads used to value our Senior Notes since December 31, 2023. 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 90 days from the date of purchase included in cash and cash equivalents in our consolidated balance sheets:

(In millions)	As of December 31,	
	2024	2023
Money market funds	\$ 1,664.9	\$ 610.7
Total	\$ 1,664.9	\$ 610.7

The carrying value of our money market funds approximates fair value due to their short-term maturities.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Our marketable equity securities gains (losses) are recorded in other (income) expense, net in our consolidated statements of income. The following tables summarize our available-for-sale marketable equity securities:

(In millions)	As of December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable equity securities:				
Marketable equity securities, non-current	\$ 668.7	\$ —	\$ (489.0)	\$ 179.7
Total marketable equity securities	\$ 668.7	\$ —	\$ (489.0)	\$ 179.7

(In millions)	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable equity securities:				
Marketable equity securities, current	\$ 31.6	\$ —	\$ (21.0)	\$ 10.6
Marketable equity securities, non-current	\$ 948.3	\$ —	\$ (542.1)	\$ 406.2
Total marketable equity securities	\$ 979.9	\$ —	\$ (563.1)	\$ 416.8

### Proceeds from Marketable Debt Securities

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

(In millions)	For the Years Ended December 31,	
	2023	2022
Proceeds from maturities and sales	\$ 7,380.8	\$ 3,671.0
Realized gains	1.4	—
Realized losses	18.4	12.6

We partially funded our Reata acquisition through available cash, cash equivalents and marketable securities. As of December 31, 2023, we had sold all of our marketable debt securities. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

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

### Strategic Investments

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, as well as venture capital funds where the underlying investments are in equity securities of certain biotechnology companies and non-marketable equity securities.

As of December 31, 2024, our strategic investment portfolio was comprised of investments totaling \$226.7 million which are included in investments and other assets in our consolidated balance sheets. As of December 31, 2023, our strategic investment portfolio was comprised of investments totaling \$460.7 million which are included in other current assets and investments and other assets in our consolidated balance sheets.

The decrease in our strategic investment portfolio for the year ended December 31, 2024, was primarily due to the decrease in the fair value of our investment in Sage common stock, partially offset by an increase in the fair value of our investment in Denali common stock. Additionally, during 2024 we sold a portion of our Denali common stock and the remaining portion of our Sangamo common stock.

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.



**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**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, 2024 and 2023, had durations of 1 to 12 months. These contracts have been designated as cash flow hedges and unrealized gains and losses on the portion of these foreign currency forward contracts and foreign currency options that are included in the effectiveness test are reported in AOCI. Realized gains and losses of such contracts and options are recognized in revenue when the sale of product in the currency being hedged is recognized and in operating expense when the expense in the currency being hedged is recorded. We recognize all cash flow hedge reclassifications from AOCI and fair value changes of excluded portions in the same line item in our 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:

(In millions)	Notional Amount As of December 31,	
	2024	2023
Euro	\$ 1,062.6	\$ 1,169.0
British pound	133.8	—
Canadian dollar	38.6	—
Total foreign currency forward contracts and options	\$ 1,235.0	\$ 1,169.0

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Unrealized gains	\$ 50.6	\$ —	\$ 29.9
Unrealized (losses)	(0.3)	(34.8)	(21.3)
Net unrealized gains (losses)	\$ 50.3	\$ (34.8)	\$ 8.6

We expect the net unrealized gains of approximately \$50.3 million to be settled over the next 12 months, with any amounts in AOCI to be reported as an adjustment to revenue or operating expense. We consider the impact of our and our counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its contractual obligations. As of December 31, 2024 and 2023, credit risk did not materially change the fair value of our foreign currency forward contracts and forward currency options.

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

For the Years Ended December 31,							
Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)				Net Gains/(Losses) Excluded from Effectiveness Testing and Recognized in Operating Income (in millions)			
Location	2024	2023	2022	Location	2024	2023	2022
Revenue	\$ 18.1	\$ 11.6	\$ 201.6	Revenue	\$ (0.8)	\$ (2.4)	\$ (8.6)
Operating expense	(12.9)	3.7	(5.5)	Operating expense	—	—	—

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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. Our investment in the equity of Samsung Bioepis related to this transaction was exposed to the currency fluctuations in the South Korean won.

In order to mitigate the currency fluctuations between the U.S. dollar and South Korean won, we entered into foreign currency forward contracts. These contracts were designated as net investment hedges. In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to Samsung BioLogics and closed these foreign currency forward contracts. Upon completing this sale, the cumulative gains on our net investment hedges of \$57.0 million were reclassified from AOCI 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 the year ended December 31, 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 following table summarizes the effect of our net investment hedges in our consolidated financial statements:

For the Year Ended December 31, 2022					
Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)		Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)		Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)	
Location	2022	Location	2022	Location	2022
Gains (losses) on net investment hedges <sup>(1)</sup>	\$ 20.4	Gains (losses) on net investment hedges <sup>(1)</sup>	\$ (3.2)	Other (income) expense <sup>(1)</sup>	\$ (4.6)

<sup>(1)</sup> 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 \$738.7 million and \$1,301.5 million as of December 31, 2024 and 2023, respectively. Net losses of \$49.7 million, net gains of \$3.8 million and net losses of \$34.7 million related to these contracts were recorded as a component of other (income) expense, net for the years ended December 31, 2024, 2023 and 2022, respectively.

#### Summary of Derivative Instruments

While certain of our derivative instruments are subject to netting arrangements with our counterparties, we do not offset derivative assets and liabilities in our 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)		As of December 31,	
		2024	2023
<i>Cash Flow Hedging Instruments:</i>			
Asset derivative instruments	Other current assets	\$ 58.4	\$ 0.3
Liability derivative instruments	Accrued expense and other	0.3	26.5
<i>Other Derivative Instruments:</i>			
Asset derivative instruments	Other current assets	4.1	11.6
Liability derivative instruments	Accrued expense and other	11.4	5.1

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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,	
	2024	2023
Land	\$ 202.4	\$ 202.4
Buildings	1,963.7	1,601.3
Leasehold improvements	137.8	135.7
Machinery and equipment	2,109.8	1,703.8
Computer software and hardware	1,070.5	1,032.1
Furniture and fixtures	59.5	61.5
Construction in progress	308.4	975.4
Total cost	5,852.1	5,712.2
Less: accumulated depreciation	(2,670.8)	(2,402.5)
Total property, plant and equipment, net	\$ 3,181.3	\$ 3,309.7

Depreciation expense totaled \$286.7 million, \$254.2 million and \$272.4 million for the years ended December 31, 2024, 2023 and 2022, respectively.

For the years ended December 31, 2024, 2023 and 2022, we capitalized interest costs related to construction in progress totaling approximately \$3.2 million, \$21.7 million and \$17.1 million, respectively.

#### Solothurn, Switzerland Manufacturing Facility

In order to support our future growth and drug development pipeline, we built a large-scale biologics manufacturing facility in Solothurn, Switzerland. This facility includes 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, 2023, we had approximately \$728.8 million capitalized as construction in progress related to this facility. In the second quarter of 2021 a portion of this facility (the first manufacturing suite) received a GMP multi-product license from SWISSMEDIC and was placed into service. The second manufacturing suite, which was also licensed to operate by SWISSMEDIC, became operational in the first quarter of 2024, resulting in approximately \$717.3 million of fixed assets being placed into service. Solothurn has been approved for the manufacture of LEQEMBI.

#### 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, net 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 fourteen 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 less than one year to ten years.

In addition, we sublease certain real estate to third parties. Our sublease portfolio consists of operating leases, with remaining lease terms ranging from less than one year to five years.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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	2024	2023
Assets:			
Operating lease assets	Operating lease assets	\$ 356.4	\$ 420.0
Liabilities			
Current operating lease liabilities	Accrued expense and other	\$ 86.4	\$ 90.3
Non-current operating lease liabilities	Long-term operating lease liabilities	334.5	400.0
Total operating lease liabilities		\$ 420.9	\$ 490.3

The following table summarizes the effect of lease costs in our consolidated statements of income:

(In millions)	Income Statement Location	For the Years Ended December 31,		
		2024	2023	2022
Operating lease cost	Research and development	\$ 2.4	\$ 2.0	\$ 2.0
	Selling, general and administrative	110.1	128.1	95.9
Variable lease cost	Research and development	0.4	0.5	0.4
	Selling, general and administrative	31.2	37.3	25.4
Sublease income	Selling, general and administrative	(14.8)	(23.5)	(24.0)
	Other (income) expense, net	(4.0)	(4.1)	(4.1)
Net lease cost		\$ 125.3	\$ 140.3	\$ 95.6

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 are expected to be as follows:

(In millions)	As of December 31, 2024
2025	\$ 103.4
2026	88.5
2027	88.3
2028	50.2
2029	21.9
Thereafter	152.4
Total lease payments	\$ 504.7
Less: interest	83.8
Present value of operating lease liabilities	\$ 420.9

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

	As of December 31,	
	2024	2023
Weighted average remaining lease term in years	7.20	7.37
Weighted average discount rate	4.5 %	4.5 %

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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:

(In millions)	2024	As of December 31,	
		2023	2022
Cash paid for amounts included in the measurement of lease liabilities	\$ 115.8	\$ 116.4	\$ 107.4
Operating lease assets obtained in exchange for lease obligations	16.9	146.0	108.3

### 6100 Legacy Drive Lease

In connection with our acquisition of Reata in September 2023 we assumed responsibility for a single-tenant, build-to-suit building of approximately 327,400 square feet of office and laboratory space located in Plano, Texas, with an initial lease term of 16 years. We recorded a lease liability of approximately \$151.8 million, which represents the net present value of rental expense over the remaining lease term of approximately 15 years, with a corresponding right-of-use asset of approximately \$121.2 million, which represents our estimate of the fair value for a market participant of the current rental market in the Dallas, Texas area. Included in our estimate of the market rental rate is the value of any leasehold improvements or tenant allowances related to the building. We do not intend to occupy this building and are evaluating opportunities to sublease the property.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

