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, 2020

or

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

Commission file number: 0-19311

BIOGEN INC.

(Exact name of registrant as specified in its charter)

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

225 Binney Street, Cambridge, MA 02142
(617) 679-2000
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $42,102,640,463.

As of February 2, 2021, the registrant had 152,335,731 shares of common stock, $0.0005 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

BIOGEN INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2020
TABLE OF CONTENTS

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the anticipated amount, timing and accounting of revenues; 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 expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- patent terms, patent term extensions, patent office actions and expected availability and period of regulatory exclusivity;
- our plans and investments in our core and emerging growth areas as well as implementation of our corporate strategy;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of certain business development transactions;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals, of our products, drug candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- adverse safety events involving our marketed products, generic or biosimilar versions of our marketed products or any other products from the same class as one of our products;
- the direct and indirect impact of the COVID-19 pandemic on our business and operations, including sales, expenses, supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;
- the potential impact of healthcare reform in the United States (U.S.) and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities, activities in new or existing manufacturing facilities and the expected timeline for the Solothurn manufacturing facility to be partially operational;
- the impact of the continued uncertainty of the credit and economic conditions in certain countries in Europe and our collection of accounts receivable in such countries;
- the potential impact on our results of operations and liquidity of the United Kingdom's (U.K.) departure from the European Union (E.U.);
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations; and

- the impact of new laws, regulatory requirements, judicial decisions and accounting standards.

These forward-looking statements involve risks and uncertainties, including those that are described in *Item 1A. Risk Factors* included in this report and elsewhere in this report, that could cause actual results to differ materially from those reflected in such statements. You should not place undue reliance on these statements. Forward-looking statements speak only as of the date of this report. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

References in this report to:

- "Biogen," the "company," "we," "us" and "our" refer to Biogen Inc. and its consolidated subsidiaries; and
- "RITUXAN" refers to both RITUXAN (the trade name for rituximab in the U.S., Canada and Japan) and MabThera (the trade name for rituximab outside the U.S., Canada and Japan).

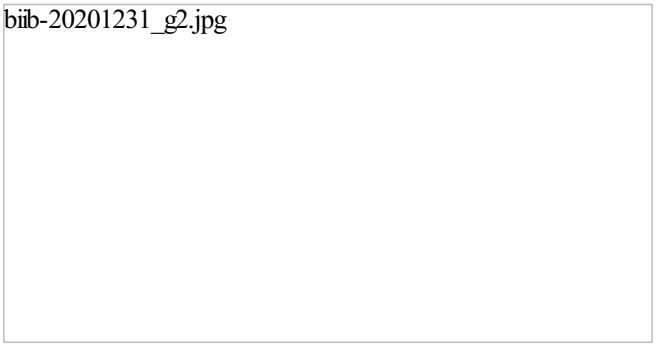
NOTE REGARDING TRADEMARKS

PART I

Item 1. Business

Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology; Alzheimer's disease and dementia; neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS); movement disorders, including Parkinson's disease; ophthalmology; and neuropsychiatry. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; acute neurology; and neuropathic pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.



Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS; SPINRAZA for the treatment of SMA; and FUMADERM for the treatment of severe plaque psoriasis. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions; RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL; GAZYVA for the treatment of CLL and follicular lymphoma; OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS); and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

For over two decades we have led in the research and development of new therapies to treat MS, resulting in our leading portfolio of MS treatments. Now our research is focused on developing next generation treatments for MS. We introduced the first approved treatment for SMA and are continuing to pursue research and development for potential advancements in the treatment of SMA. We are also applying our scientific expertise to solve some of the most challenging and complex diseases, including Alzheimer's disease, ALS, Parkinson's disease, choroideremia (CHM), major depressive disorder, postpartum depression, X-linked retinitis pigmentosa (XLRP), systemic lupus erythematosus (SLE), cutaneous lupus erythematosus (CLE), cognitive impairment associated with schizophrenia (CIAS), stroke and neuropathic pain.

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduces the cost burden for healthcare systems. Through our agreements with Samsung Bioepis Co., Ltd. (Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics), we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe and have an option to acquire exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, 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 2020.

For additional information on our acquisitions, collaborative and other relationships discussed below, please read *Note 2, Acquisitions*, *Note 18, Collaborative and Other Relationships,* and *Note 19, Investments in Variable Interest Entities,* to our consolidated financial statements included in this report.

Acquisitions, Collaborative and Other Relationships

BIIB118 Acquisition

In March 2020 we acquired BIIB118 (CK1 inhibitor), a novel CNS-penetrant small molecule inhibitor of casein kinase 1, for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). We are developing BIIB118 for the potential treatment of irregular sleep wake rhythm disorder (ISWRD) in Parkinson's disease and plan to develop BIIB118 for the potential treatment of sundowning in Alzheimer's disease.

Sangamo Therapeutics, Inc.

In April 2020 we closed a collaboration and license agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including, Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. The companies are leveraging Sangamo's proprietary zinc finger protein technology delivered via adeno-associated virus to modulate the expression of key genes involved in neurological diseases. In connection with the closing of this transaction, we purchased $225.0 million of Sangamo common stock, or approximately 24 million shares at approximately $9.21 per share.

Denali Therapeutics Inc.

In October 2020 we closed a collaboration and license agreement with Denali Therapeutics Inc. (Denali) to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle (ATV): ATV enabled anti-amyloid beta (Abeta) program and a second program utilizing its Transport Vehicle technology. Further, we have a right of first negotiation on two additional Transport Vehicle-enabled therapeutics, should Denali decide to seek a collaboration for such programs. As part of this collaboration we purchased approximately $465.0 million of Denali common stock in September 2020, or approximately 13 million shares at approximately $34.94 per share.

Sage Therapeutics, Inc.

In December 2020 we closed a global collaboration and license agreement with Sage Therapeutics, Inc. (Sage) to jointly develop and commercialize zuranolone (SAGE-217) for the potential treatment of major depressive disorder, postpartum depression and other psychiatric disorders and SAGE-324 for the potential treatment of essential tremor and other neurological disorders. In connection with the closing of this transaction we purchased $650.0 million of Sage common stock, or approximately 6.2 million shares at approximately $104.14 per share.

Other Key Developments

Aducanumab (Aβ mAb)

In July 2020 we completed the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the approval of aducanumab, an anti-amyloid beta antibody candidate for the potential treatment of Alzheimer's disease that we are developing in collaboration with Eisai Co., Ltd. (Eisai). In August 2020 the FDA accepted the BLA and granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date on March 7, 2021.

In November 2020 the FDA held a virtual meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (the Advisory Committee) to review data supporting the BLA for aducanumab and to vote on questions presented at the meeting. A majority of the Advisory Committee members voted against each of the questions presented at the meeting.

In January 2021 the FDA extended the review period for the BLA for aducanumab by three months. The updated PDUFA action date is June 7, 2021. As part of the ongoing review, we submitted a response to an information request by the FDA, including additional analyses and clinical data, which the FDA considered a Major Amendment to the application that will require additional time for review.

In October 2020 the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for aducanumab.

In December 2020 the Ministry of Health, Labor and Welfare accepted for review the Japanese New Drug Application for aducanumab.

SB11 (referencing LUCENTIS)

In October 2020 the EMA accepted for review the MAA for SB11 and in November 2020 the FDA accepted the BLA for SB11. We have exclusive rights to commercialize SB11 in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia, pursuant to our 2019 agreement with Samsung Bioepis.

2020 Share Repurchase Programs

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

Healthy Climate, Healthy Lives

In September 2020 we announced Healthy Climate, Healthy Lives, a $250.0 million, 20-year initiative to eliminate our fossil fuels across our operations and collaborate with renowned institutions with the aim to improve health, especially for the world's most vulnerable populations.

Management Changes

In July 2020 we announced the appointment of Michael R. McDonnell as Executive Vice President and Chief Financial Officer.

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

Core Growth Areas

Multiple Sclerosis and Neuroimmunology

TYSABRI (natalizumab)

- In March 2020 we made a regulatory submission to the EMA for a subcutaneous (SC) formulation of TYSABRI (natalizumab). In June 2020 we submitted a Supplemental Biologics License Application for a SC formulation of natalizumab to the FDA. The filings are supported by data from the DELIVER and REFINE studies, which demonstrated that natalizumab 300 mg SC every 4 weeks (Q4W) was comparable to standard 300 mg intravenous Q4W dosing with respect to clinical and magnetic resonance imaging (MRI) efficacy, pharmacokinetics/pharmacodynamics, immunogenicity and safety.
- In May 2020, through the 2020 American Academy of Neurology (AAN) Science Highlights virtual platform, an analysis of TYSABRI contributed to data demonstrating the reduced risk of progressive multifocal leukoencephalopathy (PML) through extended interval dosing (approximately every six weeks) as compared to the currently approved Q4W dosing.
- In September 2020, at MSVirtual2020, the eighth joint meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS), we presented new real-world MRI data suggesting that the effectiveness of extended interval dosing of TYSABRI is similar to the approved Q4W dosing.

VUMERITY (diroximel fumarate; DRF)

- In May 2020, through the 2020 AAN Science Highlights virtual platform, we announced new data that support VUMERITY as an important oral treatment option in RMS.
- In September 2020, at MSVirtual2020, the eighth joint meeting of ACTRIMS-ECTRIMS, we presented new data further defining the effectiveness and safety profile of VUMERITY.
- In November 2020 we submitted a MAA for VUMERITY to the EMA.

PLEGRIDY (peginterferon beta-1a)

- In December 2020 the European Commission (EC) approved a new intramuscular (IM) injection route of administration for PLEGRIDY for the treatment of relapsing-remitting MS (RRMS).
- In January 2021 the FDA approved a new IM injection route of administration for PLEGRIDY for the treatment of RRMS.

Alzheimer's Disease and Dementia

Aducanumab (Aβ mAb)

- In March 2020 the first patient was dosed in the aducanumab re-dosing study, EMBARK, which is a global re-dosing clinical study designed to evaluate aducanumab in eligible Alzheimer's disease patients who were actively enrolled in aducanumab studies (PRIME, EVOLVE, EMERGE and ENGAGE) in March 2019.
- In November 2020 we presented on the study design of the ongoing EMBARK re-dosing study of aducanumab at the 2020 Clinical Trials on Alzheimer's Disease digital conference.

BAN2401 (lecanemab)

- In September 2020 the first patient was dosed in the Phase 3 AHEAD 3-45 clinical study of BAN2401, an anti-amyloid beta antibody, in individuals with preclinical Alzheimer's disease who have intermediate or elevated levels of amyloid in their brains. We are collaborating with Eisai on the development of BAN2401.

Neuromuscular Disorders

SPINRAZA (nusinersen)

- In March 2020 the first patient was dosed in the global DEVOTE study, which is evaluating the safety, tolerability and potential for even greater efficacy of SPINRAZA when administered at a higher dose than currently approved for the treatment of SMA.
- In March 2020 a study on the efficacy and safety of SPINRAZA in teen and adult patients was published in *Lancet Neurology*, showing clinically meaningful improvements in motor function in a real-world cohort. This study included 139 teens and adults with later-onset SMA (age 16-65 years) from 10 neuromuscular treatment centers in Germany. Patients were followed for 6-14 months and experienced statistically significant increases in HFMSE (Hammersmith Functional Motor Scale Expanded) scores compared to baseline at 6 months, 10 months and 14 months. Clinically meaningful improvements (≥3 points increase) in HFMSE scores were seen in 28% of patients at 6 months, 35% of patients at 10 months and 40% of patients at 14 months. The most frequent adverse events were headache, back pain and nausea.
- In June 2020 we announced new results from NURTURE, the longest study of presymptomatic patients with SMA. In infants genetically diagnosed with SMA, new data demonstrated that early and sustained treatment with SPINRAZA for up to 4.8 years enabled unprecedented survival. Patients continued to maintain and make progressive gains in motor function compared to the natural course of the disease. These results were presented at the virtual Cure SMA Research & Clinical Care Meeting.
- In May 2020, through the 2020 AAN Science Highlights virtual platform, we announced additional data from the SPINRAZA clinical development program that further demonstrated the sustained efficacy and longer-term safety of SPINRAZA in a broad range of patients with SMA. The SHINE open-label extension study (NCT02594124) has enrolled 292 patients (infants through teenagers) from 5 previous SPINRAZA clinical studies, including ENDEAR. New findings from the SHINE study show that treatment with SPINRAZA resulted in motor function improvement or disease stabilization in toddlers, children and young adults who were treated continuously, some for up to six and a half years.

BIIB067 (tofersen) - ALS

- In July 2020 positive results from a Phase 1/2 study of tofersen for the potential treatment of superoxide dismutase 1 (SOD1) ALS were published in *The New England Journal of Medicine*. Final Phase 1/2 study results demonstrated proof-of-concept and proof-of-biology of tofersen.

BIIB105 (ataxin-2 ASO) - ALS

- In September 2020 the first patient in a Phase 1 study of BIIB105, an antisense oligonucleotide (ASO) targeting ataxin-2 in ALS, was dosed.

Movement Disorders

BIIB101 (ION464) - Multiple System Atrophy

- In July 2020 the first patient in the Phase 1 study of BIIB101, an ASO targeting alpha synuclein in multiple system atrophy, was dosed.

Emerging Growth Areas

Immunology

Dapirolizumab Pegol (anti-CD40L) - SLE

- In August 2020 the first patient was dosed in the Phase 3 program for dapirolizumab pegol in patients with active SLE despite being treated by standard of care therapies. Dapirolizumab pegol is being developed in collaboration with UCB Pharma S.A.

BIIB059 (anti-BDCA2) - CLE/SLE

- In June 2020 we shared positive data from the 16-week CLE portion of the Phase 2 LILAC study. The study evaluated the efficacy and safety of BIIB059, a fully humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) expressed on plasmacytoid dendritic cells (pDCs). The data were presented at the European E-Congress of Rheumatology (EULAR).
- In November 2020 we shared positive data from the 24-week SLE portion of the Phase 2 LILAC study (part A) demonstrating that BIIB059 was associated with a statistically significant reduction in total active joint count. These data, along with the previously reported findings from the CLE portion of the LILAC study, were presented at the American College of Rheumatology's virtual ACR Convergence 2020.

Biosimilars

Samsung Bioepis - Biogen's Joint Venture with Samsung BioLogics

- In May 2020 Samsung Bioepis announced that the primary endpoints were met in the randomized, double-masked, Phase 3 trial comparing the efficacy, safety and immunogenicity of SB11 to the reference product (LUCENTIS). Ranibizumab is an anti-VEGF (vascular endothelial growth factor) for retinal vascular disorders, which are a leading cause of blindness.
- In June 2020 Samsung Bioepis initiated a Phase 3 study for SB15, a proposed aflibercept biosimilar referencing EYLEA. EYLEA is widely used to treat ophthalmologic conditions such as neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema (DME) and diabetic retinopathy in patients with DME.

Discontinued Programs

- In March 2020 we announced that the Phase 2 OPUS study investigating natalizumab as an adjunctive therapy in adults with drug-resistant focal epilepsy did not meet its primary endpoint. Safety data were in-line with the known safety profile of natalizumab. Based on these results, we discontinued development of natalizumab in drug-resistant focal epilepsy.
- In October 2020 we announced that the Phase 2 AFFINITY study of opicinumab (anti-LINGO) in MS did not meet its primary or secondary endpoints. Based on these results, we discontinued development of opicinumab.
- In February 2021 we announced that the Phase 2 SPARK study of BIIB054 (cinpanemab) in Parkinson's disease did not meet its primary or secondary endpoints. Based on these results, we discontinued development of BIIB054.

Marketed Products

The following graph shows our revenues by product and revenues from anti-CD20 therapeutic programs for the years ended December 31, 2020, 2019 and 2018.

(1) Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
(2) Interferon includes AVONEX and PLEGRIDY.
(3) For 2020, 2019 and 2018 other includes FAMPYRA, FUMADERM, BENEPALI, IMRALDI and FLIXABI. For 2020 and 2019 other also includes VUMERITY, which became commercially available in the U.S. in November 2019. For 2018 other also includes ZINBRYTA, which was voluntary withdrawn from the market in March 2018.
(4) Anti-CD20 therapeutic programs include RITUXAN, RITUXAN HYCELA, GAZYVA and OCREVUS.

Product sales for TECFIDERA, AVONEX, TYSABRI and SPINRAZA each accounted for more than 10.0% of our total revenues for the years ended December 31, 2020, 2019 and 2018. For additional financial information about our product and other revenues and geographic areas where we operate, please read *Note 4, Revenues,* and *Note 24, Segment Information,* to our consolidated financial statements included in this report and *Item 6. Selected Financial Data* and *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this report. A discussion of the risks attendant to our operations is set forth in *Item 1A. Risk Factors* included in this report.

Multiple Sclerosis and Neuroimmunology

We develop, manufacture and market a number of products designed to treat patients with MS. MS is a progressive neurological 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
biib-20201231_g4.jpg	RMS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Japan Spain U.K.
biib-20201231_g5.jpg	RMS in the U.S.	Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes)	U.S.
	RMS	None	U.S. France Germany Italy Japan Spain
	RMS in the U.S. RRMS in the E.U.	None	U.S. France Germany Italy Spain U.K.
	RMS RRMS in the E.U. Crohn's disease in the U.S.	None	U.S. France Germany Italy Spain U.K.
	Walking ability for patients with MS	Acorda Therapeutics, Inc. (Acorda)	France Germany

Neuromuscular Disorders

SMA is characterized by loss of motor neurons in the spinal cord and lower brain stem, resulting in severe and progressive muscular atrophy and weakness. Ultimately, individuals with the most severe type of SMA can become paralyzed and have difficulty performing the basic functions of life, like breathing and swallowing. Due to a deletion or mutations in the SMN1 gene, people with SMA do not produce enough survival motor neuron (SMN) protein, which is critical to the survival of the neurons that control muscles. The severity of SMA correlates with the amount of SMN protein. People with Type 1 SMA, the most severe life-threatening form, produce very little SMN protein and do not achieve the ability to sit without support, and typically do not live beyond two years of age without respiratory support and nutritional interventions. People with Type 2 and Type 3 SMA produce greater amounts of SMN protein and have less severe, but still life-altering, forms of SMA.

Our SMA product and major markets are as follows:

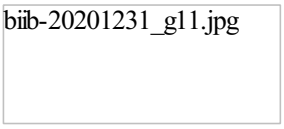
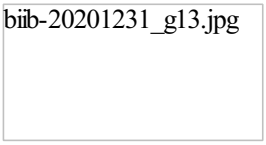
Product	Indication	Collaborator	Major Markets
	SMA	Ionis Pharmaceuticals Inc. (Ionis)	U.S. Brazil Canada France Germany Italy Japan Spain Turkey

For additional information on our collaboration arrangements with Ionis, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Biosimilars

Biosimilars are a group of biologic medicines that are similar to currently available biologic therapies developed by companies known as "originators". Under our agreements with Samsung Bioepis, we commercialize three anti-tumor necrosis factor (TNF) biosimilars in certain countries in Europe: BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE. We also have an option to acquire exclusive rights to commercialize BENEPALI, IMRALDI and FLIXABI in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia.

Our current biosimilar products and major markets are as follows:

Product	Indication	Major Markets
	Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Axial spondyloarthritis Plaque psoriasis Paediatric plaque psoriasis	France Germany Italy Spain 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	France Germany U.K.
	Rheumatoid arthritis Crohn's disease Paediatric Crohn's disease Ulcerative colitis Paediatric ulcerative colitis Ankylosing spondylitis Psoriatic arthritis Psoriasis	France Germany Italy

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, 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 and 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
biib-20201231_g15.jpg	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.
biib-20201231_g17.jpg	RMS PPMS	U.S. Australia Germany Switzerland

For additional information on our collaboration arrangements with Genentech, please read *Note 1, Summary of Significant Accounting Policies,* and *Note 18, 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 better lives. Among other things, we provide customer service and other related programs for our products, such as disease and product specific websites, insurance research services, financial assistance programs and the facilitation of the procurement of our marketed products.

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

We believe all healthcare stakeholders have a shared responsibility to ensure patients have equitable access to new, innovative medicines. We regularly review our pricing strategy and prioritize patient access to our therapies. We have a value-based contracting program designed to align the price of our therapies to the value our therapies deliver to patients. We also work with regulators, clinical

researchers, ethicists, physicians and patient advocacy organizations and communities, among others, to determine how best to address requests for access to our investigational therapies in a manner that is consistent with our patient-focused values and compliant with regulatory standards and protocols. In appropriate situations, patients may have access to investigational therapies through Early Access Programs, single patient access or emergency use based on humanitarian or compassionate grounds.

Marketing and Distribution

Sales Force and Marketing

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

We and Eisai co-promote AVONEX, TYSABRI and TECFIDERA in Japan in certain settings.

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

We commercialize BENEPALI, IMRALDI and FLIXABI pursuant to our agreement with Samsung Bioepis in certain countries in Europe.

We focus our sales and marketing efforts on specialist physicians in private practice or at major medical centers. We use customary industry practices to market our products and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, direct mail, public relations and other methods.

Distribution Arrangements

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

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

RITUXAN, RITUXAN HYCELA, GAZYVA and OCREVUS 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.

Our product sales to two wholesale distributors each accounted for more than 10.0% of our total revenues for the years ended December 31, 2020, 2019 and 2018, and on a combined basis, accounted for approximately 45.8%, 47.0% and 50.0% of our gross product revenues for the years ended December 31, 2020, 2019 and 2018, respectively. For additional information, please read *Note 4, Revenues*, to our consolidated financial statements included in this report.