### 125 Broadway Building Sale and Leaseback Transaction

In connection with the sale of our 125 Broadway building during the third quarter of 2022, 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 a new lease liability and right-of-use asset 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 125 Broadway 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, 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 a right-of-use asset of approximately \$47.4 million and a lease liability 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. As of December 31, 2024, we no longer lease any portion of this space.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 13: Indebtedness**

Our indebtedness is summarized as follows:

(In millions)	As of December 31,	
	2024	2023
<i>Current portion:</i>		
2023 Term Loan 364-day tranche	\$ —	\$ 150.0
4.050% Senior Notes due September 15, 2025	1,748.6	—
Current portion of notes payable and term loan	\$ 1,748.6	\$ 150.0
<i>Non-current portion:</i>		
2023 Term Loan three-year tranche	\$ —	\$ 500.0
4.050% Senior Notes due September 15, 2025	—	1,746.6
2.250% Senior Notes due May 1, 2030	1,494.7	1,493.8
5.200% Senior Notes due September 15, 2045	1,101.1	1,100.7
3.150% Senior Notes due May 1, 2050	1,475.0	1,474.3
3.250% Senior Notes due February 15, 2051	476.4	472.8
Non-current portion of notes payable and term loan	\$ 4,547.2	\$ 6,788.2

In connection with our acquisition of Reata we drew \$1.0 billion from our 2023 Term Loan, comprised of a \$500.0 million floating rate 364-day tranche and a \$500.0 million floating rate three-year tranche. As of December 31, 2024, our 2023 Term Loan was repaid in full.

As of December 31, 2024, we were in compliance with our senior note covenants and term loan covenants.

### 2023 Term Loan Credit Agreement

In connection with our acquisition of Reata in September 2023 we entered into a \$1.5 billion term loan credit agreement. On the closing date of the Reata acquisition we drew \$1.0 billion from the 2023 Term Loan, comprised of a \$500.0 million floating rate 364-day tranche and a \$500.0 million floating rate three-year tranche. The remaining unused commitment of \$500.0 million was terminated. As of December 31, 2023, we repaid \$350.0 million of the 364-day tranche. The remaining \$150.0 million portion of the 364-day tranche was repaid during the first quarter of 2024.

Additionally, during the first quarter of 2024 we repaid \$250.0 million of the three-year tranche, with the remaining \$250.0 million portion being subsequently repaid in full during the second quarter of 2024. For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

### 2021 Exchange Offer Senior Notes

The following is a summary of our currently outstanding senior unsecured notes issued in 2021 as part of our Exchange Offer (the 2021 Exchange Offer Senior Notes), consisting of the following:

- \$700.7 million aggregate principal amount of 3.25% Senior Notes due February 15, 2051, valued at 99.298% of par.

Our 2021 Exchange Offer 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 2021 Exchange Offer 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.

The costs associated with this exchange offer of approximately \$5.4 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. Interest on our 2021 Exchange Offer Senior Notes is payable February 15 and August 15 of each year, commencing August 15, 2021.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 2020 Senior Notes

The following is a summary of our currently outstanding senior unsecured notes issued in 2020 (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.

The original costs associated with this offering of approximately \$24.4 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. 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.

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.

The original costs associated with this offering of approximately \$47.5 million, of which approximately \$23.6 million pertains to our currently outstanding notes, 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. Interest on our 2015 Senior Notes is payable March 15 and September 15 of each year, commencing March 15, 2016.

#### *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.

#### 2024 Revolving Credit Facility

In August 2024 we entered into a \$1.5 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 January 2020. As of December 31, 2024, we had no outstanding borrowings and were in compliance with all covenants under this facility.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Debt Maturity

The total gross payments due under our debt arrangements are as follows:

(In millions)	As of December 31, 2024
2025	\$ 1,750.0
2026	—
2027	—
2028	—
2029	—
2030 and thereafter	4,817.3
Total current and non-current debt	6,567.3
Less: debt discount and issuance fees	(271.5)
Total current and non-current debt, net	\$ 6,295.8

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 2024, 2023 and 2022.

##### Common Stock

The following table describes the number of shares authorized, issued and outstanding of our common stock as of December 31, 2024, 2023 and 2022:

(In millions)	As of December 31, 2024			As of December 31, 2023			As of December 31, 2022		
	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding
Common stock	1,000.0	169.5	145.8	1,000.0	168.7	144.9	1,000.0	167.9	144.0

##### Share Repurchases

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to \$5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All shares repurchased under our 2020 Share Repurchase Program were retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 3.6 million shares of our common stock at a cost of approximately \$750.0 million during the year ended December 31, 2022. There were no share repurchases of our common stock during the years ended December 31, 2024 and 2023. Approximately \$2.1 billion remained available under our 2020 Share Repurchase Program as of December 31, 2024.

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.



**BIAGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Accumulated Other Comprehensive Income (Loss)**

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

(In millions)	December 31, 2024			
	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments, Net of Tax	Total
Balance, December 31, 2023	\$ (25.0)	\$ (2.6)	\$ (126.1)	\$ (153.7)
Other comprehensive income (loss) before reclassifications	80.8	(14.0)	(45.1)	21.7
Amounts reclassified from AOCI	(4.2)	—	—	(4.2)
Net current period other comprehensive income (loss)	76.6	(14.0)	(45.1)	17.5
Balance, December 31, 2024	\$ 51.6	\$ (16.6)	\$ (171.2)	\$ (136.2)

(In millions)	December 31, 2023				
	Unrealized Gains (Losses) on Securities Available for Sale, Net of Tax	Unrealized Gains (Losses) on Cash Flow Hedges, Net of Tax	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments, Net of Tax	Total
Balance, December 31, 2022	\$ (15.7)	\$ 15.1	\$ (1.1)	\$ (163.2)	\$ (164.9)
Other comprehensive income (loss) before reclassifications	2.3	(26.8)	(1.5)	37.1	11.1
Amounts reclassified from AOCI	13.4	(13.3)	—	—	0.1
Net current period other comprehensive income (loss)	15.7	(40.1)	(1.5)	37.1	11.2
Balance, December 31, 2023	\$ —	\$ (25.0)	\$ (2.6)	\$ (126.1)	\$ (153.7)

(In millions)	December 31, 2022					
	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 <sup>(1)</sup>	Unrealized Gains (Losses) on Pension Benefit Obligation, Net of Tax	Currency Translation Adjustments, Net of Tax	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 AOCI	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)

<sup>(1)</sup> 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.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table summarizes the amounts reclassified from AOCI:

	Amounts Reclassified from AOCI			
	For the Years Ended December 31,			
(In millions)	2024	2023	2022	Income Statement Location
Gains (losses) on securities available for sale	\$ —	\$ (17.0)	\$ (12.6)	Other (income) expense, net
	—	3.6	2.6	Income tax (benefit) expense
Gains (losses) on cash flow hedges	18.1	11.6	201.6	Revenue
	(12.9)	3.7	(5.5)	Operating expense
	(0.4)	(0.3)	(0.3)	Other (income) expense, net
	(0.6)	(1.7)	(19.8)	Income tax (benefit) expense
Gains (losses) on net investment hedges <sup>(1)</sup>	—	—	38.1	Other (income) expense, net
Currency translation adjustments	—	—	(58.9)	Other (income) expense, net
Total reclassifications, net of tax	\$ 4.2	\$ (0.1)	\$ 145.2	

<sup>(1)</sup> 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:

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
<i>Numerator:</i>			
Net income attributable to Biogen Inc.	\$ 1,632.2	\$ 1,161.1	\$ 3,046.9
<i>Denominator:</i>			
Weighted-average number of common shares outstanding	145.6	144.7	145.3
Effect of dilutive securities:			
Time-vested restricted stock units	0.3	0.7	0.5
Market stock units	—	—	0.1
Performance stock units settled in stock	—	0.2	0.1
Dilutive potential common shares	0.3	0.9	0.7
Shares used in calculating diluted earnings per share	145.9	145.6	146.0

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

Earnings per share for the year ended December 31, 2022, reflects the repurchase of approximately 3.6 million shares of our common stock, respectively, under our 2020 Share Repurchase Program. There were no share repurchases of our common stock during the years ended December 31, 2024 and 2023. For additional information on our 2020 Share Repurchase Program, please read *Note 14, Equity*, to these consolidated financial statements.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 16: Share-Based Payments**

**Share-Based Compensation Expense**

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Research and development	\$ 154.1	\$ 296.7	\$ 98.5
Selling, general and administrative	198.6	371.7	175.1
Subtotal	352.7	668.4	273.6
Capitalized share-based compensation costs	(10.3)	(10.2)	(9.3)
Share-based compensation expense included in total cost and expense	342.4	658.2	264.3
Income tax effect	(63.4)	(132.6)	(49.2)
Share-based compensation expense included in net income attributable to Biogen Inc.	\$ 279.0	\$ 525.6	\$ 215.1

In connection with our acquisition of Reata in September 2023 we recognized Reata equity-based compensation expense, inclusive of employer taxes, of approximately \$393.4 million attributable to the post-acquisition service period, of which \$196.4 million was recognized as a charge to selling, general and administrative expense with the remaining \$197.0 million as a charge to research and development expense within our consolidated statements of income for the year ended December 31, 2023. These amounts were associated with the accelerated vesting of stock options and RSUs previously granted to Reata employees that required no future services to vest.