Patents and Other Proprietary Rights

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

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

Regulatory exclusivity, which may consist of regulatory data protection and market protection, also can provide meaningful protection for our products. Regulatory data protection provides to the holder of a drug or biologic marketing authorization, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it created at

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

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

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

Our Patent Portfolio

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

Product	Territory	Patent No.	General Subject Matter	Patent Expiration[1]
TECFIDERA	U.S.	8,399,514	Methods of treatment	2028[2]
	Europe	1131065	Formulations of dialkyl fumarates and their use for treating autoimmune diseases	2024[3]
	Europe	2137537	Methods of use	2028[4]
PLEGRIDY	U.S.	7,446,173	Polymer conjugates of interferon beta-1a	2022
	U.S.	8,524,660	Methods of treatment	2023
	U.S.	8,017,733	Polymer conjugates of interferon beta-1a	2027
	Europe	1656952	Polymer conjugates of interferon-beta-1a and uses thereof	2024[5]
	Europe	1476181	Polymer conjugates of interferon-beta-1a and uses thereof	2023[6]
TYSABRI	U.S.	7,807,167	Methods of treatment	2023
	U.S.	9,493,567	Methods of treatment	2027
	Europe	1485127	Methods of use	2023[2]
	Europe	2676967	Methods of use	2027
FAMPYRA	Europe	1732548	Sustained-release aminopyridine compositions for increasing walking speed in patients with MS	2025[7]
	Europe	2377536	Sustained-release aminopyridine compositions for treating MS	2025[8]
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
SPINRAZA	U.S.	7,101,993	Oligonucleotides containing 2'-O-modified purines	2023
	U.S.	7,838,657	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2027
	U.S.	8,110,560	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2025
	U.S.	8,361,977	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	8,980,853	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	9,717,750	Compositions and methods for modulation of SMN2 splicing	2030
	U.S.	9,926,559	Compositions and methods for modulation of SMN2 splicing	2034
	U.S.	10,266,822	SMA treatment via targeting of SMN2 splice site inhibitory sequences	2025
	U.S.	10,436,802	Methods for Treating Spinal Muscular Atrophy	2035
	Europe	1910395	Compositions and methods for modulation of SMN2 splicing	2026[9]
	Europe	2548560	Compositions and methods for modulation of SMN2 splicing	2026[10]
	Europe	3305302	Compositions and methods for modulation of SMN2 splicing	2030
	Europe	3308788	Compositions and methods for modulation of SMN2 splicing	2026
	Europe	3449926	Compositions and methods for modulation of SMN2 splicing	2030

Footnotes follow on next page.

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

Product	Territory	Expected Expiration
TECFIDERA	E.U.	2024
PLEGRIDY	U.S.	2026
	E.U.	2024
FAMPYRA	E.U.	2021
SPINRAZA	U.S.	2023
	E.U.	2029

(2) For additional information as to the validity of this patent, please read *Note 20, Litigation*, to our consolidated financial statements included in this report.

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

(4) This patent was revoked in a European opposition. This decision is being appealed. This patent is subject to granted SPCs in certain European countries, which extended the patent term in those countries to 2029.

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

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

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

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

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

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

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 20, Litigation,* to our consolidated financial statements included in this report.

Competition

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

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

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

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

In addition, the commercialization of certain of our own approved products, products of our collaborators and pipeline product candidates may negatively impact future sales of our existing products.

We also face increased competitive pressures 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, which may significantly reduce both the price that we are able to charge for our products and the volume of products we sell. 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 revenues in a short period of time.

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

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

Multiple Sclerosis

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

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

In addition, multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020, and is expected to have a

substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

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

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

Spinal Muscular Atrophy

We face competition from a gene therapy product that was approved in the U.S. and the E.U. and a new oral product that was approved in the U.S. and has been accepted for review in the E.U. We expect that we will experience competition from both products in additional jurisdictions in the future. Additionally, we are aware of other products now in development that, if launched, may also compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products.

Psoriasis

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

Biosimilars

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

Genentech Relationships in Other Indications

RITUXAN, RITUXAN HYCELA and GAZYVA in Oncology

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

We also expect that over time RITUXAN HYCELA and GAZYVA will increasingly compete with RITUXAN in the oncology market. In addition, we are aware of several other anti-CD20 molecules, including biosimilar products, that have recently been approved and are expected to compete with RITUXAN, RITUXAN HYCELA and GAZYVA in the oncology market. In November 2019, January 2020 and January 2021 biosimilar products referencing RITUXAN were launched in the U.S and are being offered at lower prices. This competition has adversely affected the pre-tax profits of our collaboration arrangements with Genentech and could have a significant adverse affect our co-promotion profits in the U.S. in future years.

RITUXAN in Rheumatoid Arthritis

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

We are also aware of other products, including biosimilars, in development that, if approved, may compete with RITUXAN in the rheumatoid arthritis market.

Research and Development Programs

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

We intend to continue committing significant resources to targeted research and development opportunities where there is a significant unmet need and where a drug candidate has the potential to be highly differentiated. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and technologies and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

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

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

Core Growth Areas	MS and Neuroimmunology	BIIB061 (oral remyelination) - MS	Phase 1
		BIIB091 (BTK inhibitor) - MS	Phase 1
		BIIB107 (anti-VLA4) - MS	Phase 1
	Alzheimer's Disease and Dementia	Aducanumab (Aβ mAb)* - Alzheimer's	Filed in U.S., E.U. and Japan
		BAN2401 (lecanemab)* - Alzheimer's	Phase 3
		BIIB092 (gosuranemab) - Alzheimer's	Phase 2
		BIIB076 (anti-tau mAb) - Alzheimer's	Phase 1
		BIIB080 (tau ASO) - Alzheimer's	Phase 1
	Neuromuscular Disorders, including SMA and ALS	BIIB067 (tofersen) - ALS	Phase 3
		BIIB078 (IONIS-$C9_{Rx}$)# - ALS	Phase 1
		BIIB105 (ataxin-2 ASO)# - ALS	Phase 1
		BIIB100 (XP01 inhibitor) - ALS	Phase 1
		BIIB110 (ActRIIA/B ligand trap) - SMA	Phase 1
	Parkinson's Disease and Movement Disorders	BIIB124 (SAGE-324)* - Essential Tremor	Phase 2
		BIIB094 (ION859)# - Parkinson's	Phase 1
		BIIB118 (CK1 inhibitor) - ISWRD in Parkinson's	Phase 1
		BIIB101 (ION464)# - Multiple System Atrophy	Phase 1
		BIIB122 (DNL151)* - Parkinson's	Phase 1
	Ophthalmology	BIIB111 (timrepigene emparvovec) - CHM	Phase 3
		BIIB112 (RPGR gene therapy) - XLRP	Phase 2/3
	Neuropsychiatry	BIIB125 (zuranolone)* - PPD	Phase 3
		BIIB125 (zuranolone)* - MDD	Phase 3
		BIIB104 (AMPA PAM) - CIAS	Phase 2
Emerging Growth Areas	Immunology	Dapirolizumab pegol (anti-CD40L)* - SLE	Phase 3
		BIIB059 (anti-BDCA2) - CLE/SLE	Phase 2
	Acute Neurology	BIIB093 (glibenclamide IV) - LHI^ Stroke	Phase 3
		TMS-007# - Acute Ischemic Stroke	Phase 2
		BIIB093 (glibenclamide IV) - Brain Contusion	Phase 2
	Neuropathic Pain	BIIB074 (vixotrigine) - Trigeminal Neuralgia	Phase 2
		BIIB074 (vixotrigine) - Small Fiber Neuropathy	Phase 2
		BIIB095 (Nav 1.7) - Neuropathic Pain	Phase 1
	Biosimilars	SB11 (referencing LUCENTIS)*	Filed in U.S. and E.U.
		SB15 (referencing EYLEA)*	Phase 3

* Collaboration program
# Option agreement
^ Large Hemispheric Infarction (LHI); postpartum depression (PPD); major depressive disorder (MDD)

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 18, Collaborative and Other Relationships*, and *Note 19, 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 2, Acquisitions*, *Note 18, Collaborative and Other Relationships,* and *Note 19, Investments in Variable Interest Entities,* to our consolidated financial statements included in this report.

Acorda Therapeutics, Inc.

We have a collaboration and license agreement with Acorda to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S. We are responsible for all regulatory activities and the future clinical development of related products in those markets.

Alkermes

We have an exclusive license and collaboration agreement with Alkermes for VUMERITY, which was approved for the treatment of RMS in the U.S. in October 2019 and became commercially available in the U.S. in November 2019. Under this agreement, we have an exclusive, worldwide license to develop and commercialize VUMERITY.

Bristol-Myers Squibb Company

We have an exclusive license agreement with Bristol-Myers Squibb Company (BMS) for the development and potential commercialization of BIIB092 (gosuranemab), a Phase 2 investigational therapy in Alzheimer's disease. Under this agreement, we received worldwide rights to gosuranemab and are responsible for the full development and potential commercialization of gosuranemab in Alzheimer's disease.

Denali Therapeutics Inc.

We have a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of LRRK2 for Parkinson's disease. In the LRRK2 collaboration, we and Denali share responsibility and costs for global development 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 pay Denali tiered royalties.

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

Eisai Co., Ltd.

We have a collaboration agreement with Eisai to jointly develop and commercialize BAN2401, an Eisai product candidate for the potential treatment of Alzheimer's disease. Eisai serves as the global operational and regulatory lead for BAN2401 and all costs, including research, development, sales and marketing expenses, are shared equally between us and Eisai. If BAN2401 receives marketing approval, we and Eisai will co-promote BAN2401 and share profits equally.

We also have a collaboration agreement with Eisai to jointly develop and commercialize aducanumab (the Aducanumab Collaboration Agreement). Under the Aducanumab Collaboration Agreement, the two companies will co-promote aducanumab with a region-based profit split and we lead the ongoing development of aducanumab.

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

Genentech, Inc. (Roche Group)

We have collaboration arrangements with Genentech which entitle us to certain business and financial rights with respect to RITUXAN, RITUXAN HYCELA, GAZYVA, OCREVUS and other potential anti-CD20 therapies.

Ionis Pharmaceuticals, Inc.

We have an exclusive, worldwide option and collaboration agreement with Ionis relating to the development and commercialization of antisense therapeutics for up to three gene targets. Under a

separate collaboration and license agreement with Ionis, we have an exclusive, worldwide license to develop and commercialize SPINRAZA for the treatment of SMA. We also have a 10-year exclusive collaboration agreement with Ionis to develop novel ASO drug candidates for a broad range of neurological diseases.

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

Neurimmune SubOne AG

We have a collaboration and license agreement with Neurimmune SubOne AG (Neurimmune) for the development and commercialization of antibodies for the potential treatment of Alzheimer's disease, including aducanumab (as amended, the Neurimmune Agreement). We are responsible for the development, manufacturing and commercialization of all licensed products.

Samsung Bioepis Co., Ltd.

We and Samsung BioLogics established a joint venture, Samsung Bioepis, to develop, manufacture and market biosimilar products. We also have an agreement with Samsung Bioepis to commercialize, over a 10-year term, 3 anti-TNF biosimilar product candidates in certain countries in Europe and, in the case of BENEPALI, Japan. Under this agreement, we are commercializing BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe.

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. We also acquired an option to extend our existing commercial agreement with Samsung Bioepis for BENEPALI, IMRALDI and FLIXABI in certain countries in Europe and obtained an option to acquire exclusive rights to commercialize these products in China.

In addition to our joint venture and 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.

Sage Therapeutics, Inc.

We have a global collaboration and license agreement with Sage to jointly develop and commercialize zuranolone for the potential treatment of major depressive disorder, postpartum depression and other psychiatric disorders and SAGE-324 for the potential treatment of essential tremor and other neurological disorders. We and Sage share equal responsibility and costs for development as well as profits and losses for commercialization in the U.S. Outside the U.S., we are responsible for development and commercialization, excluding Japan, Taiwan and South Korea with respect to zuranolone, and will pay Sage tiered royalties.

Sangamo Therapeutics, Inc.

We have a collaboration and license agreement with Sangamo to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. The companies are leveraging Sangamo's proprietary zinc finger protein technology delivered via adeno-associated virus to modulate the expression of key genes involved in neurological diseases. Sangamo will perform early research activities, costs for which will be shared by the companies, and we will assume responsibility and costs beyond the early research activities.

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 New Drug Application (NDA). In response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval.

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

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

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

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

POST-MARKETING STUDIES

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

ADVERSE EVENT REPORTING

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

APPROVAL OF CHANGES TO AN APPROVED PRODUCT

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

REGULATION OF PRODUCT ADVERTISING AND PROMOTION

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

Regulation of Combination Products

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

In May 2017 new regulations governing medical devices (MDR) and in-vitro diagnostic medical devices (IVDR) entered into force in the E.U. although these are not expected to fully apply until May 2021 with respect to the MDR regulations and May 2022 with respect to the IVDR regulations. All products covered by these regulations will be required to comply with them at the end of the transitional periods. These regulations introduce new requirements, including for clinical investigation of certain classifications of medical devices, require increased regulatory scrutiny, enhance the requirements for post market surveillance and vigilance and provide for greater transparency. These regulations also change the requirements for assessment of the medical device components of integral drug-device combination products, necessitating assessment of the device components under both the medical device and medicinal product regulatory regimes.

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

We market our products in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, for example, where a substantial part of our ex-U.S. efforts are focused, there are several routes for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing authorization application is similar to the NDA or BLA in the U.S. and is evaluated by the Committee for Medicinal Products for Human Use (CHMP), the expert scientific committee of the EMA responsible for human medicines. If the CHMP determines that the marketing authorization application 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 E.U. member states:

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

As in the U.S., the E.U. also has distinct approaches intended to optimize the regulatory pathways for therapeutically important drugs, including the Priority Medicines Evaluation Scheme (PRIME), accelerated assessment and conditional marketing authorization. PRIME is intended to provide additional support to medicine developers throughout the development process. Regulatory review timelines in the E.U. may be truncated under accelerated assessment for products that address an unmet medical need. In addition, conditional marketing authorizations may be granted for such products in the interest of public health, where the benefit of immediate availability outweighs the risk of 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 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 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., E.U. and other jurisdictions, regulatory agencies, including the FDA, conduct periodic inspections of NDA, BLA and marketing authorization holders to assess their compliance with pharmacovigilance obligations.

Good Manufacturing Practices

Regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing and testing of pharmaceutical and biologic products prior to approving a product. If, after receiving approval from regulatory agencies, a

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

Good Clinical Practices

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

In April 2014 the EC adopted a new Clinical Trial Regulation, which was effective in June 2014 but is not expected to apply until 2021. 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

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

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

Orphan Drug Act

Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a “rare disease or condition,” which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. If a product which has an orphan drug designation subsequently receives an initial FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years following marketing approval, except in certain very limited circumstances, such as if the later product is shown to be clinically superior to the orphan product. Legislation similar to the U.S. Orphan Drug Act has been enacted in other countries to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases. In the E.U., medicinal products that receive and maintain an orphan designation are entitled to 10 years of market exclusivity following approval, protocol assistance and access to the centralized procedure for marketing

authorization. SPINRAZA has been granted orphan drug designation in the U.S., E.U. and Japan.

Regulation Pertaining to Pricing and Reimbursement

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

Within the U.S.

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

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

  In November 2020 CMS issued an interim final rule that seeks to lower prescription drug costs by paying no more for certain Medicare Part B drugs than the lowest price paid for such drugs in certain other countries (the "most favored nation" rule). One of the drugs subject to the rule is TYSABRI. Under the rule, the lower payment rates for affected drugs would be phased in over a period of four years, beginning in 2021. Although the rule is being challenged by industry associations on a number of grounds, if the challenges are unsuccessful, the rule could harm our business. In addition, if the rule were expanded to include other drugs or to include Medicare Part D, such expansions could cause additional harm.

  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% on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

- *Federal Agency Discounted Pricing*: Our products are subject to discounted pricing when

purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for our products to be covered and reimbursed by the Veterans Administration (VA), Department of Defense, Coast Guard and Public Health Service (PHS). Coverage under Medicaid, Medicare and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the VA, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties.

- *340B Discounted Pricing*: To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend significant discounts to certain covered entities that purchase products under Section 340B of the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive certain types of grants under the PHSA. For all of our products, we must agree to charge a price that will not exceed the amount determined under statute (the "ceiling price") when we sell outpatient drugs to these covered entities. In addition, we may, but are not required to, offer these covered entities a price lower than the 340B ceiling price. The 340B discount formula is based on AMP and is generally similar to the level of rebates calculated under the Medicaid Drug Rebate Program.

Outside the U.S.

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

Regulation Pertaining to Sales and Marketing

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

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include federal "sunshine" provisions. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to

teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

Other Regulations

Foreign Anti-Corruption

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

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

NIH Guidelines

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

Other Laws

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

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

Environmental Matters

We strive to comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our operations or competitive position.

Manufacturing

We seek to ensure an uninterrupted supply of medicines to patients around the world. To that end, we continually review our manufacturing capacity,

capabilities, processes and facilities. We believe that our manufacturing facilities, together with the third-party contract manufacturing organizations we outsource to, currently provide sufficient capacity for our products and to Samsung Bioepis, our joint venture that develops, manufactures and markets biosimilar products, and other strategic contract manufacturing partners. In order to support our future growth and drug development pipeline, we are expanding our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially operational during the first half of 2021.

Manufacturing Facilities

Our drug substance manufacturing facility includes:

Facility	Drug Substance Manufactured
RTP, NC	AVONEX PLEGRIDY TYSABRI Other*

* Other includes products manufactured for contract manufacturing partners.

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

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

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

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which we expect to be partially operational during the first half of 2021.

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

Third-Party Suppliers and Manufacturers

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

We source all of our fill-finish and the majority of final product assembly and storage operations for our products, along with a substantial part of our label and packaging operations, to a concentrated group of third-party contract manufacturing organizations. Raw materials, delivery devices, such as syringes and auto-injectors, and other supplies required for the production of our products and product candidates are procured from various third-party suppliers and manufacturers in quantities adequate to meet our needs. Continuity of supply of such raw materials, devices and supplies is assured using a strategy of dual sourcing where possible or by a risk-based inventory strategy. 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.

Human Capital

As of December 31, 2020, we had approximately 9,100 employees worldwide. Approximately 5,675 employees were employed in the U.S. and approximately 3,425 employees were employed in foreign countries.

Diversity, Equity and Inclusion

At Biogen, prejudice, racism and intolerance are unacceptable. We are committed to Diversity, Equity and Inclusion (DE&I) across all aspects of our organization, including hiring, promotion and development practices. As of December 31, 2020, 28% of Biogen's director-level and above positions were held by ethnic or racial minorities in the U.S. Our policies and practices are global, but the laws in many countries outside the U.S. do not permit us to collect ethnic or racial data on our employees. Globally, 48%

of Biogen's positions at director-level and above were held by women.

In 2020 we introduced an updated DE&I strategy that outlines actionable steps to deepen our commitment across the business, building upon a strong foundation. This plan includes a four-part strategy to build our talent and leadership pipeline, improve health outcomes for the African American, Black, Latinx and other minority communities in the disease areas we treat and expand sourcing with minority-owned businesses. We plan to create greater awareness and capability in our organization through leadership accountability and transparency. To establish and progress this strategy, we rely on a cross-company governing body of employees known as the Diversity, Equity & Inclusion Strategic Council.

We are honored to be recognized as a company of choice. We scored 100.0% on the 2020 Disability Equality Index, which measures our policies and practices related to disability inclusion, for the third consecutive year. Additionally, for the seventh consecutive year, we were recognized as a Best Place to Work for LGBTQ Equality by the Human Rights Campaign, scoring 100.0% on their Corporate Equality Index.

Philosophy on Pay Equity

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

We regularly review our compensation practices and analyze the equity of compensation decisions, for individual employees and our workforce as a whole. If we identify employees with pay gaps, we review and take appropriate action to ensure fidelity between our stated philosophy and actions.

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

Talent and Development

Our employees are encouraged to take advantage of an array of professional development resources. Managers coach employees for performance, and also engage in employee development discussions to support growth and learning.

We provide our employees access to over 8,000 on-demand learning modules in English, French, German, Spanish, Japanese and Portuguese. Additionally, we have a wide selection of courses and trainings that are offered through Biogen University, our global validated learning management system.

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

- Activate, Reflect and Co-Create: Preparing top talent for the rigors of executive roles.
- Women's Leadership Program: Addressing the unique challenges faced by female leaders to increase influence and impact.
- Executive Leadership Retreat: Immersing leaders in topics designed to help them shape culture and build resilience.
- The Partnership, Inc's BioDiversity Fellows Program: To continue to bolster our talent pipeline with a diverse mix of leaders, high potential, mid-career, underrepresented minorities participate in this program, which we helped create.

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

- IGNITE: Brings together early-career professionals and their advocates.
- AccessAbility: Supports employees with disabilities and employees who are caretakers of individuals with disabilities.
- Biogen Veterans Network: Encourages veterans and allies of veterans to connect and support one another.
- Mosaic: Fosters awareness and appreciation of different cultural backgrounds, in addition to promoting networking and development opportunities for members.
- ReachOUT: Supports a best-in-class working environment for LGBTQ employees and embraces all LGBTQ employees and their allies.

- Women's Innovation Network: Creates networking, mentoring and learning opportunities for women and allies worldwide.
- ourIMPACT: Advances climate, health and equity at work, in employees' personal lives and in the communities where we live and work.

Creating a culture where all colleagues feel supported and valued is paramount to our corporate mission. The ongoing COVID-19 pandemic has led to unique challenges, and we are striving to ensure the health, safety and general well-being of our employees. We continue to evolve our programs to meet our employees' health and wellness needs, which we believe is essential to attract and retain employees of the highest caliber. For example, we have refreshed our flexible working arrangement policies to allow for more flexibility around work hours to help employees balance the demands of their work and home lives, shifted many of our on-site wellness services to virtual, including virtual behavior health, nutrition, fitness and overall well-being classes and counseling, rolled out the Headspace meditation app globally at no cost, provided workshops and programming to help employees cope with stress, isolation and building resilience, along with financial planning workshops and counseling sessions, expanded our child- and back-up care services to meet the growing childcare needs of our employees and provided additional holidays and time off for recharging, voting and volunteering.

Employee surveys

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

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

Workplace Health and Safety

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

In 2020 we continued to make significant progress integrating Human Performance into our Environment, Health and Safety programs. We believe that, when it comes to safety, workers are part of the solution. We encourage employees to collaboratively engage in proactive problem solving through practices such as Open Reporting and Work Observation and Risk Conversations. We also utilize "After Action Reviews" following the completion of a project. These reviews enable us to not only focus on areas for improvement, but also to learn and apply good practices from what goes well. By engaging and empowering our employees through such programs, we believe that we can help change how the entire industry approaches safety performance and risk management.

Information about our Executive Officers (as of February 3, 2021)

Officer	Current Position	Age	Year Joined Biogen
Michel Vounatsos	Chief Executive Officer	59	2016
Susan H. Alexander	Executive Vice President, Chief Legal Officer and Secretary	64	2006
Michael R. McDonnell	Executive Vice President and Chief Financial Officer	57	2020
Alphonse Galdes, Ph.D.	Executive Vice President, Pharmaceutical Operations and Technology	68	1995
Ginger Gregory, Ph.D.	Executive Vice President and Chief Human Resources Officer	53	2017
Chirfi Guindo	Executive Vice President, Global Product Strategy and Commercialization	55	2017
Robin C. Kramer	Senior Vice President, Chief Accounting Officer	55	2018
Alfred W. Sandrock, Jr., M.D., Ph.D.	Executive Vice President, Research and Development	63	1998

Michel Vounatsos

Experience

Mr. Vounatsos has served as our Chief Executive Officer and as a member of our Board of Directors since January 2017. Prior to that, from April 2016 to December 2016, Mr. Vounatsos served as our Executive Vice President, Chief Commercial Officer. Prior to joining Biogen, Mr. Vounatsos spent 20 years at Merck & Co., Inc. (Merck), a pharmaceutical company, where he most recently served as President, Primary Care, Customer Business Line and Merck Customer Centricity. In this role, he led Merck's global primary care business unit, a role which encompassed Merck's cardiology-metabolic, general medicine, women's health and biosimilars groups and developed and instituted a strategic framework for enhancing the company's relationships with key constituents, including the most significant providers, payors and retailers and the world's largest governments. Mr. Vounatsos previously held leadership positions across Europe and in China for Merck. Prior to that, Mr. Vounatsos held management positions at Ciba-Geigy, a pharmaceutical company. Mr. Vounatsos currently serves on the advisory board of Tsinghua University School of Pharmaceutical Sciences, on the Supervisory Board of Liryc, the Electrophysiology and Heart Modeling Institute at the University of Bordeaux, on the board of directors of N-Lorem Foundation and as a member of the MIT Presidential CEO Advisory Board.

Public Company Boards

- PerkinElmer, Inc., a global scientific technology and life science research company

Education

- Universite Victor Segalen, Bordeaux II, France, C.S.C.T. Certificate in Medicine
- HEC School of Management - Paris, M.B.A.

Susan H. Alexander

Experience

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

Public Company Boards

- Invacare Corporation, a medical and healthcare product company

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 has a Bachelor of Science degree in accounting from Georgetown University and is a certified public accountant.

Education

- Georgetown University, B.S. Accounting

Alphonse Galdes, Ph.D.

Experience

Dr. Galdes has served as our Executive Vice President, Pharmaceutical Operations and Technology since September 2019. Since joining Biogen in 1995, Dr. Galdes has held several senior executive positions, including most recently as Senior Vice President, Asset Development and Portfolio Management from November 2015 to September 2019 and Senior Vice President, Technical Development from October 2010 to November 2015. Dr. Galdes was a Rhodes Scholar at Oxford University and performed post-doctoral research work at the Department of Biological Chemistry at Harvard Medical School.

Education

- University of Malta, B.Sc. Chemistry and Biology
- University of Malta, M.Sc. Biochemistry
- Oxford University, Ph.D. Biochemistry

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

Chirfi Guindo

Experience

Mr. Guindo has served as our Executive Vice President, Global Product Strategy and Commercialization since February 2019. Prior to that, Mr. Guindo served as our Executive Vice President and Head of Global Marketing, Market Access and Customer Innovation from November 2017 to February 2019. Prior to joining Biogen, Mr. Guindo spent 27 years in the global pharmaceutical industry and held several leadership positions at Merck, a pharmaceutical company, in Canada, the U.S., France, Africa and the Netherlands. He worked in several disciplines including Finance, Sales & Marketing, General Management and Global Strategy/Product Development in specialty, acute and hospital care. Most recently Mr. Guindo was Vice President and Managing Director and President and Managing Director of Merck Canada from October 2014 to November 2017. From January 2011 to October 2014 he was Vice President and General Manager, Global HIV Franchise at Merck.

Education

- Ecole Central de Paris (France), Engineering
- Stern School of Business, New York University, M.B.A. Finance/Economics

Robin C. Kramer

Experience

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

Public Company Boards

- Armata Pharmaceuticals, Inc., a biotechnology company

Education

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

Alfred W. Sandrock, Jr., M.D., Ph.D.

Experience

Dr. Sandrock has served as our Executive Vice President, Research and Development since September 2019. Prior to that, Dr. Sandrock served as our Chief Medical Officer from October 2017 to January 2020, as our Executive Vice President, Chief Medical Officer Neurology and Neurodegeneration from October 2015 to October 2017, as our Chief Medical Officer and Group Senior Vice President from April 2013 to October 2015 and as our Chief Medical Officer and Senior Vice President of Development Sciences from February 2012 to April 2013. Prior to that, Dr. Sandrock held several other senior executive positions since joining Biogen in 1998, including Senior Vice President of Neurology Research and Development and Vice President of Clinical Development, Neurology.

Education

- Stanford University, B.A. Human Biology
- Harvard Medical School, M.D.
- Harvard University, Ph.D. Neurobiology
- Massachusetts General Hospital, internship in Medicine, residency and chief residency in Neurology and clinical fellowship in Neuromuscular Disease and Clinical Neurophysiology (electromyography)

Available Information

Our principal executive offices are located at 225 Binney Street, Cambridge, MA 02142 and our telephone number is (617) 679-2000. Our website address is www.biogen.com. We make available free of charge through the *Investors* section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is

electronically filed with or furnished to the U.S. Securities and Exchange Commission. We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

Item 1A. Risk Factors

Risks Related to Our Business

We are substantially dependent on revenues from our products.

Our revenues depend 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 revenues are concentrated on sales of our products in increasingly competitive markets and in markets affected directly and indirectly by the COVID-19 pandemic. Any of the following negative developments relating to any of our products or any of our anti-CD20 therapeutic programs may adversely affect our revenues and results of operations or could cause a decline in our stock price:

- the introduction or greater acceptance of competing products, including new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways;
- safety or efficacy issues;
- limitations and additional pressures on product pricing or price increases, including those resulting from governmental or regulatory requirements; increased competition, including from generic or biosimilar versions of our products; or changes in, or implementation of, reimbursement policies and practices of payors and other third parties;
- adverse legal, administrative, regulatory or legislative developments;
- our ability to maintain a positive reputation among patients, healthcare providers and others, which may be impacted by our pricing and reimbursement decisions; or
- the inability or reluctance of patients to receive a diagnosis, prescription or administration of our products or a decision to prescribe and administer competitive therapies as a direct or indirect result of the COVID-19 pandemic.

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 and technologies from our research and development activities or our licenses or acquisitions from third parties, including our commercialization agreements with Samsung Bioepis, as well as additional indications for our existing products.

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

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

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

Sales of new products or products with additional indications may also 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 revenues. For instance, demand and price for TECFIDERA declined significantly as a result of multiple TECFIDERA generic entrants entering the U.S. market during the year ended December 31, 2020. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenues in a short period of time.

In the MS market, we face intense competition as the number of products and competitors continues to expand. Due to our significant reliance on sales of our MS products, our business could be harmed if we are unable to successfully compete in the MS market. More specifically, our ability to compete, maintain and grow our share in the MS market may be adversely affected due to a number of factors, including:

- the introduction of more efficacious, safer, less expensive or more convenient alternatives to our MS products, including our own products and products of our collaborators;
- the introduction of generic versions of branded MS products, including our own products, biosimilars, follow-on products, prodrugs or products approved under abbreviated regulatory pathways, which would be significantly less costly than our products to bring to market and would be offered for sale at lower prices, and could result in a significant percentage of the sales of our products being lost to such products;
- the off-label use by physicians of therapies indicated for other conditions to treat MS patients;
- patient dynamics, including the size of the patient population and our ability to attract and maintain new and current patients to our therapies;
- damage to physician and patient confidence in any of our MS products, generic or biosimilars of our MS 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 or adverse experiences or events that may occur with patients treated with our MS products or generic or biosimilars of our MS products;
- inability to obtain appropriate pricing and reimbursement for our MS products compared to our competitors in key international markets; or
- our ability to obtain and maintain patent, data or market exclusivity for our MS products.

In the SMA market, we face competition from a gene therapy product that was approved the U.S. and the E.U. and a new oral product that was approved in the U.S. and has been accepted for review in the E.U. We expect that we will experience competition from both products in additional jurisdictions in the future. Additionally, we are aware of other products now in development that, if launched, may compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products as well as the delay of SPINRAZA doses due, directly or indirectly, to the COVID-19 pandemic.

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

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

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

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

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

We may fail to initiate or complete transactions for many reasons and we may not be able to achieve the full strategic and financial benefits expected to result from transactions, or the benefits may be delayed or not occur at all. We may also face additional costs or liabilities in completed transactions that were not contemplated prior to completion.

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

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

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

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

- changes in, and implementation of, federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- pressure by employers on private health insurance plans to reduce costs;
- consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value; and
- our value-based contracting program pursuant to which we aim to tie the pricing of our products to their clinical values by either aligning price to patient outcomes or adjusting price for patients who discontinue therapy for any reason, including efficacy or tolerability concerns.

Our ability to set the price for our products varies significantly from country to country and, as a result, so can the price of our products. Certain countries set prices by reference to the prices in other countries where our products are marketed. Our inability to obtain and maintain adequate prices in a particular country may not only limit the revenues from our products within that country but may also adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. This may create the opportunity for third-party cross-border trade or influence our decision to sell or not to sell a product, thus adversely affecting our geographic expansion plans and revenues.

Drug prices are under significant scrutiny in the markets in which our products are prescribed. We expect drug pricing and other health care costs to continue to be subject to intense political and societal pressures on a global basis. Competition from current and future competitors may negatively impact our ability to maintain pricing and our market share. New products marketed by our competitors could cause our revenues 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, revenues and results of operations.

We depend on relationships with collaborators, joint venture partners and other third parties for revenues, and for the development, regulatory approval, commercialization and marketing of certain of our products and product candidates, which are outside of our full control.

We rely on a number of significant collaborative, joint venture and other third-party relationships for revenues and the development, regulatory approval, commercialization and marketing of certain of our products and product candidates. We also outsource certain aspects of our regulatory affairs and clinical development relating to our products and product candidates to third parties. Reliance on third parties subjects us to a number of risks, including:

- we may be unable to control the resources our collaborators, joint venture partners or third parties devote to our programs, products or product candidates;
- disputes may arise under an agreement, including with respect to the achievement and payment of milestones or ownership of rights to technology developed, and the underlying agreement may fail to provide us with significant protection or may fail to be effectively enforced if the collaborators, joint ventures partners or third parties fail to perform;
- the interests of our collaborators, joint venture partners or third parties may not always be aligned with our interests, and such parties may not pursue regulatory approvals or market a product in the same manner or to the same extent that we would, which could adversely affect our revenues, or may adopt tax strategies that could have an adverse effect on our business, results of operations or financial condition;
- third-party relationships require the parties to cooperate, and failure to do so effectively could adversely affect product sales or the clinical development or regulatory approvals of product candidates under joint control, could result in termination of the research, development or commercialization of product candidates or could result in litigation or arbitration;
- any failure on the part of our collaborators, joint venture partners or other 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 revenues as well as involve us in possible legal proceedings; and
- any improper conduct or actions on the part of our collaborators, joint venture partners or other third parties could subject us to civil or criminal investigations and monetary and injunctive penalties, impact the accuracy and timing of our financial reporting and/or adversely impact our ability to conduct business, our operating results and our reputation.

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

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

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our products are prescribed and purchased. For example, provisions of the PPACA have resulted in changes in the way health care is paid for by both governmental and private insurers, including increased rebates owed by manufacturers under the Medicaid Drug Rebate Program, annual fees and taxes on manufacturers of certain branded prescription drugs, the requirement that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D

and the expansion of the number of hospitals eligible for discounts under Section 340B of the PHSA. These changes have had and are expected to continue to have a significant impact on our business.

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

There is increasing public attention on the costs of prescription drugs and there have been, are expected to continue to be, legislative proposals to address prescription drug pricing. Some of these proposals could have significant effects on our business, including an executive order issued in September 2020 to test a "most favored nation" model for Part B and Part D drugs that tie reimbursement rates to international drug pricing metrics. These actions and the uncertainty about the future of the PPACA and healthcare laws may put downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs.

There is also significant economic pressure on state budgets, including as a result of the COVID-19 pandemic, that may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. In recent years, some states have considered legislation and ballot initiatives that would control the prices of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. and laws intended to impose price controls on state drug purchases. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Government efforts to reduce Medicaid expenses 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 revenues and may continue to adversely affect our revenues and results of operations in the future.

Our success in commercializing biosimilars developed by Samsung Bioepis is subject to risks and uncertainties inherent in the development, manufacture and commercialization of biosimilars. If Samsung Bioepis is unsuccessful in such activities, we may not realize the anticipated benefits of our investment in Samsung Bioepis.

Our success in commercializing biosimilars developed by Samsung Bioepis is subject to a number of risks, including:

- *Reliance on Third Parties.* We are dependent on the efforts of Samsung Bioepis and other third parties over whom we have limited or no control in the development and manufacturing of biosimilars products. If Samsung Bioepis or other third parties fail to perform successfully, we may not realize the anticipated benefits of our investment in Samsung Bioepis;
- *Regulatory Compliance.* Biosimilar products may face regulatory hurdles or delays due to the evolving and uncertain regulatory and commercial pathway of biosimilars products in certain jurisdictions;
- *Intellectual Property and Regulatory Challenges.* Biosimilar products may face extensive patent clearances, patent infringement litigation, injunctions or regulatory challenges, which could prevent the commercial launch of a product or delay it for many years or result in imposition of monetary damages, penalties or other civil sanctions and damage our reputation;
- *Failure to Gain Market and Patient Acceptance.* Market success of biosimilar products will be adversely affected if patients, physicians and/or payors do not accept biosimilar products as safe and efficacious products offering a more competitive price or other benefit over existing therapies;
- *Ability to Provide Adequate Supply.* Manufacturing biosimilars is complex. If we encounter any manufacturing or supply chain difficulties we may be unable to meet higher than anticipated demand. We are dependent on a third-party for the manufacture of 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;

- *Competitive Challenges.* Biosimilar products face significant competition, including from innovator products and biosimilar products offered by other companies. Local tendering processes may restrict biosimilar products from being marketed and sold in some jurisdictions. The number of competitors in a jurisdiction, the timing of approval and the ability to market biosimilar products successfully in a timely and cost-effective manner are additional factors that may impact our success and/or the success of Samsung Bioepis in this business area; and
- *Legal and Regulatory Requirements.* Any improper conduct or actions on the part of Samsung Bioepis or our joint venture partner, Samsung BioLogics, could damage our reputation and be distracting to management. The former chief executive officer (the incumbent chairman of the board) and the chief financial officer of our joint venture partner, Samsung BioLogics, are currently subject to ongoing criminal proceedings that may impact its operations and business or divert the attention of the Samsung Bioepis management team from its ongoing operations.

If Samsung Bioepis is unsuccessful in the development, manufacture and commercialization of biosimilar products, we may not realize the anticipated benefits of our investment in Samsung Bioepis.

In addition, as Samsung Bioepis is a privately-held entity, our ability to liquidate our investment in Samsung Bioepis may be limited and we may realize significantly less than the value of such investment.

Risks Related to Development, Clinical Testing and Regulation of Our Products and Product Candidates

Successful preclinical work or early stage clinical trials does not ensure success in later stage trials, regulatory approval or commercial viability of a product.

Positive results in a clinical trial may not be replicated in subsequent or confirmatory trials. Additionally, success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful or that regulatory approval will be obtained. Even if later stage clinical trials are successful, regulatory authorities may delay or decline approval of our product candidates. Regulatory authorities may disagree with our view of the data, require additional studies or disagree with our trial design or endpoints. Regulatory authorities may also fail to approve the facilities or processes used to manufacture a product candidate, our dosing or delivery methods or companion devices. Regulatory authorities may grant marketing approval that is more restricted than anticipated, including limiting indications to narrow patient populations and the imposition of safety monitoring, educational requirements and risk evaluation and mitigation strategies. The occurrence of any of these events could result in significant costs and expenses, 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 cGCP. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or denied.

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

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

Adverse safety events involving our marketed products, generic or biosimilar versions of our marketed products or products from the same class as one of our products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and

requirements for additional labeling or safety monitoring, withdrawal of products from the market and/or the imposition of fines or criminal penalties. Adverse safety events may also damage physician, patient and/or investor confidence in our products and our reputation. Any of these could result in adverse impacts on our results of operations.

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

Restrictions on use or significant safety warnings that may be required to be included in the label of our products, such as the risk of developing PML in the label for certain of our products, may significantly reduce expected revenues for those products and require significant expense and management time.

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

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

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

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and creates 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 any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Risks Related to Intellectual Property

If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our business may be harmed.

Our success, including our long-term viability and growth, depends, in part, on our ability to obtain and defend patent and other intellectual property rights, including certain regulatory forms of exclusivity, that are important to the commercialization of our products and product candidates. Patent protection and/or regulatory exclusivity in the U.S. and other important markets remains uncertain and depends, in part, upon decisions of the patent offices, courts, administrative bodies and lawmakers in these countries. We may fail to obtain or preserve patent and other intellectual property rights, including certain regulatory forms of exclusivity, or the protection we obtain may not be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business, which could result in financial, business or reputational harm to us or could cause a decline or volatility in our stock price. In addition, settlements of such proceedings often result in reducing the period of patent and other protections, resulting in a reduction in revenue from affected products.

In many markets, including the U.S., manufacturers may be allowed to rely on the safety and efficacy data of the innovator's product and do not need to conduct clinical trials before marketing a competing version of a product after there is no longer patent or regulatory exclusivity. In such cases, manufacturers often charge significantly lower prices and a major portion of the company's revenues may be reduced in a short period of time. In addition, manufacturers of generics and biosimilars may choose to launch or attempt to launch their products before the expiration of our patent or other intellectual property protections.

Furthermore, our products may be determined to infringe patents or other intellectual property rights held by third parties. Legal proceedings, administrative challenges or other types of proceedings are and may in the future be necessary to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Such proceedings are unpredictable and are often protracted and expensive. Negative outcomes of such proceedings could hinder or prevent us from manufacturing and marketing our products, could require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. A failure to obtain necessary licenses for an infringed product or technology could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits from the covered products and services. Any of these circumstances could result in financial, business or reputational harm to us or could cause a decline or volatility in our stock price.

Risks Related to Our Operations

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

Our business could be materially adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures and other measures. These measures may disrupt normal business operations both in and outside of affected areas and may have significant negative impacts on businesses and financial markets worldwide.

We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic, including limiting travel and working from home. We have also suspended the vast majority of our in-person interactions by our customer-facing professionals in healthcare settings. This limits our ability to market our products and educate physicians, which, in turn, could have an adverse effect on our ability to compete in the marketing and sales of our products.

Prolonged remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses, employee productivity and employee work culture. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks.

The COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to the COVID-19 pandemic, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. Furthermore, delays and disruptions experienced by our collaborators, joint venture partners or other third parties due to the COVID-19 pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect product sales or the clinical development or regulatory approvals of product candidates under joint control.

Our ability to continue our existing clinical trials or to initiate new clinical trials may be adversely affected, directly or indirectly, by the COVID-19 pandemic. For example, our Phase 3 study of BIIB093 for LHI has been delayed as this study involves administration of BIIB093 in an acute hospital setting. Restrictions on travel and/or transport of clinical materials as well as diversion of hospital staff and resources to COVID-19 infected patients could disrupt trial operations and recruitment, possibly resulting in a slowdown in enrollment and/or deviations from or disruptions in key clinical trial activities, such as clinical trial site monitoring. These challenges may lead to difficulties in meeting protocol-specified procedures. We may need to make certain adjustments to the operation of clinical trials in an effort to minimize risks to trial data integrity during the COVID-19 pandemic. In addition, the impact of the COVID-19 pandemic on the operations of the FDA and other health authorities may delay potential approvals of our product candidates.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law in the U.S. in March 2020 and is aimed at providing emergency assistance and health care for individuals, families and businesses and generally supporting the U.S. economy. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures. The COVID-19 pandemic may introduce temporary or permanent healthcare reform measures for which we cannot predict the financial implication of on our business.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business, operations, employees, customers, suppliers or collaboration partners, continued spread of COVID-19, measures taken by governments, actions taken to protect employees and the broad impact of the pandemic on all business activities may materially and adversely affect our business, results of operations and financial condition.