In connection with our acquisition of HI-Bio in July 2024 we recognized HI-Bio equity-based compensation expense, inclusive of employer taxes, of approximately \$56.4 million attributable to the post-acquisition service period, of which \$42.5 million was recognized as a charge to research and development expense with the remaining \$13.9 million as a charge to selling, general and administrative expense within our consolidated statements of income for the year ended December 31, 2024. These amounts were associated with the accelerated vesting of stock options and RSUs previously granted to HI-Bio employees and required no future services to vest.

For additional information on our acquisitions of HI-Bio and Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Time-vested restricted stock units	\$ 236.4	\$ 220.0	\$ 202.3
Performance stock units settled in stock	48.4	35.5	35.0
Performance stock units settled in cash	(2.5)	6.8	10.1
Employee stock purchase plan	9.7	10.5	12.7
Stock options	3.7	3.7	0.3
Market stock units	0.6	4.9	13.2
Reata equity awards <sup>(1)</sup>	—	387.0	—
HI-Bio equity awards <sup>(1)</sup>	56.4	—	—
Subtotal	352.7	668.4	273.6
Capitalized share-based compensation costs	(10.3)	(10.2)	(9.3)
Share-based compensation expense included in total cost and expense	\$ 342.4	\$ 658.2	\$ 264.3

<sup>(1)</sup> Relates to the Reata and HI-Bio equity-based compensation expense attributable to the post-acquisition service period, associated with the accelerated vesting of stock options and RSUs previously granted to Reata and HI-Bio employees that required no future services to vest. For additional information on our acquisitions of Reata and HI-Bio, please read *Note 2, Acquisitions*, to these consolidated financial statements.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As of December 31, 2024, unrecognized compensation cost related to unvested share-based compensation was approximately \$292.2 million, net of estimated forfeitures. We expect to recognize the cost of these unvested awards over a weighted-average period of 1.8 years.

#### Share-Based Compensation Plans

We have two share-based compensation plans pursuant to which awards are currently being made: (i) the Biogen Inc. 2024 Omnibus Equity Plan (2024 Omnibus Equity Plan); and (ii) the Biogen Inc. 2024 Employee Stock Purchase Plan (2024 ESPP).

We have three share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be 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).

#### 2024 Omnibus Equity Plan

In June 2024 our shareholders approved the 2024 Omnibus Equity Plan for share-based awards to our prospective and current employees, non-employee directors, officers or consultants. Awards granted from the 2024 Omnibus Equity Plan may include stock options, shares of restricted stock, restricted stock units, 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 plan. Shares of common stock available for grant under the 2024 Omnibus Equity Plan consist of 3.7 million shares reserved for this purpose, plus shares of common stock that remained available for grant under our 2017 Omnibus Equity Plan (including shares available by reason of a predecessor plan) on the date that our shareholders approved the 2024 Omnibus Equity Plan, plus shares that were subject to awards under the 2017 Omnibus Equity Plan (including shares available by reason of a predecessor plan) that remain unissued upon the cancellation, surrender, exchange, termination or forfeiture of such awards. The 2024 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 2017 Omnibus Equity Plan or the Directors Plan since our shareholders approved the 2024 Omnibus Equity Plan, and do not intend to make any awards pursuant to the 2017 Omnibus Equity Plan or the Directors Plan in the future, except that unused shares under the 2017 Omnibus Equity Plan have been carried over for use under the 2024 Omnibus Equity Plan. Awards outstanding under the 2017 Omnibus Equity Plan and the Directors Plan as of the date our shareholders approved the 2024 Omnibus Equity Plan will remain outstanding and subject to the terms and conditions of the 2017 Omnibus Equity Plan and the Directors Plan, as applicable, and the relevant award agreements.

#### Stock Options

In 2022 we granted approximately 81,000 stock options to our 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 value of the stock option grant is estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair value of the stock option is 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 option has a 10-year term and is exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant.

	December 31, 2024		
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2023	81,000	\$ 301.85	8.9 years
Granted	—	—	—
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2024	81,000	\$ 301.85	7.9 years
Exercisable at December 31, 2024	54,000	\$ 301.85	7.9 years

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Market Stock Units

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, 2024	
	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	34,000	\$ 359.77
Granted	—	—
Vested	(29,000)	375.59
Forfeited	(5,000)	375.20
Unvested at December 31, 2024	—	\$ —

The fair values of MSUs vested in 2024, 2023 and 2022 totaled \$6.3 million, \$20.7 million and \$18.8 million, respectively.

#### Performance Stock Units

##### *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. Beginning in 2024 we began granting PSUs with a performance metric based on the three-year cumulative aggregate growth rate of our earnings per share during the performance period.

# **BIOGEN INC. AND SUBSIDIARIES** **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table summarizes our PSUs that settle in stock activity:

	December 31, 2024	
	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	389,000	\$ 325.73
Granted <sup>(1)</sup>	266,000	280.60
Vested	(59,000)	277.05
Forfeited	(46,000)	308.84
Unvested at December 31, 2024	550,000	\$ 310.61

<sup>(1)</sup> PSUs settled in stock granted in 2024 include awards granted in conjunction with our annual awards made in February 2024 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.

PSUs settled in stock granted in 2023 and 2022 had weighted average grant date fair values of \$383.61 and \$294.43, respectively.

We value grants of PSUs with a performance metric based on a three-year cumulative rTSR metric 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:

	For the Years Ended December 31,		
	2024	2023	2022
Expected dividend yield	—%	—%	—%
Range of expected stock price volatility	35.1%	44.7%	44.0% - 45.9%
Range of risk-free interest rates	4.1%	4.1%	1.8% - 3.9%
30 calendar day average stock price on grant date	\$251.69	\$283.93	\$231.31 - \$294.86
Weighted-average per share grant date fair value	\$280.60	\$383.61	\$294.43

The fair values of PSUs settled in stock that vested in 2024, 2023 and 2022 totaled \$13.2 million, \$28.6 million and \$9.5 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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes our PSUs that settle in cash activity:

	December 31, 2024
	Shares
Unvested at December 31, 2023	41,000
Granted	—
Vested	(39,000)
Forfeited	(2,000)
Unvested at December 31, 2024	—

The fair values of PSUs settled in cash that vested in 2024, 2023 and 2022 totaled \$9.5 million, \$11.7 million and \$11.0 million, respectively.

#### Time-Vested Restricted Stock Units

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, 2023	1,866,000	\$ 256.74
Granted <sup>(1)</sup>	1,300,000	235.82
Vested	(830,000)	254.33
Forfeited	(275,000)	249.22
Unvested at December 31, 2024	2,051,000	\$ 246.22

<sup>(1)</sup> RSUs granted in 2024 primarily represent RSUs granted in conjunction with our annual awards made in February 2024 and awards made in conjunction with the hiring of new employees. RSUs granted in 2024 also include approximately 11,200 RSUs granted to our Board of Directors.

RSUs granted in 2023 and 2022 had weighted average grant date fair values of \$282.92 and \$221.28, respectively.

The fair values of RSUs vested in 2024, 2023 and 2022 totaled \$193.6 million, \$232.1 million and \$116.3 million, respectively.

#### Employee Stock Purchase Plan

##### 2024 Employee Stock Purchase Plan

In June 2024 our shareholders approved the 2024 ESPP. The 2024 ESPP, which became effective on July 1, 2024, replaced the 2015 ESPP, which expired on June 30, 2024. The maximum number of shares of our common stock that may be purchased under the 2024 ESPP is 2.5 million.

The following table summarizes our ESPP activity:

	For the Years Ended December 31,			
(In millions, except share amounts)	2024	2023	2022	
Shares issued under the 2024 ESPP	40,000	—	—	
Shares issued under the 2015 ESPP	175,000	199,000	241,000	
Cash received under the 2024 ESPP	\$ 5.1	\$ —	\$ —	
Cash received under the 2015 ESPP	\$ 31.2	\$ 45.1	\$ 44.2	

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 17: Income Taxes**

**Income Tax Expense**

Income before income tax (benefit) expense and the income tax (benefit) expense consist of the following:

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
<i>Income before income tax (benefit) expense:</i>			
Domestic	\$ 853.4	\$ 192.4	\$ 1,842.0
Foreign	1,052.6	1,104.4	1,749.8
Total income before income tax (benefit) expense	\$ 1,906.0	\$ 1,296.8	\$ 3,591.8
<i>Income tax (benefit) expense:</i>			
Current:			
Federal	\$ 448.9	\$ 377.6	\$ 694.5
State	50.5	15.1	39.0
Foreign	(67.5)	48.4	67.9
Total current	431.9	441.1	801.4
Deferred:			
Federal	(154.5)	(587.4)	(328.3)
State	(17.3)	(12.7)	2.5
Foreign	13.7	294.3	157.2
Total deferred	(158.1)	(305.8)	(168.6)
Total income tax (benefit) expense	\$ 273.8	\$ 135.3	\$ 632.8

**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 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, 2024 and 2023, we have accrued income tax liabilities of \$234.0 million and \$419.5 million, respectively, under the Transition Toll Tax. The amount accrued as of December 31, 2024, is expected to be paid within one year. The Transition Toll Tax is being paid in installments over an eight-year period, which started in 2018, and will not accrue interest.

**Unremitted Earnings**

At December 31, 2024, 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, 2024, 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, 2024. The residual U.S. tax liability, if these differences reverse, would be between \$300.0 million and \$400.0 million as of December 31, 2024.