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

We are increasingly dependent upon technology systems and data to operate our business. Further, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that most of our office-based employees in the U.S. and our other key markets work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies, including Software as a Service (SaaS), Platform as a Service (PaaS) and Infrastructure as a Service (IaaS). A breakdown, invasion, corruption, destruction or breach of our technology systems, including our cloud technologies, and/or unauthorized access to our data and information could subject us to liability or negatively impact the operation of our business. Our technology systems, including our cloud technologies, continue to increase in multitude and complexity, making them potentially vulnerable to breakdown, malicious intrusion and random attack. Data privacy or security breaches also pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, customers or other business partners, may be exposed to unauthorized persons or to the public.

Cyber-attacks are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. They are often carried out by motivated, well-resourced, skilled and persistent actors, including nation states, organized crime groups, "hacktivists" and employees or contractors acting with malicious intent. Cyber-attacks could include the deployment of harmful malware and key loggers, ransomware, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our technology systems and data. Cyber-attacks could also include supply chain attacks, which could cause a delay in the manufacturing of our products or products produced for contract manufacturing. 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 could heighten these and other operational risks, and any failure by cloud technology service providers to adequately safeguard their systems and prevent cyber-attacks could disrupt our operations and result in misappropriation, corruption or loss of confidential or propriety information.

While we continue to build and improve our systems and infrastructure, including our business continuity plans, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, operational or reputational harm to us, loss of competitive advantage or loss of consumer confidence. Our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

Regulators are imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the E.U.'s GDPR established regulations regarding the handling of personal data, and provides an enforcement authority and imposes large penalties for noncompliance. New U.S. data privacy and security laws, such as the California Consumer Privacy Act (CCPA), and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with the CCPA may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Failure to comply with these current and future laws, policies, industry standards or legal obligations or any security incident resulting in the unauthorized access to, or acquisition, release or transfer of personal information may result in governmental enforcement actions, litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have a material adverse effect on our business and results of operations.

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

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

Our success is dependent upon our ability to attract and retain qualified management and key personnel in a highly competitive environment. Qualified individuals are in high demand, and we may incur significant costs to attract them, particularly at the executive level. We may face difficulty in attracting and retaining key talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more late stage programs or recruitment by competitors. 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. The FDA and comparable foreign agencies directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting, product risk management and our compliance with good practice quality guidelines and regulations. Our interactions with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of products and place significant restrictions on the marketing practices of health care companies. Health care companies are facing heightened scrutiny of their relationships with health care providers and have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. There is also enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. The U.S. government has challenged some of our donations to third-party charities that provide patient assistance. If we, or our vendors or donation recipients, are found to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to significant fines or penalties. Risks relating to compliance with laws and regulations may be heightened as we continue to expand our global operations and enter new therapeutic areas with different patient populations, which may have different product distribution methods, marketing programs or patient assistance programs from those we currently utilize or support.

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

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

Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. We could also be required to repay amounts we received from government payors or pay additional rebates and interest if we are found to have miscalculated the pricing

information we submitted to the government. We cannot ensure that our compliance controls, policies and procedures will protect us from acts committed by our employees, collaborators or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, 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 revenues. There is no guarantee that our efforts and strategies to expand sales in international markets will succeed. Emerging market countries may be especially vulnerable to periods of global and local political, legal, regulatory and financial instability and may have a higher incidence of corruption and fraudulent business practices. Certain countries may require local clinical trial data as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements previously utilized by companies we collaborate with or acquire in emerging markets.

Our sales and operations are subject to the risks of doing business internationally, including:

- the impact of public health epidemics, such as the COVID-19 pandemic, on the global economy and the delivery of healthcare treatments;
- less favorable intellectual property or other applicable laws;
- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- limitations and additional pressures on our ability to obtain and maintain product pricing or receive price increases, including those resulting from governmental or regulatory requirements;
- 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 revenues, net income and value of certain of our investments;
- the imposition of governmental controls;
- diverse data privacy and protection requirements;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the Bribery Act, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- the effects of the U.K.'s departure from the E.U., known as Brexit;
- 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 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.

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

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

We expect the Solothurn facility to be partially operational during the first half of 2021; however, there can be no assurance that we will be able to meet our expected timeline or that there will not be any direct or indirect delays resulting from the COVID-19 pandemic. We have had delays, and if there are additional delays, in bringing the Solothurn facility online, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.

If we are unable to adequately and timely manufacture and supply our products and product candidates or if we do not fully utilize our manufacturing facilities, our business may be harmed. Charges resulting from excess capacity would have a negative effect on our financial condition and results of operations.

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

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

- *Risks of Reliance on Third Parties and Single Source Providers.* We rely on third-party suppliers and manufacturers for many aspects of our manufacturing process for our products and product candidates. In some cases, due to the unique manner in which our products are manufactured, we rely on single source providers of raw materials and manufacturing supplies. These third parties are independent entities subject to their own unique operational and financial risks that are outside of our control, including the impact of the COVID-19 pandemic. 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.
- *Risks Relating to Compliance with cGMP.* We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and other regulatory authorities to confirm compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or operations or those of third parties to 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.
- *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 shortages, public health epidemics, natural disasters, power failures, cyber-attacks and many other factors. In addition, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which we expect to be partially operational during the first half of 2021. However, there can be no assurance that we will be able to meet our expected timeline or that there will not be any direct or indirect delays resulting from the COVID-19 pandemic. We have had delays, and if there are additional delays, in bringing the Solothurn facility online, we may not have sufficient large-scale manufacturing capacity to meet our long-term manufacturing requirements.
- *Risk of Product Loss.* The manufacturing process for our products is extremely susceptible to product loss due to contamination, oxidation, equipment failure or improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remediate the contaminant.
- *Risk Relating to Government Actions*. We and/or our third-party providers may be required by the U.S. federal government to manufacture medical supplies needed to treat COVID-19 patients under the Defense

Production Act or other acts or orders of government entities, which may result in delays in the manufacturing and supply of our products.

Any adverse developments affecting our manufacturing operations or the operations of our third-party suppliers and manufacturers may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We may also have to take inventory write-offs and incur other charges and expenses 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 revenues 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.

Our effective tax rate fluctuates, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

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

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

The Tax Cuts and Jobs Act of 2017 (2017 Tax Act) resulted in significant changes to the U.S. corporate income tax system. Our estimates concerning the impact of the 2017 Tax Act on our accounting and on our business remain subject to developing interpretations of the provisions of the 2017 Tax Act, which may require further adjustments and changes in our estimates, which could have a material adverse effect on our business, results of operations or financial condition. Further, the new administration could introduce new tax laws or revise or issue new interpretations of the 2017 Tax Act.

The Swiss Federal Act on Tax Reform and AHV Financing (TRAF) resulted in significant changes to the Swiss cantonal income tax system. Final interpretation of the transitional and new regimes of the TRAF may require further adjustments and changes in our estimates, which could have a significant adverse effect on our business, results of operations or financial condition.

The enactment of some or all of the recommendations set forth or that may be forthcoming in the Organization for Economic Cooperation and Development's project on "Base Erosion and Profit Shifting" (BEPS) by tax authorities and economic blocs in the countries in which we operate, could unfavorably impact our effective tax rate. These initiatives focus on common international principles for the entitlement to taxation of global corporate profits and minimum global tax rates.

Risks Related to Holding Our Common Stock

Our operating results are subject to significant fluctuations.

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

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

Our revenues 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 expenses, lease termination fees, rent expense in excess of sublease income and impairment of leasehold improvements and accelerated depreciation of assets. Any of these events may have an adverse impact on our results of operations.

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

We maintain a portfolio of marketable securities for investment of our cash as well as investments in equity securities of certain biotechnology companies. Changes in the value of our investment portfolio could adversely affect our earnings. The value of our investments may decline due to, among other things, increases in interest rates, downgrades of the bonds and other securities in our portfolio, instability in the global financial markets that reduces the liquidity of securities in our portfolio, declines in the value of collateral underlying the securities in our portfolio and other factors. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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

From time to time our Board of Directors authorizes share repurchase programs. The amount and timing of share repurchases are subject to capital availability and our determination that share repurchases are in the best interest of our shareholders and are in compliance with all respective laws and our applicable agreements. Our ability to repurchase shares will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, our results of operations, our financial condition and other factors beyond our control that we may deem relevant. A reduction in repurchases under, or the completion of, our share repurchase programs could have a negative effect on our stock price. We can provide no assurance that we will repurchase shares at favorable prices, if at all.

We may not be able to access the capital and credit markets on terms that are favorable to us.

We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets are experiencing, and have in the past experienced, extreme volatility and disruption, which leads to uncertainty and liquidity issues for both borrowers and investors. In the event of adverse market conditions, we may be unable to obtain capital or credit market financing on favorable terms. Changes in credit

ratings issued by nationally recognized credit rating agencies could also adversely affect our cost of financing and the market price of our securities.

Our indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

Our indebtedness, together with our significant contingent liabilities, including milestone and royalty payment obligations, could have important consequences to our business; for example, such obligations could:

- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to access capital markets and incur additional debt in the future;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development, research and development and mergers and acquisitions; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that have less debt.

Some of our collaboration agreements contain change in control provisions that may discourage a third party from attempting to acquire us.

Some of our collaboration agreements include change in control provisions that could reduce the potential acquisition price an acquirer is willing to pay or discourage a takeover attempt that could be viewed as beneficial to shareholders. Upon a change in control, some of these provisions could trigger reduced milestone, profit or royalty payments to us or give our collaboration partner rights to terminate our collaboration agreement, acquire operational control or force the purchase or sale of the programs that are the subject of the collaboration.

General Risk Factors

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Below is a summary of our owned and leased properties as of December 31, 2020.

Massachusetts

In Cambridge, MA we own approximately 508,000 square feet of real estate space, consisting of a building that houses a research laboratory and a cogeneration plant totaling approximately 263,000 square feet and a building that contains research, development and quality laboratories totaling approximately 245,000 square feet.

In addition, we lease a total of approximately 1,169,000 square feet in Massachusetts, which is summarized as follows:

- 800,000 square feet in Cambridge, MA, which is comprised of offices for our corporate headquarters and other administrative and development functions and laboratories, of which 265,000 square feet is subleased by multiple companies for general office space, laboratories and manufacturing facilities;

- 357,000 square feet of office space in Weston, MA, of which 174,000 square feet is subleased through the remaining term of our lease agreement; and
- 12,000 square feet of office space in Waltham, MA.

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

North Carolina

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

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

In addition, we lease approximately 65,000 square feet of warehouse space and 103,000 square feet of office space in Durham, NC. Our North Carolina lease agreements expire at various dates through the year 2031.

Switzerland

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially operational during the first half of 2021. Upon completion, the facility will include 393,000 square feet related to a large-scale biologics manufacturing facility, 290,000 square feet of warehouse, utilities and support space and 51,000 square feet of administrative space.

Other International

We lease office space in Baar, Switzerland, our international headquarters; the U.K.; Germany; France; Japan; Canada and numerous other countries. Our international lease agreements expire at various dates through the year 2030.

Item 3. Legal Proceedings

For a discussion of legal matters as of December 31, 2020, please read *Note 20, Litigation,* to our consolidated financial statements included in this report, which is incorporated into this item by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market and Stockholder Information

Our common stock trades on The Nasdaq Global Select Market under the symbol "BIIB." As of February 2, 2021, there were approximately 505 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 2020:

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 2020	—	$ —	—	$ 5,000.0
November 2020	—	$ —	—	$ 5,000.0
December 2020	1,620,969	$ 246.77	—	$ 4,600.0
Total	1,620,969	$ 246.77		

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million shares of our common stock at a cost of approximately $400.0 million during the year ended December 31, 2020.

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

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program), which was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million and 14.7 million shares of our common stock at a cost of approximately $1.3 billion and $3.7 billion during the years ended December 31, 2020 and 2019, respectively.

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program), which was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million and 4.3 million shares of our common stock at a cost of approximately $2.1 billion and $1.4 billion during the years ended December 31, 2019 and 2018, respectively.

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired approximately 10.5 million shares of common stock at a cost of approximately $3.0 billion during the year ended December 31, 2018.

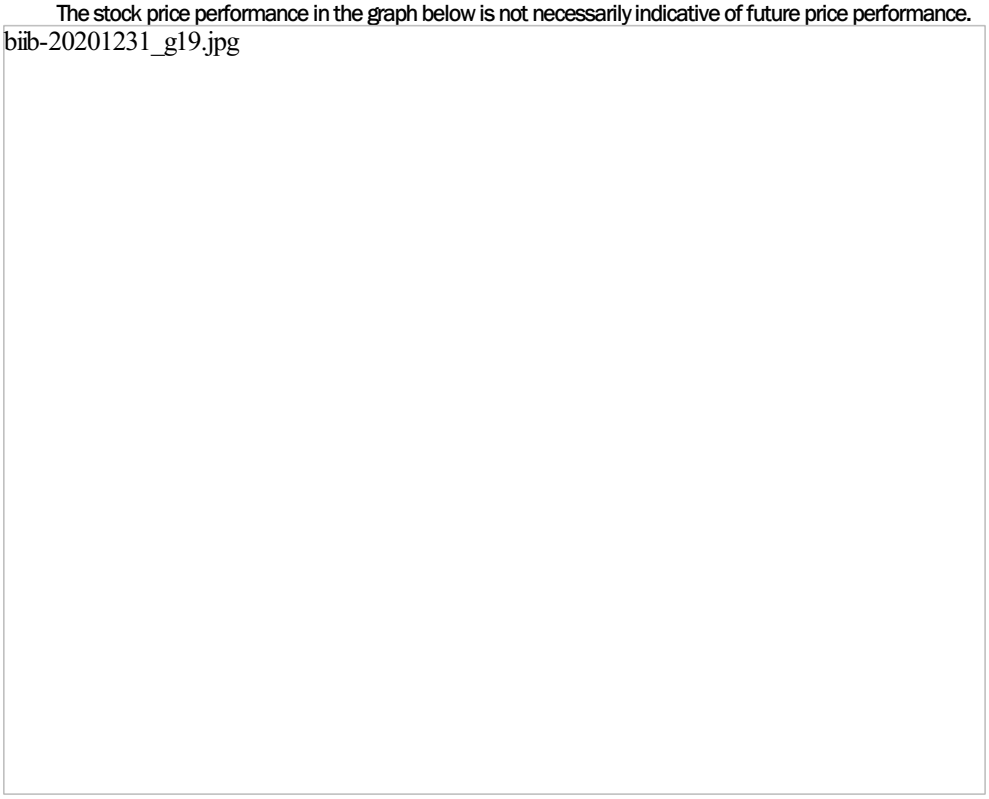
Performance Graph

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.

On February 1, 2017, we completed the spin-off of our hemophilia business, Bioverativ Inc. (Bioverativ), as an independent, publicly traded company. In connection with the spin-off, each Biogen shareholder received one share of Bioverativ common stock for every two shares of Biogen common stock they owned. For additional information on the spin-off of our hemophilia business, please read *Note 3, Hemophilia Spin-Off*, to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018.

The performance graph below assumes the investment of $100.00 on December 31, 2015, in our common stock and each of the three indexes, with dividends being reinvested. Our stock prices have been adjusted for the effect of the spin-off of our hemophilia business. The five-year cumulative total stockholder return for Biogen does not reflect the reinvestment by Biogen shareholders of the distribution they received in connection with the spin-off of our hemophilia business or any subsequent increase or decrease in value of Bioverativ stock subsequent to the spin-off.

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



	2015	2016	2017	2018	2019	2020
Biogen Inc.	$100.00	$92.57	$112.74	$106.49	$105.01	$86.65
Nasdaq Pharmaceutical Index	$100.00	$98.91	$117.83	$127.20	$145.65	$160.97
S&P 500 Index	$100.00	$111.96	$136.40	$130.42	$171.49	$203.04
Nasdaq Biotechnology Index	$100.00	$78.65	$95.69	$87.21	$109.11	$137.94

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. Selected Financial Data

BIOGEN INC. AND SUBSIDIARIES
SELECTED FINANCIAL DATA

Our results of operations are summarized as follows:

	For the Years Ended December 31,				
(In millions, except per share amounts)	**2020**	**2019**	**2018**	**2017**	**2016**
Results of Operations					
Product revenues, net	$ 10,692.2	$ 11,379.8	$ 10,886.8	$ 10,354.7	$ 9,817.9
Revenues from anti-CD20 therapeutic programs	1,977.8	2,290.4	1,980.2	1,559.2	1,314.5
Other revenues	774.6	707.7	585.9	360.0	316.4
Total revenues	13,444.6	14,377.9	13,452.9	12,273.9	11,448.8
Total cost and expenses	8,894.5	7,335.3	7,564.3	6,928.1	6,297.1
Income from operations	4,550.1	7,042.6	5,888.6	5,345.8	5,151.7
Other income (expense), net	497.4	83.3	11.0	(217.0)	(218.7)
Income before income tax expense and equity in loss of investee, net of tax	5,047.5	7,125.9	5,899.6	5,128.8	4,933.0
Income tax expense	992.3	1,158.0	1,425.6	2,458.7	1,237.3
Equity in loss of investee, net of tax	(5.3)	79.4	—	—	—
Net income	4,060.5	5,888.5	4,474.0	2,670.1	3,695.7
Net income (loss) attributable to noncontrolling interests, net of tax	59.9	—	43.3	131.0	(7.1)
Net income attributable to Biogen Inc.	$ 4,000.6	$ 5,888.5	$ 4,430.7	$ 2,539.1	$ 3,702.8
Diluted Earnings Per Share					
Diluted earnings per share attributable to Biogen Inc.	$ 24.80	$ 31.42	$ 21.58	$ 11.92	$ 16.93
Weighted-average shares used in calculating diluted earnings per share attributable to Biogen Inc.	161.3	187.4	205.3	213.0	218.8

Our financial condition is summarized as follows:

	As of December 31,				
(In millions)	**2020**	**2019**	**2018**	**2017**	**2016**
Financial Condition					
Cash, cash equivalents and marketable securities	$ 3,382.2	$ 5,884.0	$ 4,913.9	$ 6,746.3	$ 7,724.5
Total assets	$ 24,618.9	$ 27,234.3	$ 25,288.9	$ 23,652.6	$ 22,876.8
Notes payable, less current portion	$ 7,426.2	$ 4,459.0	$ 5,936.5	$ 5,935.0	$ 6,512.7
Total Biogen Inc. shareholders' equity	$ 10,700.3	$ 13,343.2	$ 13,039.6	$ 12,612.8	$ 12,140.1

The financial data included within the tables above should be read in conjunction with our consolidated financial statements and related notes and *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this report and our previously filed Annual Reports on Form 10-K.

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, 2019, compared to the year ended December 31, 2018, 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, 2019.

Executive Summary

Introduction

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include MS and neuroimmunology; Alzheimer's disease and dementia; neuromuscular disorders, including SMA and ALS; movement disorders, including Parkinson's disease; ophthalmology; and neuropsychiatry. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; acute neurology; and neuropathic pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS; SPINRAZA for the treatment of SMA; and FUMADERM for the treatment of severe plaque psoriasis. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, 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; and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech. For additional information on our collaboration arrangements with Genentech, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduces the cost burden for healthcare systems. Through our agreements with Samsung Bioepis, our joint venture with Samsung BioLogics, we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe and have an option to acquire exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

We seek to ensure an uninterrupted supply of medicines to our patients around the world. To that end, we continually review our manufacturing capacity, capabilities, processes and facilities. In order to support our future growth and drug development pipeline, we are expanding our large molecule production capacity by building a large-scale biologics manufacturing facility in Solothurn, Switzerland, which we expect to be partially operational during the first half of 2021. We believe that the Solothurn manufacturing facility will provide us with the ability to further expand if our future growth and drug development plans increase.

Our revenues depend upon continued sales of our products as well as the financial rights we have in our anti-CD20 therapeutic programs, and, unless we develop, acquire rights to and/or commercialize new products and technologies, we will be substantially dependent on sales from our products and our financial rights in our anti-CD20 therapeutic programs for many years.

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

Business Environment

For a detailed discussion on our business environment, please read *Item 1. Business* included in this report. For additional information on our competition and pricing risks that could negatively impact our product sales, please read *Item 1A. Risk Factors* and *Item 7A. Quantitative and Qualitative Disclosures About Market Risk* included in this report.

TECFIDERA

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Hatch-Waxman Act in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 20, Litigation,* to our consolidated financial statements included in this report.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020, and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition. For additional information, please read the discussion under *Results of Operations - Product Revenues - Multiple Sclerosis (MS) - Fumarate* below.

Business Update Regarding COVID-19

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

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

While we are currently continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have impacted the timeline for some of our clinical trials and these precautions may, directly or indirectly, have a further impact on timing in the future. For example, our Phase 3 study of BIIB093 for LHI, a severe form of ischemic stroke, has been delayed as this study involves administration of BIIB093 in an acute hospital setting. To help mitigate the impact of the COVID-19 pandemic to our clinical trials, we are pursuing innovative approaches such as remote monitoring, remote patient visits and supporting home infusions. These alternative measures have resulted in an immaterial increase to the cost of the clinical trials underway.

For additional information on the various risks posed by the COVID-19 pandemic, please read *Item 7A. Quantitative and Qualitative Disclosures About Market Risk* and *Item 1A. Risk Factors* included in this report.

Brexit

Effective January 31, 2020, the U.K. ceased to be a member state of the E.U., a process known as Brexit, and began a transition period, which expired on December 31, 2020.

In December 2020 the U.K. and the E.U. agreed on a trade and cooperation agreement, under which the E.U. and the U.K. will now form two separate markets governed by two distinct regulatory and legal regimes. The trade and cooperation agreement covers the general objectives and framework of the relationship between the U.K. and the E.U., including as it relates to trade, transport and visas. Notably, under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire E.U. single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the E.U. Depending on the application of the terms of the trade and cooperation agreement, we could face new regulatory costs and challenges.

We do not expect Brexit to have a material impact on our consolidated results of operations as less than 4.0% of our total product revenues in 2020, 2019 and 2018 were derived from U.K. sales. However, we cannot predict the direction Brexit-related developments will take nor the impact of those developments on our European operations and the economies of the markets where we operate. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate, including U.K. competition laws. Therefore, we will continue to monitor for developments in this area and assess any potential impacts on our business and results of operations.

Financial Highlights

Diluted earnings per share attributable to Biogen Inc. were $24.80 for 2020, representing a decrease of 21.1% as compared to $31.42 in the same period in 2019.

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, 2020, compared to the year ended December 31, 2019, reflects the following:

Revenues

- Total revenues were $13,444.6 million for 2020, representing a decrease of 6.5% as compared to $14,377.9 million in 2019.
- Product revenues, net totaled $10,692.2 million for 2020, representing a decrease of 6.0% as compared to $11,379.8 million in 2019. This decrease was primarily due to a $697.2 million, or 8.2%, decrease in MS product revenues and a $44.9 million, or 2.1%, decrease in revenues from SPINRAZA, partially offset by a $57.5 million, or 7.8%, increase in revenues from our biosimilar business. Product revenues, net, compared to the same period in 2019, further reflects the unfavorable impact of foreign currency exchange of $111.6 million.
    - The decrease in MS product revenues was primarily due to a decrease in TECFIDERA demand and price as a result of multiple TECFIDERA generic entrants entering the U.S. market during the year ended December 31, 2020.
- Revenues from anti-CD20 therapeutic programs totaled $1,977.8 million for 2020, representing a decrease of 13.6% as compared to $2,290.4 million in 2019. This decrease was primarily due to a $490.7 million, or 31.7%, decrease in RITUXAN revenues, partially offset by a $157.9 million, or 23.0%, increase in royalty revenues on sales of OCREVUS. Sales of RITUXAN have been adversely affected primarily by the onset of biosimilars competition in the U.S.
- Other revenues totaled $774.6 million for 2020, representing an increase of 9.5% over $707.7 million in 2019. This increase was due to higher contract manufacturing revenues, primarily resulting from $346.2 million in revenues related to the delivery of the license for certain of our manufacturing-related intellectual property to a contract manufacturing customer.

Expenses

- Total cost and expenses were $8,894.5 million for 2020, representing an increase of 21.3% from $7,335.3 million in 2019. This increase was primarily due to a $1,710.3 million, or 75.0%, increase in research and development expense.
    - The increase in research and development expense was primarily due to $1,893.3 million in charges recognized in connection with upfront payments associated with entering into our collaborations with Sangamo, Denali and Sage.

  This increase was partially offset by:
    - a 5.1% decrease in amortization and impairment of acquired intangible assets; and
    - a $92.5 million gain recognized in 2020 associated with the divestiture of our Hillerød, Denmark manufacturing operations.

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

- We generated $4,229.8 million of net cash flows from operations for 2020.
- Cash, cash equivalents and marketable securities totaled approximately $3,382.2 million as of December 31, 2020.
- We repurchased and retired approximately 22.4 million shares of our common stock at a cost of approximately $6.7 billion during 2020 under our 2020, December 2019 and March 2019 Share Repurchase Programs.

Acquisitions, Collaborative and Other Relationships

For additional information on our acquisitions, collaborative and other relationships discussed below, please read *Note 2, Acquisitions*, *Note 18, Collaborative and Other Relationships*, and *Note 19, Investments in Variable Interest Entities*, to our consolidated financial statements included in this report.

BIIB118 Acquisition

In March 2020 we acquired BIIB118, a novel CNS-penetrant small molecule inhibitor of casein kinase 1, for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer. We are developing BIIB118 for the potential treatment of ISWRD in Parkinson's disease and plan to develop

BIIB118 for the potential treatment of sundowning in Alzheimer's disease.

For additional information on our acquisition of BIIB118, please read *Note 2, Acquisitions,* to our consolidated financial statements included in this report.

Sangamo Therapeutics, Inc.

In April 2020 we closed a collaboration and license agreement with Sangamo to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period.

For additional information on our collaboration arrangement with Sangamo, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Denali Therapeutics Inc.

In October 2020 we closed a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of LRRK2 for Parkinson's disease. In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle: Abeta program and a second program utilizing its Transport Vehicle technology. Further, we have a right of first negotiation on two additional Transport Vehicle-enabled therapeutics, should Denali decide to seek a collaboration for such programs.

For additional information on our collaboration arrangement with Denali, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Sage Therapeutics, Inc.

In December 2020 we closed a global collaboration and license agreement with Sage to jointly develop and commercialize zuranolone for the potential treatment of major depressive disorder, postpartum depression and other psychiatric disorders and SAGE-324 for the potential treatment of essential tremor and other neurological disorders.

For additional information on our collaboration arrangement with Sage, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Other Key Developments

Aducanumab (AB mAb)

In July 2020 we completed the submission of a BLA for the approval of aducanumab to the FDA. In August 2020 the FDA accepted the BLA and granted Priority Review with a PDUFA action date on March 7, 2021. In November 2020 the FDA held a virtual meeting of the Advisory Committee to review data supporting the BLA for aducanumab and to vote on questions presented at the meeting. A majority of the Advisory Committee members voted against each of the questions presented at the meeting.

In January 2021 the FDA extended the review period for the BLA for aducanumab by three months. The updated PDUFA action date is June 7, 2021. As part of the ongoing review, we submitted a response to an information request by the FDA, including additional analyses and clinical data, which the FDA considered a Major Amendment to the application that will require additional time for review.

In October 2020 the EMA accepted for review the MAA for aducanumab.

In December 2020 the Ministry of Health, Labor and Welfare accepted for review the Japanese New Drug Application for aducanumab.

2020 Share Repurchase Program

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

Results of Operations

Revenues

Revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2020	2019	2018	% Change 2020 vs. 2019	% Change 2019 vs. 2018	$ Change 2020 vs. 2019	$ Change 2019 vs. 2018
Product revenues, net:							
United States	$ 5,900.1	$ 6,713.8	$ 6,800.5	(12.1)%	(1.3)%	$ (813.7)	$ (86.7)
Rest of world	4,792.1	4,666.0	4,086.3	2.7	14.2	126.1	579.7
Total product revenues, net	10,692.2	11,379.8	10,886.8	(6.0)	4.5	(687.6)	493.0
Revenues from anti-CD20 therapeutic programs	1,977.8	2,290.4	1,980.2	(13.6)	15.7	(312.6)	310.2
Other revenues	774.6	707.7	585.9	9.5	20.8	66.9	121.8
Total revenues	$ 13,444.6	$ 14,377.9	$ 13,452.9	(6.5)%	6.9 %	$ (933.3)	$ 925.0

Product Revenues

Product revenues are summarized as follows:

(In millions, except percentages)	For the Years Ended December 31, 2020	2019	2018	% Change 2020 vs. 2019	% Change 2019 vs. 2018	$ Change 2020 vs. 2019	$ Change 2019 vs. 2018
Multiple Sclerosis (MS):							
Fumarate*	$ 3,905.4	$ 4,438.2	$ 4,274.1	(12.0)%	3.8 %	$ (532.8)	$ 164.1
Interferon**	1,877.5	2,101.8	2,363.0	(10.7)	(11.1)	(224.3)	(261.2)
TYSABRI	1,946.1	1,892.2	1,864.0	2.8	1.5	53.9	28.2
FAMPYRA	103.1	97.1	92.7	6.2	4.7	6.0	4.4
ZINBRYTA	—	—	1.4	—	nm	—	(1.4)
Subtotal: MS product revenues	7,832.1	8,529.3	8,595.2	(8.2)	(0.8)	(697.2)	(65.9)
Spinal Muscular Atrophy:							
SPINRAZA	2,052.1	2,097.0	1,724.2	(2.1)	21.6	(44.9)	372.8
Biosimilars:							
BENEPALI	481.6	486.2	485.2	(0.9)	0.2	(4.6)	1.0
IMRALDI	216.3	184.0	16.7	17.6	nm	32.3	167.3
FLIXABI	97.9	68.1	43.2	43.8	57.6	29.8	24.9
Subtotal: Biosimilar product revenues	795.8	738.3	545.1	7.8	35.4	57.5	193.2
Other:							
FUMADERM	12.2	15.2	22.3	(19.7)	(31.8)	(3.0)	(7.1)
Total product revenues, net	$ 10,692.2	$ 11,379.8	$ 10,886.8	(6.0)%	4.5 %	$ (687.6)	$ 493.0

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
**Interferon includes AVONEX and PLEGRIDY.
nm Not meaningful.

Multiple Sclerosis (MS)

Fumarate

Fumarate revenues include sales from TECFIDERA and VUMERITY. In October 2019 the FDA approved VUMERITY for the treatment of RMS and VUMERITY became commercially available in the U.S. in November 2019.

For 2020 compared to 2019, the 17.2% decrease in U.S. Fumarate revenues was primarily due to a decrease in TECFIDERA demand and price as a result of multiple TECFIDERA generic entrants entering the U.S. market during the year ended December 31, 2020. This decrease was partially offset by an increase of approximately $60.0 million in VUMERITY sales, which became commercially available in the U.S. in November 2019.

For 2020 compared to 2019, the 3.3% increase in rest of world Fumarate revenues was primarily due to an increase in TECFIDERA sales volumes of 8.6%, partially offset by pricing reductions in certain European countries and the unfavorable impact of foreign currency exchange. The increase in volumes was primarily due to continued strong patient growth in our E.U. direct markets, including Italy, Spain and the U.K., as well as growth in Japan and Brazil.

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Hatch-Waxman Act in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 20, Litigation,* to our consolidated financial statements included in this report.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020, and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

We anticipate an increase in TECFIDERA sales volume in rest of world in 2021, compared to 2020, notwithstanding the increasing competition from additional treatments for MS and potential disruptions due, directly or indirectly, to the COVID-19 pandemic.

We expect an increase in VUMERITY sales volume in the U.S., mostly driven by the continued launch of VUMERITY.

For additional information on our collaboration arrangement with Alkermes, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Interferon

For 2020 compared to 2019, the 10.7% decrease in U.S. Interferon revenues was primarily due to a decrease in Interferon sales volumes of 12.0%. The net decline in sales volumes reflects the continued decline of the Interferon market as patients transition to other higher efficacy and oral MS therapies.

For 2020 compared to 2019, the 10.5% decrease in rest of world Interferon revenues was primarily due to a decrease in Interferon sales volumes of 7.1%, which negatively impacted comparative revenue of $48.1 million.

We expect that Interferon revenues will continue to decline in both the U.S. and rest of world markets in 2021, compared to 2020, as a result of increasing

competition from our other MS products as well as other treatments for MS, including biosimilars, and pricing reductions in certain European markets.

AVONEX

For 2020, 2019 and 2018 U.S. AVONEX revenues totaled $1,083.4 million, $1,202.1 million and $1,420.2 million, respectively.

For 2020, 2019 and 2018 rest of world AVONEX revenues totaled $408.5 million, $463.8 million and $495.3 million, respectively.

PLEGRIDY

For 2020, 2019 and 2018 U.S. PLEGRIDY revenues totaled $190.1 million, $224.5 million and $248.1 million, respectively.

For 2020, 2019 and 2018 rest of world PLEGRIDY revenues totaled $195.5 million, $211.4 million and $199.4 million, respectively.

TYSABRI

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For 2020 compared to 2019, the 5.3% increase in U.S. TYSABRI revenues was primarily due to an increase in TYSABRI sales volume of 1.0% and price increases, partially offset by higher discounts and allowance rates.

For 2020 compared to 2019, rest of world TYSABRI revenues remained flat, with stable volume and pricing.

We anticipate TYSABRI sales volume to modestly increase on a global basis in 2021, compared to 2020, despite increasing competition from additional treatments for MS, including OCREVUS. We believe that some TYSABRI infusions may be delayed due, directly or indirectly, to the COVID-19 pandemic. We expect to continue to face price reductions in certain European markets.

Spinal Muscular Atrophy (SMA)

SPINRAZA

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For 2020 compared to 2019, the 15.6% decrease in U.S. SPINRAZA revenues was primarily due to a decrease in sales volumes of 15.0%, resulting from increased competition as well as lower loading and maintenance doses due to the impact of site of care closures as a result of the COVID-19 pandemic.

For 2020 compared to 2019, the 8.7% increase in rest of world SPINRAZA revenues was primarily due to a net increase in sales volumes of 16.8%, which was reflective of the impact of a shift from loading to maintenance doses and the impact of site of care closures as a result of the COVID-19 pandemic. This increase was partially lower net prices and the unfavorable impact of foreign currency exchange.

In 2021 we expect that SPINRAZA revenues will be subject to increased competition resulting in higher discontinuations and a lower rate of new patient starts combined with the impact of loading dose dynamics as patients transition to dosing once every four months and lower prices in certain rest of world countries. We believe that some SPINRAZA doses may continue to be delayed due, directly or indirectly, to the COVID-19 pandemic.

We face competition from a gene therapy product that was approved in the U.S. and the E.U. and a new oral product that was approved in the U.S. and has been accepted for review in the E.U. We expect that we will experience competition from both products in additional jurisdictions in the future. Additionally, we are aware of other products now in development that,

if launched, may also compete with SPINRAZA. Future sales of SPINRAZA may be adversely affected by the commercialization of competing products.

For additional information on our collaboration arrangements with Ionis, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Biosimilars

BENEPALI, IMRALDI and FLIXABI

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For 2020 compared to 2019, the 7.8% increase in biosimilar revenues was primarily due to higher sales volumes and a favorable foreign currency impact, partially offset by the unfavorable impact of price decreases.

In 2021 we expect modest to moderate revenue growth for our biosimilars business depending on the impact of the COVID-19 pandemic. We expect growth to be primarily driven by the continued launch of IMRALDI in Europe, partially offset by price reductions in certain European countries.

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilars, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. In October 2020 the EMA accepted for review the MAA for SB11 and in November 2020 the FDA accepted the BLA for SB11. We also acquired an option to extend our existing commercial agreement with Samsung Bioepis for BENEPALI, IMRALDI and FLIXABI in certain countries in Europe and obtained an option to acquire exclusive rights to commercialize these products in China.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Revenues from Anti-CD20 Therapeutic Programs

Genentech (Roche Group)

Our share of RITUXAN, including RITUXAN HYCELA, and GAZYVA collaboration operating profits in the U.S. and other revenues 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.

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

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

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Product revenues, net	$ 3,334.1	$ 4,747.4	$ 4,484.3
Cost and expenses	433.0	622.7	669.6
Pre-tax profits in the U.S.	$ 2,901.1	$ 4,124.7	$ 3,814.7
Biogen's share of pre-tax profits	$ 1,080.2	$ 1,542.4	$ 1,431.9

For 2020 compared to 2019, the decrease in U.S. product revenues, net was primarily due to a decrease in sales volumes of RITUXAN in the U.S. of 26.7%, due to the onset of competition from multiple biosimilars, and we believe RITUXAN was adversely impacted by the COVID-19 pandemic.

For 2020 compared to 2019, product revenues, net also reflects increases in GAZYVA sales volumes of 24.7%.

For 2020 compared to 2019, the decrease in collaboration costs and expenses was primarily due to lower cost of sales on RITUXAN.

We are aware of several other anti-CD20 molecules, including biosimilar products, that have recently been approved and are expected to compete with RITUXAN and GAZYVA in the oncology market. In November 2019, January 2020 and January 2021 biosimilar products referencing RITUXAN were launched in the U.S. and are being offered at lower prices. This competition has adversely affected the pre-tax profits of our collaboration arrangements with Genentech and could have a significant adverse affect on our co-promotion profits in the U.S. in future years.

Other Revenues from Anti-CD20 Therapeutic Programs

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

For 2020 compared to 2019, the increase in other revenues from anti-CD20 therapeutic programs was primarily due to sales growth of OCREVUS. Royalty revenues recognized on sales of OCREVUS for the years ended December 31, 2020, 2019 and 2018, totaled $845.4 million, $687.5 million and $478.3 million, respectively.

OCREVUS royalty revenues are 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 revenues will be adjusted for in the period in which they become known, which is generally expected to be the following quarter.

For additional information on our collaboration arrangements with Genentech, including information regarding the pre-tax profit-sharing formula and its impact on future revenues from anti-CD20 therapeutic programs, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Other Revenues

Other revenues are summarized as follows:

	For the Years Ended December 31,			% Change		$ Change	
(In millions, except percentages)	2020	2019	2018	2020 vs. 2019	2019 vs. 2018	2020 vs. 2019	2019 vs. 2018
Revenues from collaborative and other relationships	$ 21.6	$ 106.2	$ 87.8	(79.7)%	21.0 %	$ (84.6)	$ 18.4
Other royalty and corporate revenues	753.0	601.5	498.1	25.2	20.8	151.5	103.4
Total other revenues	$ 774.6	$ 707.7	$ 585.9	9.5 %	20.8 %	$ 66.9	$ 121.8

Revenues from Collaborative and Other Relationships

Revenues from collaborative and other relationships primarily include revenues from our technical development services and manufacturing agreements with Samsung Bioepis and royalty revenues on biosimilar products from Samsung Bioepis.

Following the divestiture of our Hillerød, Denmark manufacturing operations in August 2019, FUJIFILM Corporation (FUJIFILM) assumed responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis. We no longer recognize revenues for the manufacturing completed after the Hillerød, Denmark manufacturing operations divestiture date under our technical development services and manufacturing agreements with Samsung Bioepis.

For the years ended December 31, 2020 and 2019, we recognized $20.9 million and $106.2 million, respectively, related to the services described above provided to Samsung Bioepis.

For additional information on our collaborative and other relationships, including revenues recognized under our technical development services and manufacturing agreements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to our consolidated financial statements included in this report.

Other Royalty and Corporate Revenues

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

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 are entitled to $500.0 million in a series of three payments. The first payment became due upon regulatory approval of such product and was received during the second quarter of 2020. Subsequent payments are due on the first and second anniversaries of the regulatory approval.

Other corporate revenues for the year ended December 31, 2020, reflect $346.2 million related to the delivery of the license for certain of our manufacturing-related intellectual property under the amended agreement discussed above and the performance of manufacturing product supply services for such customer. We have allocated the remaining $153.8 million of the $500.0 million transaction price to the performance of manufacturing product supply services for the customer, which we expect to perform through 2026. The value allocated to the manufacturing services was based on expected demand for supply and the fair value of comparable manufacturing and development services.

For 2020 compared to 2019, the increase in other royalty and corporate revenues was due to higher contract manufacturing revenues, primarily resulting from $346.2 million in revenues related to the delivery of the license for certain of our manufacturing-related intellectual property to a contract manufacturing customer, as discussed above.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances, including those associated with the implementation of pricing actions in certain international markets where we operate.

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

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

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For the years ended December 31, 2020, 2019 and 2018, reserves for discounts and allowances as

a percentage of gross product revenues were 27.1%, 24.3% and 23.7%, respectively.

Discounts

Discounts include trade term discounts and wholesaler incentives.

For 2020 compared to 2019, the increase in discounts was primarily driven by an increase in gross biosimilar sales in our international markets as well as increases in discount percentages in certain countries.

Contractual Adjustments

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

For 2020 compared to 2019, the increase in contractual adjustments was primarily due to higher pharmacy rebates and governmental rebates in the U.S. as well as higher governmental rebates and allowances in the rest of world, due in part to an increase in SPINRAZA sales volumes worldwide.

Returns

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

For 2020 compared to 2019, return reserves were relatively consistent.

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

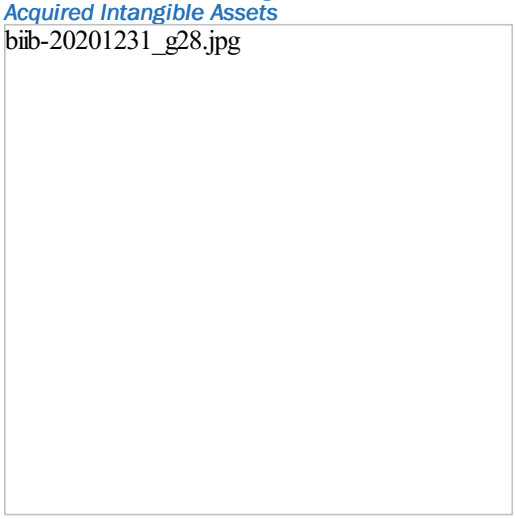
Cost and Expenses

A summary of total cost and expenses is as follows:

	For the Years Ended December 31,			% Change		$ Change	
(In millions, except percentages)	2020	2019	2018	2020 vs. 2019	2019 vs. 2018	2020 vs. 2019	2019 vs. 2018
Cost of sales, excluding amortization and impairment of acquired intangible assets	$ 1,805.2	$ 1,955.4	$ 1,816.3	(7.7)%	7.7 %	$ (150.2)	$ 139.1
Research and development	3,990.9	2,280.6	2,597.2	75.0	(12.2)	1,710.3	(316.6)
Selling, general and administrative	2,504.5	2,374.7	2,106.3	5.5	12.7	129.8	268.4
Amortization and impairment of acquired intangible assets	464.8	489.9	747.3	(5.1)	(34.4)	(25.1)	(257.4)
Collaboration profit (loss) sharing	232.9	241.6	185.0	(3.6)	30.6	(8.7)	56.6
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	(92.5)	55.3	—	nm	nm	(147.8)	55.3
(Gain) loss on fair value remeasurement of contingent consideration	(86.3)	(63.7)	(12.3)	35.5	417.9	(22.6)	(51.4)
Acquired in-process research and development	75.0	—	112.5	nm	nm	75.0	(112.5)
Restructuring charges	—	1.5	12.0	nm	(87.5)	(1.5)	(10.5)
Total cost and expenses	$ 8,894.5	$ 7,335.3	$ 7,564.3	21.3 %	(3.0)%	$ 1,559.2	$ (229.0)

[nm] Not meaningful

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



Cost of sales, as a percentage of total revenues, were 13.4%, 13.6% and 13.5% for the years ended December 31, 2020, 2019 and 2018, respectively.