**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

## Deferred Tax Assets and Liabilities

Significant components of our deferred tax assets and liabilities are summarized as follows:

(In millions)	As of December 31,	
	2024	2023
<i>Deferred tax assets:</i>		
Tax credits	\$ 294.0	\$ 252.8
Inventory, other reserves and accruals	219.2	203.7
Intangibles, net	989.6	1,153.9
IRC Section 174 capitalized research and development	733.9	570.8
Net operating loss	1,357.2	1,700.4
Share-based compensation	34.4	36.1
Other	318.4	293.3
Valuation allowance	(1,013.7)	(1,278.7)
Total deferred tax assets	\$ 2,933.0	\$ 2,932.3
<i>Deferred tax liabilities:</i>		
Purchased inventory valuation step-up and intangible assets	\$ (1,529.6)	\$ (1,257.4)
Samsung Bioepis investment installments	—	(35.5)
GILTI	(1,054.8)	(1,136.9)
Depreciation, amortization and other	(214.9)	(215.7)
Total deferred tax liabilities	\$ (2,799.3)	\$ (2,645.5)

As of December 31, 2024, 2023, 2022 and 2021, we had a valuation allowance of \$1,013.7 million, \$1,278.7 million, \$2,003.3 million and \$1,961.3 million, respectively, related to net operating losses in Switzerland and Neurimmune's tax basis in ADUHELM.

The change in the valuation allowance between December 31, 2024 and 2023, was primarily driven by movements in net operating loss deferred tax assets in Switzerland. The net income tax impact of the changes in the valuation allowance was a benefit of approximately \$56.8 million for the year ended December 31, 2024.

The change in the valuation allowance between December 31, 2023 and 2022, was primarily driven by a reduction of approximately \$470.3 million related to the elimination of Neurimmune's tax basis in ADUHELM as a result of its deconsolidation and reduction of approximately \$230.3 million due to movements in net operating loss deferred tax assets in Switzerland. The net income tax impact of the changes in the valuation allowance was an expense of approximately \$7.4 million for the year ended December 31, 2023.

The change in the valuation allowance between December 31, 2022 and 2021, was primarily driven by an addition of \$85.0 million related to Neurimmune's tax basis in ADUHELM. For additional information on the deconsolidation and our collaboration arrangement with Neurimmune, please read *Note 20, Investments in Variable Interest Entities*, to these consolidated financial statements.

In addition to deferred tax assets and liabilities, we have recorded deferred charges related to intra-entity sales of inventory. As of December 31, 2024 and 2023, the total deferred charges were \$273.1 million and \$69.3 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 are effective for periods after December 31, 2022. The IRA did not result in any material adjustments to our income tax provision or income tax balances as of December 31, 2024 and 2023. Preliminary guidance has been issued by the IRS and we expect additional guidance and regulations to be issued in future periods. We will continue to assess its potential impact on our business and results of operations as further information becomes available.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Pillar Two

The OECD has issued model rules, which generally provide for a jurisdictional minimum effective tax rate of 15.0% as defined in those rules. Various countries have or are in the process of enacting legislation intended to implement the principles effective January 1, 2024. Our income tax provision for the year ended December 31, 2024, reflects currently enacted legislation and guidance related to the OECD model rules. This enacted legislation and guidance related to the OECD model rules did not result in any material adjustments to our income tax provision or income tax balances as of December 31, 2024.

#### 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,		
	2024	2023	2022
Statutory rate	21.0%	21.0%	21.0%
State taxes	1.8	1.1	1.1
Taxes on foreign earnings, including valuation allowances	(7.6)	(5.9)	(4.9)
Tax credits	(2.2)	(7.3)	(1.7)
Purchased inventory valuation step-up and intangible assets	2.1	0.7	0.3
GILT	(1.6)	(0.6)	0.7
Sale of Samsung Bioepis	—	—	(1.6)
Litigation settlement agreement	—	—	2.6
Neurimmune tax impacts	—	—	2.3
Internal reorganization	—	(0.1)	(1.4)
Other, including permanent items	0.9	1.5	(0.8)
Effective tax rate	14.4%	10.4%	17.6%

#### Changes in Tax Rate

For the year ended December 31, 2024, compared to 2023, the increase in our effective tax rate was partially driven by the relative deferred tax effects of the changes in the value of our equity investments and amortization of purchased intangible assets and inventory. Further, 2023 benefited from the combined impacts of Reata acquisition-related expenses and the resolution of an uncertain tax matter related to tax credits. This was partially offset by a 2024 benefit related to a decrease in our valuation allowance related to projected future foreign taxable income, as discussed in the Deferred Tax Assets and Liabilities section above.

For the year ended December 31, 2023, compared to 2022, the decrease in our effective tax rate was driven by the impact of the non-cash changes in the value of our equity investments, the impact of Fit for Growth related expenses and Reata acquisition-related expenses, as well as the combined net unfavorable tax rate impacts in 2022 related to a litigation settlement agreement, the sale of our equity interest in Samsung Bioepis, the impact of a Neurimmune valuation allowance, as discussed below, and an international reorganization to align with global tax developments. The change also benefits from the resolution of an uncertain tax matter during the first quarter of 2023 related to tax credits.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

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 the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an increase in a valuation allowance of approximately \$85.0 million to reduce the net value of a previously recorded deferred tax asset in Switzerland on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM, to zero.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

This adjustment to our net deferred tax asset was 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.

During the fourth quarter of 2023 Neurimmune was deconsolidated from our consolidated financial statements. For additional information on the deconsolidation and 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, 2024, we had credit carry forwards for U.S. federal income tax purposes of approximately \$163.0 million that begin to expire in 2030 and net operating losses of approximately \$513.4 million that do not expire. For U.S. state income tax purposes, we had research and investment credit carry forwards of approximately \$165.5 million that begin to expire in 2027 and net operating losses of approximately \$220.9 million that begin to expire in 2028. For foreign income tax purposes, we had \$10.7 billion of federal net operating loss carryforwards that begin to expire in 2027 and \$10.1 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)	For the Years Ended December 31,		
	2024	2023	2022
Beginning balance	\$ 173.4	\$ 606.4	\$ 563.4
Additions based on tax positions related to the current period	1.2	5.2	36.3
Additions for tax positions of prior periods	31.5	60.2	23.4
Reductions for tax positions of prior periods	(3.1)	(485.0)	(14.9)
Statute expirations	(12.7)	(2.1)	(1.6)
Settlement refund (payment)	(4.0)	(11.3)	(0.2)
Ending balance	\$ 186.3	\$ 173.4	\$ 606.4

As of December 31, 2022, the unrecognized tax benefits related to a deferred tax asset for Swiss tax purposes for Neurimmune's tax basis in ADUHELM was approximately \$450.0 million. 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. During the year ended December 31, 2023, we decreased our gross unrecognized tax benefits by approximately \$450.0 million related to this item as a result of the deconsolidation of Neurimmune.

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 2021 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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Included in the balance of unrecognized tax benefits as of December 31, 2024, 2023 and 2022, are \$139.3 million, \$147.6 million and \$134.0 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 (benefit) expense within our consolidated statements of income. During the years ended December 31, 2024, 2023 and 2022, we recognized total interest and penalty expense of \$13.8 million, \$5.1 million and \$0.7 million, respectively. We have accrued \$40.7 million and \$30.2 million for the payment of interest and penalties as of December 31, 2024 and 2023, respectively.

It is reasonably possible that we will adjust the value of our uncertain tax positions related to certain transfer pricing, collaboration matters, withholding taxes 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 \$45.0 million in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations.

#### Note 18: Other Consolidated Financial Statement Detail

##### Supplemental Cash Flow Information

Supplemental disclosure of cash flow information is summarized as follows:

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Cash paid during the year for:			
Interest	\$ 245.4	\$ 252.2	\$ 262.5
Income taxes	355.1	740.7	932.9

##### Other (Income) Expense, Net

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Interest income	\$ (67.6)	\$ (276.5)	\$ (89.3)
Interest expense	250.3	246.9	246.6
(Gains) losses on investments, net	100.4	291.2	277.3
Foreign exchange (gains) losses, net	30.9	50.4	35.5
Gain on sale of equity interest in Samsung Bioepis <sup>(1)</sup>	—	—	(1,505.4)
Litigation settlement agreement and settlement fees	—	—	917.0
Other, net	29.6	3.5	10.1
Total other (income) expense, net	\$ 343.6	\$ 315.5	\$ (108.2)

<sup>(1)</sup> 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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Net (gains) losses recognized on equity securities	\$ 100.4	\$ 275.2	\$ 264.7
Less: Net (gains) losses realized on equity securities	(2.0)	5.2	—
Net unrealized (gains) losses recognized on equity securities	\$ 102.4	\$ 270.0	\$ 264.7

The net unrealized losses recognized during the year ended December 31, 2024, primarily reflect a decrease in the aggregate fair value of our investments in Sage common stock of approximately \$101.4 million, partially offset by an increase in the fair value of Denali and Sangamo common stock of approximately \$7.5 million.

The net unrealized losses recognized during the year ended December 31, 2023, primarily reflect a decrease in the aggregate fair value of our investments in Sage, Denali, Sangamo and Ionis common stock of approximately \$248.5 million.

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, partially offset by an increase in the fair value of Ionis and Sage common stock of approximately \$27.3 million.

#### Accrued Expense and Other

Accrued expense and other consists of the following:

(In millions)	As of December 31,	
	2024	2023
Revenue-related reserves for discounts and allowances	\$ 937.5	\$ 926.5
Employee compensation and benefits	375.8	335.1
Collaboration expense	309.0	214.6
Royalties and licensing fees	190.2	191.5
Current portion of contingent consideration obligations	291.2	—
Other	704.0	955.9
Total accrued expense and other	\$ 2,807.7	\$ 2,623.6

Other long-term liabilities were \$732.3 million and \$781.1 million as of December 31, 2024 and 2023, respectively, and included accrued income taxes totaling \$156.7 million and \$403.2 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 for the treatment of relapsed or refractory follicular lymphoma; COLUMVI, a bispecific antibody for the treatment of non-Hodgkin's lymphoma, which was granted accelerated approval by the FDA during the second quarter of 2023; and have the option to add other potential anti-CD20 therapies, pursuant to our collaboration arrangements with

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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. has impacted our percentage of the co-promotion profits for RITUXAN and LUNSUMIO, as summarized in the table below.