Product Cost of Sales

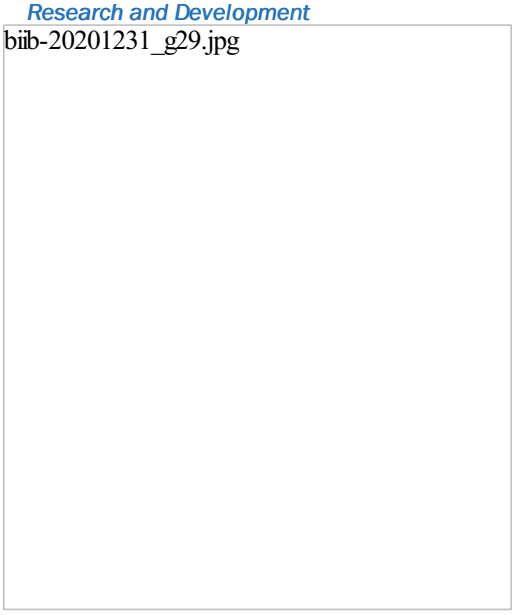
For 2020 compared to 2019, the decrease in product cost of sales was primarily due to lower cost of sales from contract manufacturing agreements, primarily resulting from the sale of hemophilia inventory, with a cost basis of $173.5 million, to Bioverativ in the first quarter of 2019 and FUJIFILM assuming responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis during the third quarter of 2019.

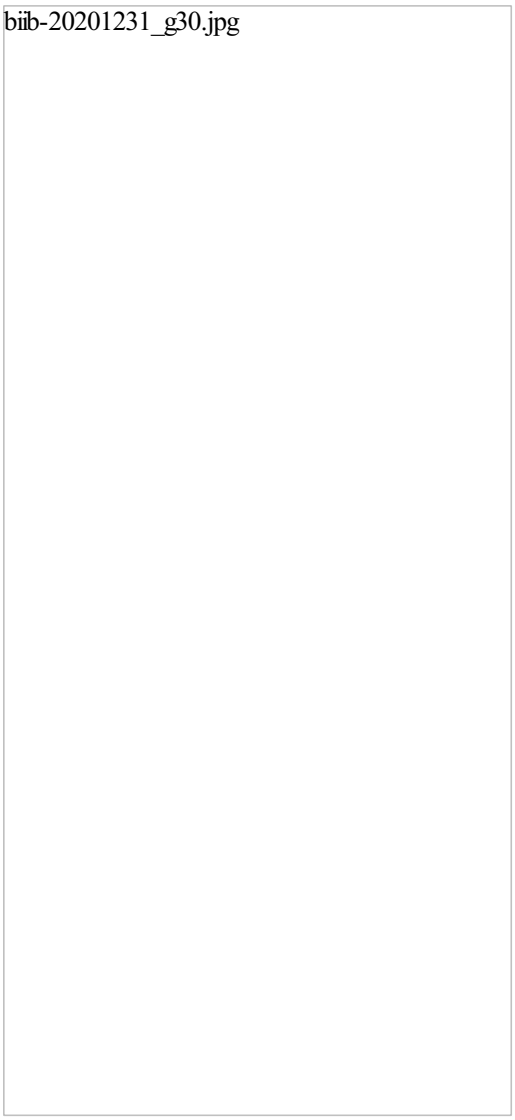
Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons totaled $26.6 million, $52.2 million and $41.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Royalty Cost of Sales

For 2020 compared to 2019, the decrease in royalty cost of sales was primarily due to lower royalties payable on lower sales of AVONEX and SPINRAZA.

Research and Development





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

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

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

For 2020 compared to 2019, the increase in research and development expense was primarily due to approximately $1,084.0 million, $601.3 million and $208.0 million of upfront payments made in connection with entering into our collaborations with Sage, Denali and Sangamo, respectively.

In 2020 we recorded significant upfront payments related to our new collaborations as part of research and development expense. Excluding upfront payments, we expect our core research and development expense to increase in 2021, driven by continued investment in our pipeline, including significant investments related to the new assets in the Sage collaboration. 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.

At December 31, 2020, we capitalized approximately $93.8 million of pre-launch inventory for aducanumab. If aducanumab does not receive regulatory approval in the U.S., we would expense this inventory as research and development expense and, under the terms of the Aducanumab Collaboration Agreement, Eisai would reimburse us for 45.0% of the costs.

Milestone and Upfront Expenses

Research and development expense for 2020 includes:

- $1,084.0 million charge to research and development expense in connection with the upfront payment associated with entering into our collaboration with Sage in the fourth quarter of 2020;

- $601.3 million charge to research and development expense in connection with the upfront payment associated with entering into our collaboration with Denali in the third quarter of 2020; and
- $208.0 million charge to research and development expense in connection with the upfront payment associated with entering into our collaboration with Sangamo in the second quarter of 2020.

Research and development expense for 2019 includes:

- $63.0 million charge to research and development expense in connection with our agreement with Samsung Bioepis to secure the exclusive rights to commercialize two potential ophthalmology biosimilar products; and
- $45.0 million charge to research and development expense upon the exercise of our option to obtain a worldwide, exclusive, royalty-bearing license from Ionis to develop and commercialize BIIB080 (tau ASO) for the potential treatment of Alzheimer's disease.

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

For additional information about these collaboration arrangements, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Early Stage Programs

For 2020 compared to 2019, the decrease in spending related to our early stage programs was primarily due to a decrease in costs associated with:

- the discontinuation of gosuranemab in progressive supraneuclear palsy;
- the advancement of toferson in ALS into late stage; and
- the discontinuation of the Phase 2b study of BG00011 for the potential treatment of idiopathic pulmonary fibrosis (IPF).

These decreases were partially offset by an increase in costs associated with:

- spending in the development of BIIB112 (RPGR gene therapy) in XLRP;
- spending in the development of BIIB080 in Alzheimer's disease; and
- spending in the development of gosuranemab in Alzheimer's disease.

Late Stage Programs

For 2020 compared to 2019, the decrease in spending associated with our late stage programs was primarily due to:

- a decrease in spending related to the discontinuation of the global Phase 3 trials of aducanumab, net of reimbursement from our collaboration partner Eisai in the first quarter of 2019;
- a decrease in spending related to the discontinuation of the global Phase 3 trials, MISSION AD1 and MISSION AD2, of elenbecestat (development code: E2609) in patients with early Alzheimer's disease in the third quarter of 2019; and
- a decrease in spending related to VUMERITY, which was approved by the FDA in the fourth quarter of 2019.

These decreases were partially offset by an increase in spending due to the advancement of toferson in ALS into late stage, an increase in spending related to BAN2401 in early Alzheimer's disease, our EMBARK redosing study for aducanumab and BIIB111 (timrepigene emparvovec) in CHM.

In the first quarter of 2019, as a result of the decision to discontinue the Phase 3 EMERGE and ENGAGE trials following a futility analysis, we accrued approximately $45.0 million related to the termination of clinical trials and research and development contracts net of the expected 45.0% Eisai reimbursement of development costs incurred by the collaboration for the advancement of aducanumab.

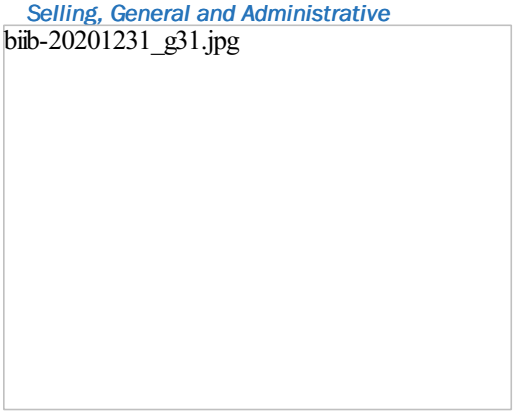
In July 2020 we completed the submission of a BLA for the approval of aducanumab to the FDA. In August 2020 the FDA accepted the BLA and granted Priority Review with a PDUFA action date on March 7, 2021. In January 2021 the FDA extended the review period for the BLA for aducanumab by three months. The updated PDUFA action date is June 7, 2021.

In March 2019 Eisai initiated a global Phase 3 trial for the development of BAN2401 in early Alzheimer's disease. Under our collaboration arrangement, Eisai serves as the global operational and regulatory lead for BAN2401 and all costs, including research, development, sales and marketing expenses, are shared equally between us and Eisai.

For additional information on our collaboration arrangements with Eisai, please read *Note 18, Collaborative and Other Relationships,* to our

consolidated financial statements included in this report.

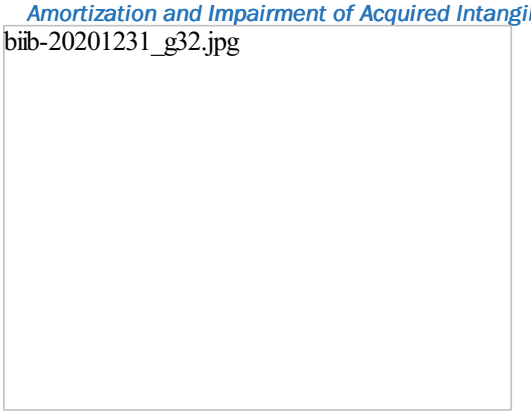
Selling, General and Administrative



For 2020 compared to 2019, the increase in selling, general and administrative expenses was primarily due to increased commercial and medical investments in support of pre-launch activities associated with the potential regulatory approval of aducanumab.

In 2021 we expect selling, general and administrative costs, including headcount and commercial infrastructure, to significantly increase as we support activities associated with the potential regulatory approvals of aducanumab in the U.S. and rest of world markets.

Amortization and Impairment of Acquired Intangible Assets



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

For the year ended December 31, 2020, amortization and impairment of acquired intangible assets reflects the impact of a $115.0 million impairment charge related to BIIB111, which was obtained as part of our acquisition of Nightstar Therapeutics plc (NST), a $75.4 million impairment charge related to BIIB054 and a $19.3 million impairment charge related to one of our other IPR&D intangible assets.

For the year ended December 31, 2019, amortization and impairment of acquired intangible assets reflects the impact of a $215.9 million impairment charge related to certain IPR&D assets associated with the Phase 2b study of BG00011 for the potential treatment of IPF, which was discontinued in the third quarter of 2019.

Amortization of acquired intangible assets, excluding impairment charges, totaled $255.1 million, $274.0 million and $381.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

For 2020 compared to 2019, the decrease in amortization of acquired intangible assets, excluding impairment charges, was primarily due to a lower rate of amortization for acquired intangible assets.

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 revenues of the relevant products. The occurrence of an adverse event could substantially increase the amount of amortization expense related to our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

IPR&D Related to Business Combinations

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

Overall, the value of our acquired IPR&D assets is dependent upon several variables, including estimates of future revenues and the effects of competition, our ability to secure sufficient pricing in a competitive market, our ability to confirm safety and efficacy based on data from clinical trials and

regulatory feedback, the level of anticipated development costs and the probability and timing of successfully advancing a particular research program from one clinical trial phase to the next. We are continually reevaluating our estimates concerning these and other variables, including our life cycle management strategies, research and development priorities and development risk, changes in program and portfolio economics and related impact of foreign currency exchange rates and economic trends and evaluating industry and company data regarding the productivity of clinical research and the development process. Changes in our estimates may result in a significant change to our valuation of our IPR&D assets.

BIIB111

During the fourth quarter of 2020 we began experiencing third-party manufacturing delays that may impact our timeline for a potential filing of a BLA for BIIB111 for regulatory approval by up to one year. In addition, we determined that forecasted costs associated with advancing the BIIB111 program through Phase 3 development and potential commercialization will exceed our original estimates. We reassessed the fair value of the program based on these changes in assumptions and determined that the program was partially impaired. We recognized an impairment charge of $115.0 million during the fourth quarter of 2020, which resulted in a reduction of the IPR&D asset from $480.0 million to $365.0 million.

BIIB054

In February 2021 we announced that we discontinued development of BIIB054 as a potential treatment of Parkinson's disease as our Phase 2 SPARK study did not meet its primary or secondary endpoints. Although we made this determination in February 2021, it was based on conditions that existed as of December 31, 2020. As a result, we recognized an impairment charge of approximately $75.4 million during the fourth quarter of 2020 to reduce the fair value of the related IPR&D intangible asset to zero.

Vixotrigine

In the periods since we acquired vixotrigine (BIIB074), there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of trigeminal neuralgia (TGN) as we engaged with the FDA regarding the design of the Phase 3 studies and awaited data and insights from mid-stage clinical trials of vixotrigine in other indications that have since been completed. The fair value of the TGN asset is not significantly in excess of carrying value. As of December 31, 2020, the carrying value associated with our vixotrigine IPR&D assets was $177.5 million.

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

Collaboration Profit (Loss) Sharing

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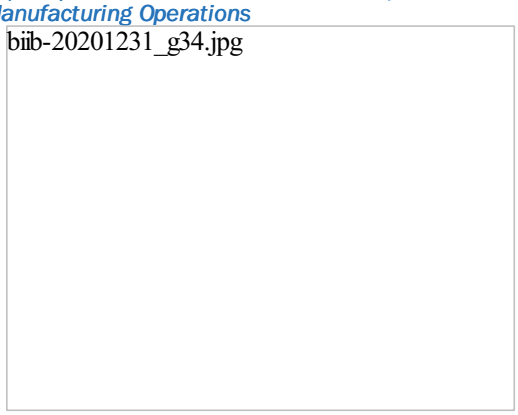
Collaboration profit (loss) sharing primarily includes Samsung Bioepis' 50.0% share of the profit or loss related to our biosimilars commercial agreement with Samsung Bioepis.

For 2020, 2019 and 2018 we recognized a net profit-sharing expense of $266.5 million, $241.6 million and $187.4 million, respectively, to reflect Samsung Bioepis' 50.0% sharing of the net collaboration profits.

For the year ended 2020, we also recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone expense related to the completed submission of the BLA for the approval of aducanumab to the FDA.

For additional information on our collaboration arrangements with Samsung Bioepis and Eisai, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

(Gain) Loss on Divestiture of Hillerød, Denmark Manufacturing Operations



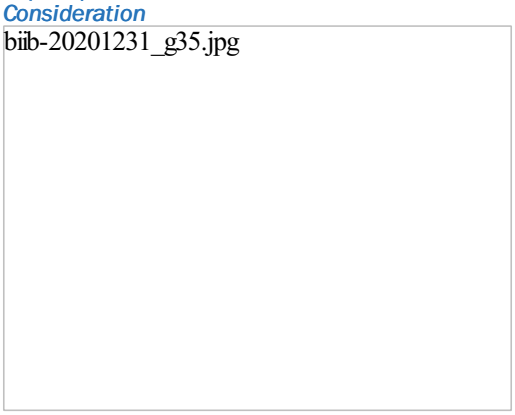
In March 2019 we entered into a share purchase agreement with FUJIFILM to sell all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark. The transaction closed in August 2019.

For the year ended December 31, 2019, we recognized a total net loss of approximately $124.2 million related to the transaction in our consolidated statements of income. This loss included a pre-tax loss of $55.3 million, which was recorded in loss on divestiture of Hillerød, Denmark manufacturing operations. The loss recognized was based on exchange rates and business conditions on the closing date of this transaction, and included costs to sell our Hillerød, Denmark manufacturing operations of approximately $11.2 million and our estimate of the fair value of adverse commitments of approximately $74.0 million, primarily associated with the guarantee of future minimum batch production at the Hillerød facility. We also recorded a tax expense of $68.9 million related to this transaction.

During the year ended December 31, 2020, we reduced our estimate of the fair value of the adverse commitment associated with the guarantee of future batch production by approximately $62.0 million based on our current manufacturing forecasts. Additionally, we recorded a reduction to our pre-tax loss of approximately $30.5 million due to a refund of interest paid associated with a tax matter.

For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, 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 includes future payments that are contingent upon the occurrence of a particular event or events. We record an obligation for such contingent consideration payments at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of income.

The gain on fair value remeasurement of contingent consideration for 2020 was primarily due to the remeasurement of the contingent consideration associated with our BIIB054 program as well as changes in the probability and the expected timing of the achievement of certain remaining developmental milestones, changes in the interest rates used to revalue our contingent consideration liabilities and the passage of time.

The gain on fair value remeasurement of contingent consideration for 2019 was primarily due to the discontinuation of the Phase 2b study of BG00011 for the potential treatment of IPF as well as changes in the probability and expected timing of achievement of certain developmental milestones, a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

For additional information on our IPR&D intangible assets, please read *Note 6, Intangible Assets and Goodwill*, to our consolidated financial statements included in this report.

Acquired In-Process Research and Development

BIIB118 Acquisition

In March 2020 we acquired BIIB118 from Pfizer for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases. In connection with this acquisition, we made an upfront payment of $75.0 million to Pfizer, which was accounted for as an asset acquisition and recorded as acquired IPR&D in our consolidated statements of income as BIIB118 has not yet reached technological feasibility.

For additional information on our acquisition of BIIB118, please read *Note 2, Acquisitions*, to our consolidated financial statements included in this report.

Other Income (Expense), Net

For 2020 compared to 2019, the change in other income (expense), net primarily reflects an increase in our net unrealized gains on our holdings in equity securities, partially offset by higher interest expense.

For the year ended December 31, 2020, net unrealized and realized gains on our holdings in equity securities were approximately $681.8 million and $12.1 million, respectively, compared to net unrealized and realized gains of $150.1 million and $50.0 million in 2019. The net unrealized gains recognized during the year ended December 31, 2020, primarily reflects an increase in the fair value of Denali and Sangamo common stock of approximately $703.9 million.

For the year ended December 31, 2020, net interest expense was $180.5 million as compared to $67.4 million in 2019. This increase was primarily due to additional borrowings in 2020 and lower interest income earned on our investments in 2020 as compared to 2019. On April 30, 2020, we issued our senior unsecured notes for an aggregate principal amount of $3.0 billion (2020 Senior Notes).

We expect interest expense will increase in 2021, as our 2020 Senior Notes will be outstanding for the entire year.

For additional information on our 2020 Senior Notes, please read *Note 12, Indebtedness*, to our consolidated financial statements included in this report.

Income Tax Provision

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

certain deductions and credits, acquisitions and licensing transactions.

For the year ended December 31, 2020, as compared to 2019, the increase in our effective tax rate was primarily due to the income tax expense related to the establishment of a valuation allowance against certain net deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S., partially offset by the benefit recognized on the effective settlement of certain tax matters. Additionally, our 2019 effective tax rate benefited from an internal reorganization of certain intellectual property rights and the enactment of a new taxing regime in the country and certain cantons of Switzerland, partially offset by tax expense related to the divestiture of our Hillerød, Denmark manufacturing operations. Although we recognized a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture required us to write-off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions.

For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to our consolidated financial statements included in this report.

Accounting for Uncertainty in Income Taxes

For additional information on our uncertain tax positions and income tax rate reconciliation for 2020, 2019 and 2018, please read *Note 16, Income Taxes,* to our consolidated financial statements included in this report.

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

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

In June 2018 we exercised our option under our joint venture agreement to increase our ownership percentage in Samsung Bioepis from approximately 5.0% to approximately 49.9%. The share purchase transaction was completed in November 2018. As of December 31, 2020, our ownership percentage remained at approximately 49.9%.

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

The former chief executive officer (the incumbent chairman of the board) and the chief financial officer of our joint venture partner, Samsung BioLogics, are currently subject to ongoing criminal proceedings that we continue to monitor. While these proceedings could impact the operations of Samsung Bioepis and its business, we have assessed the value of our investment in Samsung Bioepis and continue to believe that the fair value of the investment is in excess of its net book value.

For the year ended December 31, 2020, equity in (income) loss of investee, net of tax reflects our share of income totaling $45.3 million and amortization of basis differences totaling $40.0 million.

For the year ended December 31, 2019, equity in (income) loss of investee, net of tax reflects our share of losses totaling $1.2 million and amortization of basis differences totaling $78.2 million.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships,* to our consolidated financial statements included in this report.

Noncontrolling Interests, Net of Tax

For 2020 net income (loss) attributable to noncontrolling interests, net of tax, was primarily due to the $75.0 million milestone payment related to the completed submission of the BLA for the approval of aducanumab to the FDA.

For additional information on our collaboration arrangement with Neurimmune, please read *Note 19, 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, 2020	As of December 31, 2019	% Change 2020 vs. 2019
Financial assets:			
Cash and cash equivalents	$ 1,331.2	$ 2,913.7	(54.3) %
Marketable securities — current	1,278.9	1,562.2	(18.1)
Marketable securities — non-current	772.1	1,408.1	(45.2)
Total cash, cash equivalents and marketable securities	$ 3,382.2	$ 5,884.0	(42.5) %
Borrowings:			
Current portion of notes payable	$ —	$ 1,495.8	nm
Notes payable	7,426.2	4,459.0	66.5
Total borrowings	$ 7,426.2	$ 5,954.8	24.7 %
Working Capital:			
Current assets	$ 6,887.1	$ 8,381.8	(17.8) %
Current liabilities	(3,742.2)	(4,863.8)	(23.1)
Total working capital	$ 3,144.9	$ 3,518.0	(10.6) %

[nm] Not meaningful

For the year ended December 31, 2020, certain significant cash flows were as follows:

- $4.2 billion in net cash flows provided by operating activities, which reflected $1.9 billion of upfront payments and the premium on stock purchases made in connection with entering into our collaborations with Sage, Denali and Sangamo and recognized as research and development expenses;
- $6.7 billion used for share repurchases;
- $3.0 billion in proceeds received from the issuance of our 2020 Senior Notes;
- $1.5 billion payment made for the redemption of our 2.90% Senior Notes due September 15, 2020, prior to their maturity;
- $906.7 million in total net payments for income taxes;
- $441.0 million used to purchase Sage common stock;

- $423.7 million used to purchase Denali common stock;
- $141.8 million used to purchase Sangamo common stock; and
- $424.8 million used for purchases of property, plant and equipment.

For the year ended December 31, 2019, certain significant cash flows were as follows:

- $7.1 billion in net cash flows provided by operating activities;
- $5.9 billion used for share repurchases;
- $1.1 billion in total net payments for income taxes;
- $923.7 million in proceeds received on the divestiture of our Hillerød, Denmark manufacturing operations, including the sale of raw materials that were remaining at the Hillerød facility on the closing date of this transaction;
- $744.4 million payment made for our acquisition of NST, net of cash acquired;
- $514.5 million used for purchases of property, plant and equipment;
- $479.3 million in proceeds received on sales of strategic investments;
- $300.0 million for the final contingent payment made to former shareholders of Fumapharm AG and holders of their rights; and
- $155.0 million in payments made to Alkermes following the FDA's approval of VUMERITY.

Overview

We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. On April 30, 2020, we issued our 2020 Senior Notes for an aggregate principal amount of $3.0 billion. We expect our operating expenditures, particularly those related to research and development, clinical trials, commercialization of new products and international expansion to continue to grow. However, we expect to continue funding our current and planned operating requirements primarily through our cash flows earned from our operations as well as our existing cash resources and proceeds received from the issuance of our 2020 Senior Notes. Generic competition for TECFIDERA in the U.S. has begun and we believe that this competition will reduce our cash flow from operations in 2021 and will have a significant adverse impact on our future cash flows 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, from time to time, also seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources should we identify a significant new opportunity.

Aducanumab

In July 2020 we completed the submission of a BLA for the approval of aducanumab to the FDA. In August 2020 the FDA accepted the BLA and granted Priority Review with a PDUFA action date on March 7, 2021. In January 2021 the FDA extended the review period for the BLA for aducanumab by three months. The updated PDUFA action date is June 7, 2021. If we do not receive regulatory approval or are unable to successfully commercialize aducanumab, our financial condition, business and operations may be adversely affected.

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

Cash, Cash Equivalents and Marketable Securities

Until required for another use in our business, we typically invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments, overnight reverse repurchase agreements and other interest-bearing marketable debt instruments in accordance with our investment policy. It is our policy to mitigate credit risk in our cash reserves and marketable securities by maintaining a well-diversified portfolio that limits the amount of exposure as to institution, maturity and investment type. In March 2020 there was a severe liquidity crisis in the capital markets, particularly with respect to securities with maturities of less than one year, due to the COVID-19 pandemic. This issue impacted pricing of securities in our portfolio as we attempted to decrease our marketable securities level and increase cash, leading to approximately $8.2 million in realized losses for the year ended December 31, 2020. We believe that actions taken by the U.S. Federal Reserve to enhance liquidity have stabilized the capital markets for the time being.

As of December 31, 2020, we had cash, cash equivalents and marketable securities totaling approximately $3.4 billion compared to approximately $5.9 billion as of December 31, 2019. The net decrease in cash, cash equivalents and marketable securities at December 31, 2020, from December 31, 2019, was primarily due to cash used for share repurchases, the redemption of our 2.90% Senior Notes due September 15, 2020, upfront payments and stock purchases totaling $2.9 billion made in connection with entering into our collaborations with Sage, Denali and Sangamo and net purchases of property, plant and equipment, partially offset by cash flows from operations and net proceeds from the issuance of our 2020 Senior Notes.

Investments and other assets in our consolidated balance sheet as of December 31, 2020 and 2019, include the carrying value of our investment in Samsung Bioepis of $620.2 million and $580.2 million, respectively. As Samsung Bioepis is a privately-held entity, our ability to liquidate our investment in Samsung Bioepis may be limited and we may realize significantly less than the value of such investment. The investment is also subject to foreign currency exchange fluctuations.

In connection with our collaboration with Sangamo, we purchased approximately 24 million shares of Sangamo common stock in April 2020. As of December 31, 2020, the fair value of this investment was $333.7 million. In connection with our collaboration with Denali, we purchased approximately 13 million shares of Denali common stock in September 2020. As of December 31, 2020, the fair value of this investment was $935.7 million. In connection with our collaboration with Sage, we purchased approximately 6.2 million shares of Sage common stock in December 2020. As of December 31, 2020, the fair value of this investment was $433.9 million.

Our investment in Ionis common stock had a fair value of $249.1 million and $329.6 million as of December 31, 2020 and 2019, respectively.

For additional information on our collaboration arrangements with Ionis, Samsung Bioepis, Sangamo, Denali and Sage, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Borrowings

In April 2020 we issued our 2020 Senior Notes for an aggregate principal amount of $3.0 billion, consisting of the following:

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

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

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

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

In May 2020 we redeemed our 2.90% Senior Notes due September 15, 2020, with an aggregate principal amount of $1.5 billion.

For a summary of the fair values of our outstanding borrowings as of December 31, 2020 and 2019, please read *Note 7, Fair Value Measurements,* to our consolidated financial statements included in this report.

2020 Credit Facility

In January 2020 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. This revolving credit facility replaced the revolving credit facility entered into in August 2015. As of December 31, 2020, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Working Capital

Working capital is defined as current assets less current liabilities. Working capital was $3.1 billion and $3.5 billion as of December 31, 2020 and December 31, 2019, respectively. The change in working capital reflects a decrease in total current assets of approximately $1.5 billion and a decrease in total current liabilities of approximately $1.1 billion.

The decrease in total current assets was primarily driven by a decrease in net cash, cash equivalents and marketable securities due to cash used for share repurchases, the redemption of our 2.90% Senior Notes due September 15, 2020, upfront payments and stock purchases totaling $2.9 billion made in connection with entering into our collaborations with Sage, Denali and Sangamo and net purchases of property, plant and equipment, partially offset by cash flows from operations and net proceeds from the issuance of our 2020 Senior Notes.

The net decrease in current liabilities was primarily due to the redemption of our 2.90% Senior Notes due September 15, 2020, which were classified within current liabilities as of December 31, 2019, partially offset by an increase in accrued expenses and other.

Share Repurchase Programs

In October 2020 our Board of Directors authorized our 2020 Share Repurchase Program, which is a program to repurchase up to $5.0 billion of our common stock. Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million shares of our common stock at a cost of approximately $400.0 million during the year ended December 31, 2020.

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

In March 2019 our Board of Directors authorized our March 2019 Share Repurchase Program, which was a program to repurchase up to $5.0 billion of our common stock that was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million and 14.7 million shares of our common stock at a cost of approximately $1.3 billion and $3.7 billion during the years ended December 31, 2020 and 2019, respectively.

In August 2018 our Board of Directors authorized our 2018 Share Repurchase Program, which was a program to repurchase up to $3.5 billion of our common stock that was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million and 4.3 million shares of our common stock at a cost of approximately $2.1 billion and $1.4 billion during the years ended December 31, 2019 and 2018, respectively.

Cash Flows

The following table summarizes our cash flow activity:

	For the Years Ended December 31,			% Change	
(In millions, except percentages)	2020	2019	2018	2020 vs. 2019	2019 vs. 2018
Net cash flows provided by operating activities	$ 4,229.8	$ 7,078.6	$ 6,187.7	(40.2)%	14.4 %
Net cash flows provided by (used in) investing activities	(608.6)	470.5	(2,046.3)	(229.4)%	nm
Net cash flows used in financing activities	(5,272.7)	(5,860.4)	(4,472.0)	10.0	(31.0)

nm Not meaningful

Operating Activities

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

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

- non-cash operating items such as depreciation and amortization, impairment charges, unrealized gain (loss) on strategic investments, acquired IPR&D and share-based compensation;
- changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with

transactions and when they are recognized in results of operations; and

- changes in the fair value of contingent payments associated with our acquisitions of businesses and payments related to collaborations.

For 2020 compared to 2019, the decrease in net cash flows provided by operating activities was primarily due to lower net income as well as increases in certain working capital asset balances. Net income in 2020 reflected approximately $1,084.0 million, $601.3 million and $208.0 million of upfront payments made in connection with entering into our collaborations with Sage, Denali and Sangamo, respectively.

Investing Activities

For 2020 compared to 2019, the increase in net cash flows used in investing activities was primarily due to the purchases of the common stock of Sangamo, Denali and Sage totaling $1.0 billion during 2020 and proceeds of $923.7 million received in 2019 related to the divestiture of our Hillerød, Denmark manufacturing operations, partially offset by higher proceeds received from the sale of investments as compared to the prior year.

Financing Activities

For 2020 compared to 2019, the decrease in net cash flows used in financing activities was primarily due to the net proceeds received from the issuance of our 2020 Senior Notes offset by a higher amount spent on shares repurchased in 2020 as compared to the comparative period in 2019 and the redemption of our 2.90% Senior Notes due September 15, 2020.

Contractual Obligations and Off-Balance Sheet Arrangements

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020, excluding amounts related to uncertain tax positions, funding commitments, contingent development, regulatory and commercial milestone payments, contingent payments and contingent consideration related to our business combinations, as described below.

	Payments Due by Period				
(In millions)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Non-cancellable operating leases [1][2]	$ 387.8	$ 70.3	$ 123.6	$ 89.6	$ 104.3
Long-term debt obligations [3]	11,853.0	279.1	1,512.9	2,218.0	7,843.0
Purchase and other obligations [4]	1,248.0	398.3	420.0	424.6	5.1
Defined benefit obligation	151.2	—	—	—	151.2
Total contractual obligations	$ 13,640.0	$ 747.7	$ 2,056.5	$ 2,732.2	$ 8,103.6

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

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

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

[4] Purchase and other obligations include $697.0 million related to the remaining payments on a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and $217.2 million related to the fair value of net liabilities on derivative contracts.

Royalty Payments

TYSABRI

In 2013 we acquired from Elan Pharma International Ltd. (Elan), an affiliate of Elan Corporation plc, full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the acquisition agreement, we are obligated to make contingent payments to Elan of 18.0% on annual worldwide net sales up to $2.0 billion and 25.0% on annual worldwide net sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013 and Perrigo subsequently sold its rights to these payments to a third-party effective January 2017.

SPINRAZA

In 2016 we exercised our option to develop and commercialize SPINRAZA from Ionis. Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net 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 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

VUMERITY

In October 2019 the FDA approved VUMERITY for the treatment of RMS. Under our agreement with Alkermes, we make royalty payments to Alkermes on worldwide net commercial sales of VUMERITY using a royalty rate of 15.0%, which are recorded as cost of sales in our consolidated statements of income. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval. For additional information on our collaboration arrangement with Alkermes, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

Contingent Consideration related to Business Combinations

In connection with our acquisition of Convergence Pharmaceuticals Ltd. we agreed to make additional payments based upon the achievement of certain milestone events.

We recognized the contingent consideration liabilities associated with these transactions at their fair value on the acquisition date and revalue these obligations each reporting period. We may pay up to approximately $400.0 million in remaining milestones related to these acquisitions.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2020, we could trigger potential future milestone payments to third parties of up to approximately $10.2 billion, including approximately $1.9 billion in development milestones, approximately $1.3 billion in regulatory milestones and approximately $7.0 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of December 31, 2020, 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 $86.2 million in milestones in 2021 under our current agreements. Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay up to $200.0 million in milestones to Neurimmune in 2021, which includes $100.0 million if launched in the U.S., $50.0 million if launched in three or more countries within the E.U. and $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the Aducanumab Collaboration Agreement with Eisai.

During the second quarter of 2020, we paid Neurimmune $75.0 million upon the completed submission of the BLA for the approval of aducanumab to the FDA, which was recognized as a charge to noncontrolling interests for the year ended December 31, 2020. In addition, for the year ended December 31, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone expense.

For additional information on our collaboration arrangements with Eisai, please read *Note 18, Collaborative and Other Relationships*, to our consolidated financial statements included in this report.

For additional information on our collaboration arrangement with Neurimmune, please read *Note 19, Investments in Variable Interest Entities*, to our consolidated financial statements included in this report.

Other Funding Commitments

As of December 31, 2020, 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 expenses of approximately $21.7 million in our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2020. We have approximately $593.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2020.

As part of the sale of our Hillerød, Denmark manufacturing operations to FUJIFILM, we provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we do not expect to incur an adverse commitment obligation associated with such guarantees. We developed this estimate using a probability-weighted estimate of

future manufacturing activity and may further adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods.

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, 2020, we have approximately $79.6 million of liabilities associated with uncertain tax positions.

As of December 31, 2020 and 2019, included in other long-term liabilities we have accrued approximately $697.0 million, respectively, under a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax). Of the amounts accrued as of December 31, 2020, $62.0 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight–year period, which started in 2018, and does 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, 2020, please read *Note 20, Litigation,* to our consolidated financial statements included in this report.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. 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 revenues and expenses. 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 revenues 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 revenues following the five-step model prescribed under Financial Accounting Standards Board (FASB) Accounting Standards Codification 606, *Revenue from Contracts with Customers*: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenues

In the U.S., we sell our products primarily to wholesale distributors and specialty pharmacy providers. 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 revenues are 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 revenues are 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 revenues, 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 cumulative revenues 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.

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 revenues. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expenses.

For additional information on our revenues, please read *Note 4, Revenues*, 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, the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

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

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

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

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

Impairment and Amortization of Long-lived Assets and Accounting for Goodwill

Long-lived Assets Other than Goodwill

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 the 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. Assets that have previously been impaired, including our vixotrigine program for the potential treatment of neuropathic pain, such as TGN, could become further impaired in the future.

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

For additional information on the impairment charges related to our long-lived assets during 2020, 2019 and 2018, please read *Note 6, Intangible Assets and Goodwill,* to our consolidated financial statements included in this report.

Goodwill

Goodwill relates largely to amounts that arose in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003 and amounts that were paid in connection with the acquisition of Fumapharm AG. Our goodwill balances represent 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.

We assess our goodwill balance within our single reporting unit annually, as of October 31, and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. 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.

We completed our required annual impairment test in the fourth quarters of 2020, 2019 and 2018 and determined in each of those periods that the carrying value of goodwill was not impaired. In each year, the fair value of our reporting unit, which includes goodwill, was significantly in excess of the carrying value of our reporting unit.

Contingent Consideration

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

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

Income Taxes

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

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

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are subject to certain risks that may affect our results of operations, cash flows and fair values of assets and liabilities, including volatility in foreign currency exchange rates, interest rate movements and pricing pressures worldwide as well as changes in economic conditions in the markets in which we operate as a result of the COVID-19 pandemic. We manage the impact of foreign currency exchange rates and interest rates through various financial instruments, including derivative instruments such as foreign currency forward contracts, interest rate lock contracts and interest rate swap contracts. We do not enter into financial instruments for trading or speculative purposes. The counterparties to these contracts are major financial institutions, and there is no significant concentration of exposure with any one counterparty.

Foreign Currency Exchange Risk

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

While the financial results of our global activities are reported in U.S. dollars, the functional currency for most of our foreign subsidiaries is their respective local currency. Fluctuations in the foreign currency exchange rates of the countries in which we do business will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar strengthens versus other currencies, the value of the non-U.S. revenues 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. expenses, 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. revenues and expenses 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 flows 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, 2020, and is not expected to have a material impact on our results of operations or financial position in the future.

Revenue and Operating Expense Hedging Program

Our foreign currency hedging program is designed to mitigate, over time, a portion of the impact resulting from volatility in exchange rate changes on revenues and operating expenses. We use foreign currency forward contracts to manage foreign currency risk, with the majority of our forward contracts used to hedge certain forecasted revenue and operating expense transactions denominated in foreign currencies in the next 24 months. We do not engage in currency speculation. For a more detailed disclosure of our revenue and operating expense hedging program, please read *Note 9, Derivative Instruments,* to our consolidated financial statements included in this report.

Our ability to mitigate the impact of foreign currency exchange rate changes on revenues 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 flows from these contracts are reported as operating activities in our consolidated statements of cash flows.

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 flows from these contracts are reported as operating activities in our consolidated statements of cash flows.

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, 2020 and 2019, 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 $458.2 million and $265.0 million, respectively. The estimated fair value change was determined by measuring the impact of the hypothetical exchange rate movement on outstanding forward contracts. Our use of this methodology to quantify the market risk of such instruments is subject to assumptions and actual impact could be significantly different. The quantitative information about market risk is limited because it does not take into account all foreign currency operating transactions.

Net Investment Hedge Program

Our net investment hedging program is designed to mitigate currency fluctuations between the U.S. dollar and the South Korean won as a result of our approximately 49.9% ownership interest in Samsung Bioepis. We entered into foreign currency forward contracts to manage the foreign currency risk with our forward contracts used to hedge changes in the spot rate over the next 10 months. As of December 31, 2020 and 2019, a hypothetical adverse 10.0% movement would result in a hypothetical decrease in fair value of approximately $56.9 million and $43.0 million, respectively. The estimated fair value was determined by measuring the impact of the hypothetical spot rate movement on outstanding forward contracts.

Interest Rate Risk

Our investment portfolio includes cash equivalents and short-term investments. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates, including changes resulting from the impact of the COVID-19 pandemic. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2020 and 2019, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $13.2 million and $21.0 million, respectively, to our interest rate sensitive instruments. The fair values of our investments were determined using third-party pricing services or other market observable data.

Pricing Pressure

Governments in certain international markets in which we operate have 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. In addition, 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 revenues 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. The continued implementation of pricing actions

throughout Europe may also lead to higher levels of parallel trade.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the way our products are prescribed and purchased. It is possible that additional federal health care reform measures will be adopted in the future, which could result in increased pricing pressure and reduced reimbursement for our products and otherwise have an adverse impact on our consolidated financial position or results of operations. 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. Managed care organizations are also continuing to seek price discounts and, in some cases, impose restrictions on the coverage of certain drugs.

Our products continue to face increasing competition in many markets from new originator therapies, generics, 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 revenues. 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 revenues in a short period of time.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020, and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

Credit Risk

We are subject to credit risk from our accounts receivable related to our product sales. The majority of our accounts receivable arise from product sales in the U.S. and Europe with concentrations of credit risk limited due to the wide variety of customers and markets using our products as well as their dispersion across many different geographic areas. Our accounts receivable are primarily due from wholesale and other third-party distributors, public hospitals, pharmacies and other government entities. 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 operate in certain countries where weakness in economic conditions, including as a result of the COVID-19 pandemic, 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, 2020 and 2019. However, if significant changes occur in the availability of government funding or the reimbursement practices of these or other governments, we may not be able to collect on amounts due to us from customers in such countries and our results of operations could be adversely affected.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-80 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) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of December 31, 2020. 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, 2020, 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, 2020. 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, 2020, 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, 2020, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

Item 9B. Other Information

None.

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. The text of our code of business conduct, which includes the code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.biogen.com, under the "*Corporate Governance*" subsection of the "*Investors*" section of the site. We intend to make all required disclosures regarding any amendments to, or waivers from, provisions of our code of business conduct at the same location of our website.

The response to the remainder of this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Proposal 1 - Election of Directors," "Corporate Governance at Biogen"* and "*Miscellaneous - Stockholder Proposals*" contained in the proxy statement for our 2021 annual meeting of stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Executive Compensation Matters*" and *"Corporate Governance at Biogen"* contained in the proxy statement for our 2021 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 2021 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference from the discussion responsive thereto in the sections entitled "*Certain Relationships and Related Person Transactions*" and *"Corporate Governance at Biogen*" contained in the proxy statement for our 2021 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 2021 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:

Certain totals may not sum due to rounding.

(2) Exhibits

The exhibits listed on the Exhibit Index beginning on page 86, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

(3) Financial Statement Schedules

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

Item 16. Form 10-K Summary

Not applicable.