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 current compensation payable for GAZYVA under the collaboration arrangement until the 11 year anniversary of the first commercial sale of GAZYVA in the U.S.

#### 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 upon the first entry of an FDA approved biosimilar to OCREVUS.

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

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

OCREVUS royalty revenue is based on our estimates from third party and market research data of OCREVUS sales occurring during the corresponding period. Differences between actual and estimated royalty revenue will be adjusted for in the period in which they become known, which is generally expected to be the following quarter.

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. 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.

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

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. For the year ended December 31, 2023, we began to record our share of LUNSUMIO development and sales and marketing expense as a reduction of our share of pre-tax profits in revenue from anti-CD20 therapeutic programs within our consolidated statements of income.

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.

#### [COLUMVI \(glofitamab\)](#)

In December 2022 we entered into an agreement with Genentech related to the commercialization and sharing of economics for COLUMVI, a bispecific antibody for the treatment of B-cell non-Hodgkin's lymphoma, which was subsequently granted accelerated approval by the FDA in June 2023. Under the terms of this agreement, we will have no payment obligations. Genentech will have sole decision-making rights on the commercialization of COLUMVI within the U.S. and we will receive tiered royalties in the mid-single digit range on net sales of COLUMVI in the U.S. The commercialization of COLUMVI does not impact the percentage of the co-promotion profits we receive for RITUXAN, LUNSUMIO or GAZYVA.

If we undergo a change in control, as defined in our collaboration agreement, Genentech will be deemed to have purchased our rights to COLUMVI 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:

<a href="#">After LUNSUMIO Approval until the First Threshold Date</a>	37.5 %
<a href="#">After First Threshold Date until the Second Threshold Date</a>	35.0 %
<a href="#">After Second Threshold Date</a>	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 or (ii) January 1 of the calendar year following the calendar year in which the First Threshold Date occurs.

In March 2023 the First Threshold Date was achieved. As a result, beginning in April 2023 the pre-tax profit share for RITUXAN and LUNSUMIO was 35.0%. Our share of RITUXAN pre-tax profits in the U.S. in excess of \$50.0 million for the year ended December 31, 2022, was 37.5%.



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### GAZYVA Profit Share

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

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

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

In March 2023 the Second GAZYVA Threshold Date was achieved. As a result, beginning in April 2023 the pre-tax profit share for GAZYVA was 35.0%. Our share of GAZYVA pre-tax profits in excess of \$50.0 million for the year ended December 31, 2022, was 37.5%.

#### Revenue from Anti-CD20 Therapeutic Programs

Revenue from anti-CD20 therapeutic programs is summarized as follows:

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Royalty revenue on sales of OCREVUS	\$ 1,339.5	\$ 1,266.2	\$ 1,136.3
Biogen's share of pre-tax profits in the U.S. for RITUXAN, GAZYVA and LUNSUMIO <sup>(1)</sup>	392.0	409.4	547.0
Other revenue from anti-CD20 therapeutic programs	18.4	14.0	17.2
Total revenue from anti-CD20 therapeutic programs	<u>\$ 1,749.9</u>	<u>\$ 1,689.6</u>	<u>\$ 1,700.5</u>

<sup>(1)</sup> LUNSUMIO became commercially available in the U.S. during the first quarter of 2023.

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 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, 2024, 2023 and 2022, totaled approximately \$216.1 million, \$240.2 million and \$243.1 million, respectively.

##### 2018 Ionis Agreement

In June 2018 we entered into a 10-year exclusive collaboration agreement with Ionis to develop novel 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.

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.



**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

During the years ended December 31, 2024, 2023 and 2022, we incurred milestones of \$7.5 million, \$7.5 million and \$10.0 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.

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 BII115, an investigational ASO in development for SMA.

*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 QALSODY (tofersen), for the treatment of ALS with SOD1 mutations. Following the option exercise, we are solely responsible for the costs and expense related to the development, manufacturing and commercialization of QALSODY.

In April 2023 the FDA approved QALSODY for the treatment of ALS in adults who have a mutation in the SOD1 gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). Under this agreement, we make royalty payments to Ionis on annual worldwide net sales of QALSODY using a tiered royalty rate between 11.0% and 15.0%, which are recognized in cost of sales within our consolidated statements of income.

During the year ended December 31, 2024, we incurred a milestone payment of \$20.0 million to Ionis following the approval of QALSODY in the E.U., which was recorded within intangible assets, net in our consolidated balance sheets. Additionally, during the year ended December 31, 2024, we accrued a milestone payment of \$10.0 million to Ionis following the approval of QALSODY in Japan, which was recorded within intangible assets, net in our consolidated balance sheets, and is expected to be paid during the first quarter of 2025.

During the year ended December 31, 2023, we incurred a milestone payment of \$16.0 million to Ionis following the FDA's approval of QALSODY, which was recorded within intangible assets, net in our consolidated balance sheets.

During the year ended December 31, 2022, we incurred a milestone payment of \$17.0 million related to the advancement of a program under this agreement, which was recorded in research and development expense within our consolidated statements of income.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

### [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 in research and development expense within 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 in research and development expense within our consolidated statements of income.

### [Eisai Co., Ltd.](#)

During the first quarter of 2023 we accrued a \$31.0 million payable to Eisai related to the termination of an agreement whereby Eisai co-promoted or distributed our MS products in certain Asia-Pacific markets and settings. As of December 31, 2023, we paid approximately \$16.0 million of the \$31.0 million payable. The remaining portion was subsequently paid in January 2024. This termination fee is included in selling, general and administrative expense in our consolidated statements of income for the year ended December 31, 2023.

### [LEQEMBI \(lecanemab\) Collaboration](#)

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

In March 2022 we amended our ADUHELM Collaboration Agreement with Eisai. As of the amendment date, we have sole decision making and commercialization rights worldwide on ADUHELM, and beginning January 1, 2023, Eisai receives only a tiered royalty based on net sales of ADUHELM, and no longer participates in sharing ADUHELM's global profits and losses. 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

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

In July 2023 the FDA granted traditional approval of LEQEMBI. Prior to receiving traditional approval, LEQEMBI had been granted accelerated approval by the FDA in January 2023, at which time it became commercially available in the U.S. Outside of the U.S., LEQEMBI is now approved in Japan (September 2023), China (January 2024), South Korea (May 2024), Hong Kong (July 2024), Israel (July 2024), United Arab Emirates (August 2024), Great Britain (August 2024) and Mexico (December 2024). Additionally, in January 2025 the FDA approved LEQEMBI monthly IV maintenance dosing for the treatment of early Alzheimer's disease.

Upon commercialization of LEQEMBI in the U.S., we began recognizing our 50.0% share of LEQEMBI product revenue, net and cost of sales, including royalties, within Alzheimer's collaboration revenue in our consolidated statements of income, as we are not the principal.

Our share of LEQEMBI sales and marketing expense and development expense are recorded within selling, general and administrative expense and research and development expense, respectively, within our consolidated statements of income.

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Total development expense incurred by the collaboration related to the advancement of LEQEMBI	\$ 329.6	\$ 371.9	\$ 347.2
Biogen's share of the LEQEMBI Collaboration development expense reflected in research and development expense in our consolidated statements of income	164.8	186.0	173.6
Total sales and marketing expense incurred by the LEQEMBI Collaboration	647.0	304.4	104.6
Biogen's share of the LEQEMBI Collaboration sales and marketing expense reflected in selling, general and administrative expense in our consolidated statements of income	323.5	152.2	52.3

#### [ADUHELM Collaboration Agreement](#)

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

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

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

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

(In millions)	For the Year Ended December 31, 2022
Total ADUHELM Collaboration development expense	\$ 149.4
Biogen's share of the ADUHELM Collaboration development expense reflected in research and development expense in our consolidated statements of income	82.2
Total sales and marketing expense incurred by the ADUHELM Collaboration	134.2
Biogen's share of the ADUHELM Collaboration sales and marketing expense reflected in selling, general and administrative expense and collaboration profit sharing/(loss reimbursement) in our consolidated statements of income	71.5

#### ADUHELM Co-promotion Profits and Losses

Under our initial ADUHELM Collaboration Agreement, we recognized revenue on sales of ADUHELM in the U.S. to third parties as a component of product revenue, net in our consolidated statements of income. We also recorded the related cost of revenue and sales and marketing expense in our consolidated statements of income as these costs were incurred. Payments made to and received from Eisai for its 45.0% share of the co-promotion profits or losses in the U.S. were recognized in collaboration profit sharing/(loss reimbursement) in our consolidated statements of income. For the year ended December 31, 2022, we recognized net reductions to our operating expense of approximately \$224.7 million to reflect Eisai's 45.0% share of net collaboration losses in the U.S. for 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 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 recognized approximately \$197.0 million related to Eisai's 45.0% share of inventory, idle capacity charges and contractual commitments in collaboration profit sharing/(loss reimbursement) within our consolidated statements of income for the year ended December 31, 2022.

Amounts receivable from Eisai related to the agreements discussed above were approximately \$16.7 million and \$1.4 million as of December 31, 2024 and 2023, respectively. Amounts payable to Eisai related to the agreements discussed above were approximately \$138.0 million and \$118.4 million as of December 31, 2024 and 2023, respectively.

#### UCB

We have a collaboration agreement with UCB, effective November 2003, to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of SLE and other future agreed indications. Either we or UCB may propose development of dapirolizumab pegol in additional indications. If the parties do not agree to add an indication as an agreed indication to the collaboration, we or UCB may, at the sole expense of the applicable party, pursue development in such excluded indication(s), subject to an opt-in right of the non-pursuing party after proof of clinical activity.

All costs incurred for agreed indications, including research, development, sales and marketing expense, are shared equally between us and UCB. If marketing approval is obtained, both companies will jointly commercialize dapirolizumab pegol and share profits and losses equally.

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

(In millions)	For the Years Ended December 31,			
	2024	2023	2022	
Total UCB collaboration development expense	\$ 77.5	\$ 60.7	\$ 68.0	
Biogen's share of the UCB collaboration development expense reflected in research and development expense in our consolidated statements of income	38.7	30.3	34.0	

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Merz Therapeutics (previously Acorda Therapeutics, Inc.)**

In June 2009 we entered into a collaboration and license agreement with Acorda to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S.

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.

In January 2024 we notified Acorda of our decision to terminate our collaboration and license agreement, effective January 1, 2025, whereby Acorda regained global commercialization rights to FAMPYRA. On April 1, 2024, Acorda filed for bankruptcy protection and announced its intention to sell substantially all of Acorda's assets to a third party. On July 10, 2024, Merz Therapeutics announced that its subsidiary Merz Pharmaceuticals LLC had completed the acquisition of FAMPYRA, and related assets from Acorda. We are now working with Merz Therapeutics on the transition of global commercialization rights of FAMPYRA and we expect to recognize minimal revenue in 2025.

For the years ended December 31, 2024, 2023 and 2022, total cost of sales related to royalties and commercial supply of FAMPYRA reflected in our consolidated statements of income were approximately \$52.4 million, \$55.2 million and \$46.1 million, respectively.

**Sage Therapeutics, Inc.**

In November 2020 we entered into a global collaboration and license agreement with Sage to jointly develop and commercialize ZURZUVAE (zuranolone) for the treatment of PPD and potential treatment of MDD and BII124 (SAGE-324) for the potential treatment of essential tremor with potential in other neurological conditions such as epilepsy. In July 2024 we and Sage announced that the Phase 2 KINETIC 2 dose-range study of BII124 did not meet its endpoints. Based on these results, we discontinued our further development of BII124 and terminated our rights under the collaboration and license agreement specific to BII124, effective February 17, 2025.

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 may pay Sage development and commercial milestone payments that could total up to approximately \$700.0 million if all the specified milestones set forth in this collaboration are achieved.

In August 2023 the FDA approved ZURZUVAE for adults with PPD, pending DEA scheduling, which was completed in October 2023. Upon approval, ZURZUVAE became the first and only oral, once-daily, 14-day treatment that can provide rapid improvements in depressive symptoms by day 15 for women with PPD. ZURZUVAE for PPD became commercially available in the U.S. during the fourth quarter of 2023. Additionally, the FDA issued a CRL for the NDA for zuranolone in the treatment of adults with MDD. In October 2024 we and Sage agreed to not pursue further development of zuranolone for the potential treatment of MDD. This decision was based on the significant new investment and time we expect would be needed to conduct the additional studies required to support approval of this indication.

Under this collaboration, both companies will share equal responsibility and costs for development as well as profits and losses for commercialization in the U.S. Outside of the U.S., we are responsible for development and commercialization, excluding Japan, Taiwan and South Korea, with respect to zuranolone and may pay Sage potential tiered royalties in the high teens to low twenties. During the fourth quarter of 2023 we accrued a milestone payment due to Sage of \$75.0 million upon the first commercial sale of ZURZUVAE for PPD in the U.S., which was recorded within intangible assets, net in our consolidated balance sheets, and subsequently paid in January 2024.

We reflect revenue on sales of ZURZUVAE 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. We share 50.0% of the profit or loss related to our global collaboration and license agreement with Sage, which is recognized in collaboration profit sharing/(loss reimbursement) in our consolidated statements of income.

For the years ended December 31, 2024 and 2023, we recognized net profit-sharing expense of approximately \$27.0 million and net loss reimbursement of approximately \$4.7 million, respectively, to reflect Sage's 50.0% share

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

of net collaboration losses in the U.S., which are recognized in collaboration profit sharing/(loss reimbursement) in our consolidated statements of income.

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Total Sage collaboration development expense	\$ 34.2	\$ 176.7	\$ 173.3
Biogen's share of the Sage collaboration development expense reflected in research and development expense in our consolidated statements of income	17.1	88.3	86.7
Total sales and marketing expense incurred by the Sage collaboration	118.5	187.0	109.9
Biogen's share of the Sage collaboration sales and marketing expense reflected in selling, general and administrative expense and collaboration profit sharing/(loss reimbursement) in our consolidated statements of income	59.2	93.5	55.0

#### Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of LRRK2 for Parkinson's disease (LRRK2 Collaboration) and also entered into a separate agreement to obtain an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its ATV-enabled anti-amyloid beta program and a second program utilizing its Transport Vehicle technology. In July 2024 we terminated our license with Denali for the ATV-enabled anti-amyloid beta program. This termination also resulted in the termination of the exclusive option agreement, as discussed above.

As part of this collaboration we purchased \$465.0 million of Denali common stock in September 2020, or approximately 1.3 million shares at approximately \$34.94 per share, which were initially subject to transfer restrictions. We may pay Denali development and commercial milestone payments that could total up to approximately \$1.1 billion if the milestones related to the LRRK2 Collaboration are achieved.

Under the LRRK2 Collaboration, both companies share responsibility and costs for global development based on specified percentages as well as profits and losses for commercialization in the U.S. and China. Outside the U.S. and China we are responsible for commercialization and may pay Denali potential tiered royalties.

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

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Total Denali collaboration development expense	\$ 53.1	\$ 65.0	\$ 75.1
Biogen's share of the Denali collaboration development expense reflected in research and development expense in our consolidated statements of income	31.9	39.0	43.8

#### Sangamo Therapeutics, Inc.

In February 2020 we entered into a collaboration and license agreement with Sangamo to pursue certain neurological targets 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. These restrictions have now lapsed.

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

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

(In millions)	For the Years Ended December 31,	
	2023	2022
Total Sangamo collaboration development expense	\$ 4.1	\$ 19.1
Biogen's share of the Sangamo collaboration development expense reflected in research and development expense in our consolidated statements of income	2.4	12.1



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 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, 2024, 2023 and 2022, we recorded approximately \$54.0 million, \$4.1 million and \$39.2 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 in exchange for total consideration of approximately \$2.3 billion. Under the terms of this transaction, we received approximately \$1.0 billion in cash at closing, with approximately \$1.3 billion in cash to be deferred over two payments. The first deferred payment of \$812.5 million was received in April 2023 and the second deferred payment of \$437.5 million was received in April 2024.

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. 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 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, a ranibizumab biosimilar referencing LUCENTIS, and OPUVIZ, an aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. The agreement established that Samsung Bioepis will be responsible for development and will supply both products to us at a pre-specified gross margin of approximately 45.0%.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

In October 2024 we notified Samsung Bioepis of our decision to terminate our 2019 Development and Commercialization Agreement (the DCA Agreement) solely within the U.S. and Canada. As a result of this termination we recognized impairment charges of approximately \$20.2 million, which were recorded within amortization and impairment of acquired intangible assets within our consolidated statements of income for the year ended December 31, 2024. Biogen will transfer commercialization rights for BYOOVIZ and OPUVIZ in the U.S. and Canada back to Samsung Bioepis over a period of up to 18 months. During this transition period, we will continue to commercialize BYOOVIZ. The termination does not impact the other markets in the DCA Agreement.

In the fourth quarter of 2024 we made a milestone payment of \$15.0 million to Samsung Bioepis related to the approval of OPUVIZ in the E.U., which was recorded within intangible assets, net in our consolidated balance sheets. We may also pay Samsung Bioepis up to approximately \$150.0 million in additional development, regulatory and sales-based milestones associated with the remaining major markets covered by the agreement.

We reflect revenue on sales of BYOOVIZ 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.

#### *2013 Commercial Agreement*

In December 2013 we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, 3 anti-TNF biosimilar product candidates which includes IMRALDI, an adalimumab biosimilar referencing HUMIRA, FLIXABI, an infliximab biosimilar referencing REMICADE, and BENEPALI, an etanercept biosimilar referencing ENBREL, in Europe.

In July 2024 we exercised an option to extend this agreement by an additional five years, and paid Samsung Bioepis an option exercise fee of \$60.0 million, which was recorded within intangible assets, net within our consolidated balance sheets as of December 31, 2024.

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 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 2013 commercial agreement with Samsung Bioepis, which is recognized in collaboration profit sharing/(loss reimbursement) in our consolidated statements of income. For the years ended December 31, 2024, 2023 and 2022, we recognized net profit-sharing expense of approximately \$227.4 million, \$223.5 million and \$217.4 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 this license agreement, we granted Samsung Bioepis an exclusive license to use, develop, manufacture and commercialize biosimilar products created by Samsung Bioepis using Biogen product-specific technology. In exchange, we receive single digit royalties on biosimilar products developed and commercialized by Samsung Bioepis. Royalty revenue under the license agreement is recognized as a component of contract manufacturing, royalty and other revenue in our consolidated statements of income.

For the years ended December 31, 2024, 2023 and 2022, we recognized approximately \$14.4 million, \$13.6 million and \$20.6 million, respectively, as a component of contract manufacturing, royalty and other revenue in our consolidated statements of income related to the license agreement and other services performed under our collaboration with Samsung Bioepis.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were approximately \$7.6 million and \$9.9 million as of December 31, 2024 and 2023, respectively. Amounts payable to Samsung Bioepis related to the agreements discussed above were approximately \$60.8 million and \$73.7 million as of December 31, 2024 and 2023, respectively.



**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**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*

Beginning in 2007 we consolidated the results of Neurimmune as we determined we were the primary beneficiary because we had the power through the collaboration to direct the activities that most significantly impacted the entity's economic performance and we were required to fund 100.0% of the research and development costs incurred in support of the collaboration. The collaboration and license agreement with Neurimmune was for the development and commercialization of antibodies for the potential treatment of Alzheimer's disease, including ADUHELM (as amended, the Neurimmune Agreement).

In November 2023 we notified Neurimmune of our decision to terminate the Neurimmune Agreement. Subsequent to the termination, we reconsidered our relationship with Neurimmune and determined that we were no longer the primary beneficiary of the variable interest entity. As a result, we recorded a net gain on the deconsolidation of Neurimmune of approximately \$3.0 million, which was recorded in other (income) expense, net within our consolidated statements of income for the year ended December 31, 2023.

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an increase in a valuation allowance of approximately \$85.0 million to reduce the net value of a previously recorded deferred tax asset in Switzerland on Neurimmune's tax basis in ADUHELM, the realization of which was dependent on future sales of ADUHELM, to zero. This adjustment to our net deferred tax asset was 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 reimbursed Neurimmune are reflected in research and development expense in our consolidated statements of income. For the years ended December 31, 2023 and 2022, 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, 2024 and 2023, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled \$23.6 million and \$16.4 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, investigations and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

##### *Securities Litigation asserted against Biogen*

We and certain current and former officers are defendants in three securities actions pending in the District Court, one filed by Nadia Shash and Amjad Khan in November 2020 and related to statements about ADUHELM, one filed by the Oklahoma Firefighters Pension and Retirement System in February 2022 and related to statements about ADUHELM, and one filed by Thomas Allen Gray in June 2024 and related to statements about LEQEMBI, TECFIDERA and VUMERITY. All 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.

##### *Derivative Actions*

We and members of the Board of Directors are named as defendants in five derivative actions pending in the District Court, one filed by The Booth Family Trust in February 2022, one filed by Elaine Wang in July 2022, one filed by Jonathan Blaufarb (Blaufarb I) in July 2024, one filed by Lawrence Hollin in October 2024 and one filed by Jonathan Blaufarb (Blaufarb II) in October 2024. The Booth, Wang and Blaufarb II actions relate to ADUHELM and other matters, and the Blaufarb I and Hollin actions relate to statements about LEQEMBI, our compliance controls, 2023 earnings guidance and other matters. The actions allege breach of fiduciary duty, waste of corporate assets and other common law claims, and violations of the Securities Exchange Act of 1934, 15 U.S.C. §78a et seq. The actions seek declaratory and injunctive relief, monetary relief payable to Biogen, and attorneys' fees and costs payable to the plaintiffs. The Booth and Wang actions are stayed.

##### *IMRALDI Patent Litigation*

In June 2024, the Technical Boards of Appeal of the European Patent Office upheld the validity of Fresenius Kabi Deutschland GmbH's (Fresenius Kabi's) European Patent 3 145 488 (the EP '488 Patent), which expires in May 2035. In June 2022 Fresenius Kabi filed a claim for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis that Biogen commercializes in Europe, infringes the French counterpart of the EP '488 Patent. In March 2024 the Düsseldorf Regional Court dismissed Fresenius Kabi's claim of infringement of the German counterpart of the EP '488 Patent and Fresenius Kabi has appealed to the Higher Regional Court of Düsseldorf.

##### *Litigation with Former Convergence Shareholders*

In 2015 Biogen acquired Convergence, a U.K. company. In 2019 Shareholder Representative Services LLC, on behalf of the former shareholders of Convergence, asserted claims of \$200.0 million for alleged breaches of the contract pursuant to which we acquired Convergence. In June 2023 Shareholder Representative Services LLC and 24 former shareholders filed a suit against us in the High Court of Justice of England and Wales asserting one of the 2019 claims and seeking payment of \$49.9 million, interest and costs.

##### *Humana Patient Assistance Litigation*

In March 2023 the District Court dismissed the previously disclosed action filed against us by Humana in September 2020. Humana had alleged damages related to our providing MS patients with free medications and making

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

charitable contributions to non-profit organizations that assist MS patients and had alleged violations of the federal RICO Act and state laws. In January 2025 the United States Court of Appeals for the First Circuit affirmed the District Court's dismissal of this action.

#### *Genentech Litigation*

In February 2023 Genentech, Inc. filed suit against us in the U.S. District Court for the Northern District of California and claims that it is owed royalties of approximately \$92.7 million on sales of TYSABRI that occurred after the expiration of a patent licensed by Genentech to Biogen, plus interest and costs.

#### *Lender Litigation*

In April 2024, BioPharma Credit PLC, BPCR Limited Partnership, and BioPharma Credit Investments V (Master) LP filed suit against us and Reata Pharmaceuticals, Inc. in the Supreme Court of the State of New York alleging breach of a loan agreement with Reata and seeking payment of approximately \$23.2 million, plus interest, costs and attorneys' fees.

#### *Antitrust Litigation*

In August and September 2024, four suits were filed against us in the U.S. District Court for the Northern District of Illinois and have been consolidated for pretrial purposes. Plaintiffs are Local No. 1 Health Fund, the Mayor and City Council of Baltimore, Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund, New York State Teamsters Council Health and Hospital Fund, and UFCW Local 1500 Welfare Fund. Plaintiffs allege violations of federal antitrust laws including 15 U.S.C. §§ 1, 2 and 13(c) and of various state laws, based on contracts with pharmacy benefit managers related to TECFIDERA and VUMERITY. Plaintiffs seek declarations of the actions as class actions, monetary, declaratory and equitable relief, and attorneys' fees and costs.

#### *Other Matters*

##### *Government Investigations*

We have received subpoenas from the SEC seeking information relating to ADUHELM and its launch, and our equity plans. We have also received subpoenas from the DOJ and SEC seeking information relating to our business operations in several foreign countries. The Italian Competition Authority is investigating Biogen and other companies in relation to our biosimilar product BYOOVIZ.

##### *TYSABRI Biosimilar Patent Matter*

In September 2022 we filed an action in the U.S. District Court for the District of Delaware against Sandoz Inc., other Sandoz entities and Polpharma Biologics S.A. under the Biologics Price Competition and Innovation Act, 42 U.S.C. §262, seeking a declaratory judgment of patent infringement.

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

In July 2023 Biogen and Alkermes Pharma Ireland Limited filed patent infringement proceedings relating to VUMERITY Orange-Book listed patents (U.S. Patent Nos. 8,669,281, 9,090,558 and 10,080,733) pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC.

##### *Product Liability and Other Legal Proceedings*

We are also involved in product liability claims and other legal proceedings 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.

**BIOGEN INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**Note 22: Commitments and Contingencies**

**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 to Ionis 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.

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

**QALSODY**

We make royalty payments to Ionis on annual worldwide net sales of QALSODY using a tiered royalty rate between 11.0% and 15.0%, which are recognized 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**

We make royalty payments to Alkermes on worldwide net sales of VUMERITY using a royalty rate of 15.0%, which are recognized as cost of sales in our consolidated statements of income. Royalties payable on net sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval.

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 these consolidated financial statements.

**SKYCLARYS**

In connection with our acquisition of Reata in September 2023 we assumed additional contractual obligations related to royalty payments. Reata entered into agreements to pay royalties on future sales of SKYCLARYS, which will cumulatively range in the low- to mid-single digits.

For additional information on our acquisition of Reata, please read *Note 2, Acquisitions*, to these consolidated financial statements.

**Contingent Consideration related to Business Combinations**

In connection with our acquisition of HI-Bio in July 2024 we may make additional payments based upon the achievement of certain milestone events. We recognized the contingent consideration obligations associated with this acquisition at its fair value on the acquisition date and we revalue this obligation each reporting period. We may pay up to an additional \$650.0 million in potential future development and regulatory milestone payments. The acquisition-date fair value of these milestones was approximately \$485.1 million.

**Regulatory and Commercial Milestone Payments**

Based on our development plans as of December 31, 2024, we could trigger potential future milestone payments to third parties of up to approximately \$3.8 billion, including approximately \$0.5 billion in development milestones, approximately \$0.5 billion in regulatory milestones and approximately \$2.8 billion in commercial milestones, as part

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

of our various collaborations, including licensing and development programs and HI-Bio's pre-existing commitments, as discussed below. 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, 2024, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

If certain clinical and commercial milestones are met, we may pay up to approximately \$73.6 million in milestones in 2025 under our current agreements, excluding opt-in payments.

We acquired HI-Bio's pre-existing in-license commitments under third-party agreements, which include tiered royalties on potential future sales of felzartamab and izastobart/HIB210, ranging from high-single digit to mid-teen percentages, as well as potential future development, regulatory and commercial milestone payments related to felzartamab and izastobart/HIB210 of up to \$130.0 million, \$230.0 million and \$640.0 million, respectively. This amount includes potential milestone payments due upon the first patient dosed in a phase 3 clinical trial of felzartamab in a first and second indication of \$35.0 million and \$30.0 million, respectively.

#### Other Funding Commitments

As of December 31, 2024, 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 \$21.7 million in our consolidated balance sheets for expenditures incurred by CROs as of December 31, 2024. We have approximately \$509.2 million in cancellable future commitments based on existing CRO contracts as of December 31, 2024.

#### 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, 2024, we have approximately \$173.8 million of liabilities associated with uncertain tax positions.

As of December 31, 2024 and 2023, we have accrued income tax liabilities of approximately \$234.0 million and \$419.5 million, respectively, under the Transition Toll Tax. The amount accrued as of December 31, 2024, is expected to be paid within one year. The Transition Toll Tax is being paid in installments over an eight-year period, which started in 2018, and will not accrue interest. For additional information on the Transition Toll Tax, please read *Note 17, Income Taxes*, to these consolidated financial statements.

#### Note 23: Guarantees

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As of December 31, 2024 and 2023, 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, 2024 and 2023.

#### Note 24: Employee Benefit Plans

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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)

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 \$51.5 million, \$55.9 million and \$56.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

#### Deferred Compensation Plan

We maintain a non-qualified deferred compensation plan, known as the 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, 2024 and 2023, totaled approximately \$140.6 million and \$134.6 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 1.00% in 2024, 1.75% in 2023 and 2.00% in 2022. 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, 2024 and 2023, the Swiss plan had an unfunded net pension obligation of \$61.5 million and \$51.5 million, respectively, and plan assets that totaled \$224.7 million and \$239.6 million, respectively. In 2024, 2023 and 2022 we recognized net expense totaling \$17.5 million, \$17.6 million and \$20.0 million, respectively, related to our Swiss plan, of which \$6.0 million, \$5.1 million and \$5.3 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 \$45.6 million and \$46.5 million as of December 31, 2024 and 2023, respectively. Net periodic pension cost related to the German plans totaled \$3.8 million, \$3.6 million and \$5.9 million for the years ended December 31, 2024, 2023 and 2022, respectively, of which \$1.1 million, \$0.8 million and \$1.8 million, respectively, was included in other (income) expense, net in our consolidated statements of income.

#### Note 25: Segment Information

We operate and are managed as one operating segment, and derive revenue from activities related to the discovery, development and delivery of innovative therapies for people living with serious and complex diseases.

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. We are also supported by corporate staff functions.

Our CEO, as the CODM, manages and allocates resources to the operations of our company on a total company basis by assessing 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. In making these decisions, our CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. The

## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

CODM performs this assessment based on the segment's net income. Through this analysis, which includes a comparison to budgeted results, the CODM assesses performance and how to allocate resources across the functions discussed above. The measure of segment assets used in determining how to manage and allocate resources is reported within our consolidated balance sheets as total assets.

The tables presented below, which were prepared in accordance with the accounting policies discussed in *Note 1, Summary of Significant Accounting Policies*, contain additional information on enterprise-wide disclosures about product revenue, other revenue and long-lived assets, as well as our segment's revenue and profits, including significant segment expense and other segment items. 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, 2024					
(In millions)	U.S.	Europe <sup>(1)</sup>	Germany	Asia	Other	Total
Product revenue from external customers	\$ 3,237.3	\$ 2,171.5	\$ 955.6	\$ 366.9	\$ 482.2	\$ 7,213.5
Revenue from anti-CD20 therapeutic programs	1,673.6	0.6	—	—	75.7	1,749.9
Contract manufacturing, royalty and other revenue	395.0	0.4	—	257.2	—	652.6
Long-lived assets	1,366.1	2,139.2	13.3	8.5	10.6	3,537.7

	December 31, 2023					
(In millions)	U.S.	Europe <sup>(1)</sup>	Germany	Asia	Other	Total
Product revenue from external customers	\$ 3,141.4	\$ 2,127.4	\$ 868.0	\$ 649.4	\$ 460.5	\$ 7,246.7
Revenue from anti-CD20 therapeutic programs	1,618.5	0.4	—	—	70.7	1,689.6
Contract manufacturing, royalty and other revenue	673.6	11.7	—	214.0	—	899.3
Long-lived assets	1,443.0	2,248.0	17.5	8.3	12.9	3,729.7

	December 31, 2022					
(In millions)	U.S.	Europe <sup>(1)</sup>	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
Contract manufacturing, royalty and other revenue	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

<sup>(1)</sup> Represents amounts related to Europe less those attributable to Germany.

### Long-Lived Assets

As of December 31, 2024, 2023 and 2022, approximately \$2,056.2 million, \$2,156.4 million and \$2,198.5 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.



## BIOGEN INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Additional Segment Information

The following table includes additional information about reported segment revenue, significant segment expense and segment measure of profitability:

(In millions)	For the Years Ended December 31,		
	2024	2023	2022
Total revenue	\$ 9,675.9	\$ 9,835.6	\$ 10,173.4
Less cost and expense:			
Cost of sales, excluding amortization and impairment of acquired intangible assets:			
Product cost of sales	1,604.2	1,787.2	1,504.8
Royalty cost of sales	706.2	746.2	773.5
Research and development:			
Milestone and upfront expense	61.5	16.6	76.2
Research and discovery	201.5	212.5	289.4
Early stage programs	286.6	361.0	289.9
Late stage programs	209.7	250.5	484.5
Marketed products	534.7	766.1	361.5
Other research and development costs <sup>(1)</sup>	747.8	855.3	729.6
Selling, general and administrative	2,403.7	2,549.7	2,403.6
Other segment expense <sup>(2)</sup>	1,287.8	1,129.4	213.5
Net Income attributable to Biogen Inc.	\$ 1,632.2	\$ 1,161.1	\$ 3,046.9

<sup>(1)</sup> Other research and development costs primarily 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 and are not allocated to a specific program or stage.

<sup>(2)</sup> Other segment expense includes: amortization and impairment of acquired intangible assets; collaboration profit sharing/(loss reimbursement); (gain) loss on fair value remeasurement of contingent consideration; restructuring charges; gain on sale of priority review voucher, net; gain on sale of building, net; other (income) expense, net; income tax (benefit) expense; equity in (income) loss of investee, net of tax; and net income (loss) attributable to noncontrolling interests, net of tax.

#### Note 26: Subsequent Events

In February 2025 we entered into an arrangement with Royalty Pharma under which we will receive up to \$200.0 million in 2025 and up to \$50.0 million in 2026 to co-fund our development costs for the litifilimab program.

Following potential regulatory approval, Royalty Pharma will be eligible for regulatory milestones and royalties of a mid-single digits percentage of the applicable net sales.



## **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, 2024 and 2023, 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, 2024, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 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, 2024, 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 matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

#### *Reserves for Medicaid and Managed Care Rebates in the U.S.*

As described in Notes 1 and 5 to the consolidated financial statements, the Company recognized revenue from product sales, net of reserves, including contractual adjustments related to Medicaid and managed care rebates in the U.S. Within accrued expense and other, revenue-related reserves amounted to \$937.5 million as of December 31, 2024. A portion of this balance includes contractual adjustments for Medicaid and managed care rebates in the U.S. 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 in the U.S. 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 in the U.S. 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 estimates of the reserves for Medicaid and managed care in the U.S. 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 in the U.S. is a critical audit matter are (i) the significant judgment by management due to the significant measurement uncertainty when developing the estimate of the reserves and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to historical experience, current contractual requirements, specific known market events, and forecasted customer buying and payment patterns.

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 management's estimate of the reserves for Medicaid and managed care rebates in the U.S. These procedures also included, among others (i) developing an independent estimate of the reserves for Medicaid and managed care rebates in the U.S. 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 to evaluate the reasonableness of management's estimate; and (iii) testing, on a sample basis, rebate claims paid by the Company, including evaluating the claims for consistency with the contractual terms of the Company's rebate agreements.

*Acquisition of Human Immunology Biosciences, Inc. (HI-Bio) - Valuation of In-Process Research and Development Intangible Assets*

As described in Notes 1 and 2 to the consolidated financial statements, on July 2, 2024, the Company completed the acquisition of HI-Bio for total consideration of \$1,622.4 million. In-process research and development (IPR&D) intangible assets of \$1,635.0 million were recorded, which include \$920.0 million related to felzartamab indication for immunoglobulin A. nephropathy (IgAN), \$450.0 million related to felzartamab indication for antibody-mediated rejection (AMR), and \$265.0 million related to felzartamab indication for primary membranous nephropathy (PMN). Management uses the multi-period excess earnings method, which is a form of the income approach, utilizing post-tax cash flows and discount rates in estimating the fair value of identifiable intangible assets acquired when allocating the purchase consideration paid for the acquisition. The estimates of the fair value of identifiable intangible assets involve significant judgment by management and include assumptions with measurement uncertainty, such as the amount and timing of projected cash flow, long-term sales forecasts, discount rates, and the timing and probability of regulatory and commercial success.

The principal considerations for our determination that performing procedures relating to the valuation of IPR&D intangible assets acquired in the acquisition of HI-Bio is a critical audit matter are (i) the significant judgment by management due to the significant measurement uncertainty when developing the fair value estimate of the IPR&D intangible assets acquired; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to long-term sales forecasts, discount rate, and the probability of regulatory and commercial success for the IPR&D intangible assets acquired; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

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 acquisition accounting, including controls over management's valuation of the IPR&D intangible assets acquired. These procedures also included, among others (i) reading the purchase agreement; (ii) testing management's process for developing the fair value estimate of the IPR&D intangible assets acquired; (iii) evaluating the appropriateness of the multi-period excess earnings method used by management; (iv) testing the completeness and accuracy of certain of the data used in the multi-period excess earnings method; and (v) evaluating the reasonableness of the significant assumptions used by management related to long-term sales forecasts, discount rate, and the probability of regulatory and commercial success for the IPR&D intangible assets acquired. Evaluating management's assumptions related to long-term sales forecasts and the probability of regulatory and commercial success for the IPR&D intangible assets acquired involved evaluating whether the assumptions used by management were reasonable considering (i) the current and past performance of the acquired business and (ii) whether the assumptions were consistent with evidence obtained in other areas of the audit. Evaluating management's assumption related to long-term sales forecasts also involved considering the consistency with external market and industry data. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the appropriateness of the multi-period excess earnings method and (ii) the reasonableness of the discount rate significant assumption for the IPR&D intangible assets acquired.

/s/PricewaterhouseCoopers LLP

Boston, Massachusetts

February 12, 2025

We have served as the Company's auditor since 2003.