EXHIBIT INDEX

Exhibit No.	Description
2.1†	Asset Purchase Agreement among Biogen Idec International Holding Ltd., Elan Pharma International Limited and Elan Pharmaceuticals, Inc., dated as of February 5, 2013. Filed as Exhibit 2.1 to our Current Report on Form 8-K/A filed on February 12, 2013.
2.2	Separation Agreement between Biogen Inc. and Bioverativ Inc. dated as of January 31, 2017. Filed as Exhibit 2.1 to our Current Report on Form 8-K filed on February 2, 2017.
3.1	Amended and Restated Certificate of Incorporation, as amended. Filed as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
3.2	Certificate of Amendment to the Certificate of Incorporation. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on March 27, 2015.
3.3	Fourth Amended and Restated Bylaws. Filed as Exhibit 3.1 to our Current Report on Form 8-K filed on June 9, 2017.
4.1	Second Supplemental Indenture, dated April 30, 2020, between Biogen Inc. and U.S. Bank National Association, including the forms of Global Notes attached as Exhibit A and Exhibit B, respectively, thereto. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on April 30, 2020.
4.1	Reference is made to Exhibit 3.1 for a description of the rights, preferences and privileges of our Series A Preferred Stock and Series X Junior Participating Preferred Stock.
4.2	Indenture between Biogen Inc. and U.S. Bank National Association, dated as of September 15, 2015. Filed as Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2015.
4.3	First Supplemental Indenture between Biogen Inc. and U.S. Bank National Association, dated September 15, 2015. Filed as Exhibit 4.2 to our Current Report on Form 8-K filed on September 16, 2015.
4.4+	Description of Securities.
10.1	Credit Agreement between Biogen Inc., Bank of America, N.A., Goldman Sachs Bank USA and other lenders party thereto, dated August 28, 2015. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on September 1, 2015.
10.2	Credit Agreement, dated as of January 28, 2020, among Biogen Inc., Bank of America, N.A., as administrative agent, swing ling lender and the L/C issuer, and the other lenders party thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 3, 2020.
10.3†	Second Amended and Restated Collaboration Agreement between Biogen Idec Inc. and Genentech, Inc., dated as of October 18, 2010. Filed as Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2010.
10.4†	Letter Agreement regarding GA101 financial terms between Biogen Idec Inc. and Genentech, Inc., dated October 18, 2010. Filed as Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 31, 2010.
10.5	Settlement and License Agreement, dated January 17, 2017, between Biogen Swiss Manufacturing GmbH, Biogen International Holdings ltd., Forward Pharma A/S and other parties thereto. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 1, 2017.
10.6*	Biogen Inc. 2017 Omnibus Equity Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed on April 26, 2017.
10.7*	Form of restricted stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.8*	Form of market stock unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.9*	Form of performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.10*	Form of cash-settled performance unit award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.
10.11*	Form of performance stock units award agreement (cash-settled) under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.10 to our Annual Report on Form 10-K for the year ended December 31, 2017.
10.12*	Form of performance stock units award agreement under the Biogen Inc. 2017 Omnibus Equity Plan. Filed as Exhibit 10.11 to our Annual Report on Form 10-K for the year ended December 31, 2017.

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

Exhibit No.	Description
10.35*	Form of indemnification agreement for directors and executive officers. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 7, 2011.
10.36*	Employment Agreement between Biogen Inc. and Michel Vounatsos dated December 18, 2016 and effective as of January 6, 2017. Filed as Exhibit 10.1 to our Current Report on Form 8-K filed on December 19, 2016.
10.37*	Letter regarding employment arrangement of Michael McDonnell dated July 16, 2020. Filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.
10.38*	Letter regarding employment arrangement of Susan Alexander dated December 13, 2005. Filed as Exhibit 10.58 to our Annual Report on Form 10-K for the year ended December 31, 2009.
10.39*	Letter regarding employment arrangement of Alfred W. Sandrock, Jr. dated May 7, 2013. Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.
10.40*	Letter regarding employment arrangement of Alfred Sandrock dated October 19, 2015. Filed as Exhibit 10.37 to our Annual Report on Form 10-K for the year ended December 31, 2015.
10.41*+	Letter regarding employment arrangement of Chirfi Guindo dated October 12, 2017.
10.42*	Letter regarding employment arrangement of Jeffrey Capello dated November 14, 2017. Filed as Exhibit 10.31 to our Annual Report on Form 10-K for the year ended December 31, 2017.
10.43*	Separation Agreement between Biogen Inc. and Jeffrey Capello dated July 16, 2020. Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.
10.44*	Letter regarding employment arrangement of Michael Ehlers dated April 16, 2016. Filed as Exhibit 10.33 to our Annual Report on Form 10-K for the year ended December 31, 2017.
21+	Subsidiaries.
23+	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm.
31.1+	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from Biogen Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, 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 Flows, (v) the Consolidated Statements of Equity and (vi) Notes to Consolidated Financial Statements.

* Management contract or compensatory plan or arrangement.

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

\+ 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/ MICHEL VOUNATSOS
Michel Vounatsos
Chief Executive Officer

Date: February 3, 2021

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

Name	Capacity	Date
/S/ MICHEL VOUNATSOS Michel Vounatsos	Director and Chief Executive Officer (principal executive officer)	February 3, 2021
/S/ MICHAEL R. MCDONNELL Michael R. McDonnell	Executive Vice President and Chief Financial Officer (principal financial officer)	February 3, 2021
/S/ ROBIN C. KRAMER Robin C. Kramer	Senior Vice President, Chief Accounting Officer (principal accounting officer)	February 3, 2021
/S/ STELIOS PAPADOPOULOS Stelios Papadopoulos	Director and Chairman of the Board of Directors	February 3, 2021
/S/ ALEXANDER J. DENNER Alexander J. Denner	Director	February 3, 2021
/S/ CAROLINE D. DORSA Caroline D. Dorsa	Director	February 3, 2021
/S/ WILLIAM A. HAWKINS William A. Hawkins	Director	February 3, 2021
/S/ NANCY L. LEAMING Nancy L. Leaming	Director	February 3, 2021
/S/ JESUS B. MANTAS Jesus B. Mantas	Director	February 3, 2021
/S/ RICHARD C. MULLIGAN Richard C. Mulligan	Director	February 3, 2021
/S/ ROBERT W. PANGIA Robert W. Pangia	Director	February 3, 2021
/S/ BRIAN S. POSNER Brian S. Posner	Director	February 3, 2021
/S/ ERIC K. ROWINSKY Eric K. Rowinsky	Director	February 3, 2021
/S/ STEPHEN A. SHERWIN Stephen A. Sherwin	Director	February 3, 2021

BIOGEN INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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

	For the Years Ended December 31,		
	2020	2019	2018
Revenues:			
Product, net	$ 10,692.2	$ 11,379.8	$ 10,886.8
Revenues from anti-CD20 therapeutic programs	1,977.8	2,290.4	1,980.2
Other	774.6	707.7	585.9
Total revenues	13,444.6	14,377.9	13,452.9
Cost and expenses:			
Cost of sales, excluding amortization and impairment of acquired intangible assets	1,805.2	1,955.4	1,816.3
Research and development	3,990.9	2,280.6	2,597.2
Selling, general and administrative	2,504.5	2,374.7	2,106.3
Amortization and impairment of acquired intangible assets	464.8	489.9	747.3
Collaboration profit (loss) sharing	232.9	241.6	185.0
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	(92.5)	55.3	—
(Gain) loss on fair value remeasurement of contingent consideration	(86.3)	(63.7)	(12.3)
Acquired in-process research and development	75.0	—	112.5
Restructuring charges	—	1.5	12.0
Total cost and expenses	8,894.5	7,335.3	7,564.3
Income from operations	4,550.1	7,042.6	5,888.6
Other income (expense), net	497.4	83.3	11.0
Income before income tax expense and equity in loss of investee, net of tax	5,047.5	7,125.9	5,899.6
Income tax expense	992.3	1,158.0	1,425.6
Equity in (income) loss of investee, net of tax	(5.3)	79.4	—
Net income	4,060.5	5,888.5	4,474.0
Net income (loss) attributable to noncontrolling interests, net of tax	59.9	—	43.3
Net income attributable to Biogen Inc.	$ 4,000.6	$ 5,888.5	$ 4,430.7
Net income per share:			
Basic earnings per share attributable to Biogen Inc.	$ 24.86	$ 31.47	$ 21.63
Diluted earnings per share attributable to Biogen Inc.	$ 24.80	$ 31.42	$ 21.58
Weighted-average shares used in calculating:			
Basic earnings per share attributable to Biogen Inc.	160.9	187.1	204.9
Diluted earnings per share attributable to Biogen Inc.	161.3	187.4	205.3

See accompanying notes to these consolidated financial statements.

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

	For the Years Ended December 31,		
	2020	2019	2018
Net income attributable to Biogen Inc.	$ 4,000.6	$ 5,888.5	$ 4,430.7
Other comprehensive income:			
Unrealized gains (losses) on securities available for sale, net of tax	(2.8)	8.2	(3.9)
Unrealized gains (losses) on cash flow hedges, net of tax	(186.8)	(26.9)	139.2
Gains (losses) on net investment hedges, net of tax	(33.6)	21.6	3.5
Unrealized gains (losses) on pension benefit obligation, net of tax	(33.5)	(1.5)	5.5
Currency translation adjustment	92.9	103.8	(67.8)
Total other comprehensive income (loss), net of tax	(163.8)	105.2	76.5
Comprehensive income attributable to Biogen Inc.	3,836.8	5,993.7	4,507.2
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	60.9	(0.4)	42.9
Comprehensive income	$ 3,897.7	$ 5,993.3	$ 4,550.1

See accompanying notes to these consolidated financial statements.

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

	As of December 31, 2020	As of December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,331.2	$ 2,913.7
Marketable securities	1,278.9	1,562.2
Accounts receivable, net	1,913.8	1,880.5
Due from anti-CD20 therapeutic programs	413.5	590.2
Inventory	1,068.6	804.2
Other current assets	881.1	631.0
Total current assets	6,887.1	8,381.8
Marketable securities	772.1	1,408.1
Property, plant and equipment, net	3,411.5	3,247.3
Operating lease assets	433.3	427.0
Intangible assets, net	3,084.3	3,527.4
Goodwill	5,762.1	5,757.8
Deferred tax asset	1,369.5	3,232.1
Investments and other assets	2,899.0	1,252.8
Total assets	$ 24,618.9	$ 27,234.3
LIABILITIES AND EQUITY		
Current liabilities:		
Current portion of notes payable	$ —	$ 1,495.8
Taxes payable	142.0	71.4
Accounts payable	454.9	530.8
Accrued expenses and other	3,145.3	2,765.8
Total current liabilities	3,742.2	4,863.8
Notes payable	7,426.2	4,459.0
Deferred tax liability	1,032.8	2,810.8
Long-term operating lease liabilities	402.0	412.7
Other long-term liabilities	1,329.6	1,348.9
Total liabilities	13,932.8	13,895.2
Commitments, contingencies and guarantees (Notes 21 and 22)		
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	—	—
Accumulated other comprehensive loss	(299.0)	(135.2)
Retained earnings	13,976.3	16,455.4
Treasury stock, at cost; 23.8 million and 23.8 million shares, respectively	(2,977.1)	(2,977.1)
Total Biogen Inc. shareholders' equity	10,700.3	13,343.2
Noncontrolling interests	(14.2)	(4.1)
Total equity	10,686.1	13,339.1
Total liabilities and equity	$ 24,618.9	$ 27,234.3

See accompanying notes to these consolidated financial statements.

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

	For the Years Ended December 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 4,060.5	$ 5,888.5	$ 4,474.0
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	457.2	464.7	650.5
Impairment of intangible assets	209.7	215.9	366.1
Acquired in-process research and development	75.0	—	112.5
Share-based compensation	198.3	182.3	157.5
Contingent consideration	(86.3)	(63.7)	(12.3)
(Gain)/loss on divestiture of Hillerod, Denmark manufactuing operations	(92.5)	55.3	—
Deferred income taxes	149.0	67.1	108.3
Unrealized (gain) loss on strategic investments	(681.8)	(147.3)	(124.8)
Loss on equity method investment	(3.3)	77.4	—
Other	131.2	139.1	55.7
Changes in operating assets and liabilities, net:			
Accounts receivable	2.8	68.8	(205.2)
Due from anti-CD20 therapeutic programs	176.7	(63.3)	5.7
Inventory	(316.3)	(19.2)	(52.1)
Accrued expenses and other current liabilities	154.2	240.2	465.5
Income tax assets and liabilities	(67.5)	16.1	321.7
Other changes in operating assets and liabilities, net	(137.1)	(43.3)	(135.4)
Net cash flows provided by operating activities	4,229.8	7,078.6	6,187.7
Cash flows from investing activities:			
Proceeds from sales and maturities of marketable securities	7,299.4	6,007.0	9,173.7
Purchases of marketable securities	(6,397.7)	(5,252.6)	(7,694.8)
Contingent consideration paid related to Fumapharm AG acquisition	—	(300.0)	(1,500.0)
Acquisition of Nightstar Therapeutics plc, net of cash acquired	—	(744.4)	—
Purchase of Ionis Pharmaceuticals, Inc. stock	—	—	(462.9)
Purchase of Sangamo Therapeutics, Inc. stock	(141.8)	—	—
Purchase of Denali Therapeutics Inc. stock	(423.7)	—	—
Purchase of Sage Therapeutics, Inc. stock	(441.0)	—	—
Proceeds from divesiture of Hillerod, Denmark manufacturing operations	—	923.7	—
Purchases of property, plant and equipment	(424.8)	(514.5)	(770.6)
Acquired in-process research and development	(75.0)	—	(112.5)
Acquisitions of intangible assets	(52.0)	(155.0)	(3.0)
Investment in Samsung Bioepis	—	—	(676.6)
Proceeds from sales of strategic investments	74.9	479.3	—
Other	(26.9)	27.0	0.4
Net cash flows provided by (used in) investing activities	(608.6)	470.5	(2,046.3)
Cash flows from financing activities:			
Purchase of treasury stock	(6,679.1)	(5,868.3)	(4,352.6)
Payments related to issuance of stock for share-based compensation arrangements, net	(4.6)	—	—
Proceeds from borrowings	2,967.4	—	—
Repayments of borrowings	(1,500.0)	—	(3.2)
Net contribution (distribution) to noncontrolling interest	(71.0)	4.3	(36.4)
Contingent consideration payments	—	—	(58.2)
Other	14.6	3.6	(21.6)
Net cash flows (used in) financing activities	(5,272.7)	(5,860.4)	(4,472.0)
Net increase (decrease) in cash and cash equivalents	(1,651.5)	1,688.7	(330.6)
Effect of exchange rate changes on cash and cash equivalents	69.0	0.4	(18.6)
Cash and cash equivalents, beginning of the year	2,913.7	1,224.6	1,573.8
Cash and cash equivalents, end of the year	$ 1,331.2	$ 2,913.7	$ 1,224.6

See accompanying notes to these consolidated financial statements.

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

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

See accompanying notes to these consolidated financial statements.

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2018	—	$ —	221.0	$ 0.1	$ —	$ (240.4)	$16,257.0	(23.8)	$(2,977.1)	$ 13,039.6	$ (8.0)	$13,031.6
Net income	—	—	—	—	—	—	5,888.5	—	—	5,888.5	—	5,888.5
Other comprehensive income (loss), net of tax	—	—	—	—	—	105.2	—	—	—	105.2	(0.4)	104.8
Capital contribution from noncontrolling interest	—	—	—	—	—	—	—	—	—	—	4.3	4.3
Repurchase of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(14.7)	(3,720.9)	(3,720.9)	—	(3,720.9)
Retirement of common stock pursuant to the March 2019 Share Repurchase Program, at cost	—	—	(14.7)	—	(121.5)	—	(3,599.4)	14.7	3,720.9	—	—	—
Repurchase of common stock pursuant to the 2018 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(8.9)	(2,147.4)	(2,147.4)	—	(2,147.4)
Retirement of common stock pursuant to the 2018 Share Repurchase Program, at cost	—	—	(8.9)	—	(110.5)	—	(2,036.9)	8.9	2,147.4	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	40.8	—	—	—	—	40.8	—	40.8
Issuance of common stock under stock award plan	—	—	0.4	—	—	—	(53.8)	—	—	(53.8)	—	(53.8)
Compensation related to share-based payments	—	—	—	—	191.2	—	—	—	—	191.2	—	191.2
Balance, December 31, 2019	—	$ —	198.0	$ 0.1	$ —	$ (135.2)	$16,455.4	(23.8)	$(2,977.1)	$ 13,343.2	$ (4.1)	$13,339.1

See accompanying notes to these consolidated financial statements.

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

	Preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Treasury stock		Total Biogen Inc. shareholders' equity	Noncontrolling interests	Total equity
	Shares	Amount	Shares	Amount				Shares	Amount			
Balance, December 31, 2017	—	$ —	235.3	$ 0.1	$ 97.8	$ (318.4)	$15,810.4	(23.8)	$(2,977.1)	$ 12,612.8	$ (14.7)	$12,598.1
Net income	—	—	—	—	—	—	4,430.7	—	—	4,430.7	43.3	4,474.0
Other comprehensive income (loss), net of tax	—	—	—	—	—	76.5	—	—	—	76.5	(0.4)	76.1
Capital contribution from noncontrolling interests	—	—	—	—	—	—	—	—	—	—	13.8	13.8
Distribution to noncontrolling interests	—	—	—	—	—	—	—	—	—	—	(50.0)	(50.0)
Repurchase of common stock pursuant to the 2018 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(4.3)	(1,352.6)	(1,352.6)	—	(1,352.6)
Retirement of common stock pursuant to the 2018 Share Repurchase Program, at cost	—	—	(4.3)	—	(92.8)	—	(1,259.8)	4.3	1,352.6	—	—	—
Repurchase of common stock pursuant to the 2016 Share Repurchase Program, at cost	—	—	—	—	—	—	—	(10.5)	(3,000.0)	(3,000.0)	—	(3,000.0)
Retirement of common stock pursuant to the 2016 Share Repurchase Program, at cost	—	—	(10.5)	—	(171.1)	—	(2,828.9)	10.5	3,000.0	—	—	—
Issuance of common stock under stock option and stock purchase plans	—	—	0.2	—	41.2	—	—	—	—	41.2	—	41.2
Issuance of common stock under stock award plan	—	—	0.3	—	(43.8)	—	—	—	—	(43.8)	—	(43.8)
Compensation expense related to share-based payments	—	—	—	—	168.7	—	—	—	—	168.7	—	168.7
Adoption of new accounting guidance	—	—	—	—	—	1.5	104.6	—	—	106.1	—	106.1
Balance, December 31, 2018	—	$ —	221.0	$ 0.1	$ —	$ (240.4)	$16,257.0	(23.8)	$(2,977.1)	$ 13,039.6	$ (8.0)	$13,031.6

See accompanying notes to these consolidated financial statements.

1. Summary of Significant Accounting Policies

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

Business Overview

Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our core growth areas include multiple sclerosis (MS) and neuroimmunology; Alzheimer's disease and dementia; neuromuscular disorders, including spinal muscular atrophy (SMA) and amyotrophic lateral sclerosis (ALS); movement disorders, including Parkinson's disease; ophthalmology; and neuropsychiatry. We are also focused on discovering, developing and delivering worldwide innovative therapies in our emerging growth areas of immunology; acute neurology; and neuropathic pain. In addition, we commercialize biosimilars of advanced biologics. We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development programs and business development opportunities.

Our marketed products include TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, TYSABRI and FAMPYRA for the treatment of MS; SPINRAZA for the treatment of SMA; and FUMADERM for the treatment of severe plaque psoriasis. We have certain business and financial rights with respect to RITUXAN for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia (CLL) and other conditions; RITUXAN HYCELA for the treatment of non-Hodgkin's lymphoma and CLL; GAZYVA for the treatment of CLL and follicular lymphoma; OCREVUS for the treatment of primary progressive MS (PPMS) and relapsing MS (RMS); and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, Inc. (Genentech), a wholly-owned member of the Roche Group. For additional information on our collaboration arrangements with Genentech, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Our innovative drug development and commercialization activities are complemented by our biosimilar business that expands access to medicines and reduces the cost burden for healthcare systems. Through our agreements with Samsung Bioepis Co., Ltd. (Samsung Bioepis), our joint venture with Samsung BioLogics Co., Ltd. (Samsung BioLogics), we market and sell BENEPALI, an etanercept biosimilar referencing ENBREL, IMRALDI, an adalimumab biosimilar referencing HUMIRA, and FLIXABI, an infliximab biosimilar referencing REMICADE, in certain countries in Europe and have an option to acquire exclusive rights to commercialize these products in China. Additionally, we have exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the United States (U.S.), Canada, Europe, Japan and Australia. For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, 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 those of certain variable interest entities where we are the primary beneficiary. For consolidated entities where we own or are exposed to less than 100.0% of the economics, we record net income (loss) attributable to noncontrolling interests 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. These considerations impact the way we account for our existing collaborative relationships and other arrangements. We continuously assess whether we are the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in us consolidating or deconsolidating one or more of our collaborators or partners.

Use of Estimates

The preparation of our consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. 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 revenues and expenses. Actual results may differ from these estimates.

The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, depends on future developments that are highly uncertain, subject to change and are difficult to predict, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19 as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our condensed consolidated financial statements and there may be changes to those estimates in future periods.

Revenue Recognition

In May 2014 the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry specific guidance. This standard requires a company to recognize revenues when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This standard became effective for us on January 1, 2018, and was adopted using the modified retrospective method. The adoption of this standard as of January 1, 2018, did not change our revenue recognition.

We recognize revenues 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 revenues following the five-step model prescribed under the FASB Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenues

In the U.S., we sell our products primarily to wholesale distributors and specialty pharmacy providers. 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 revenues are 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 revenues are 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 revenues, 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 revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

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

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

- Medicaid rebates relate to our estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in other current liabilities. 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 in product revenue and 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 chargebacks consist of amounts that we expect to issue 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 expenses and other current liabilities. 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 expenses and other current liabilities. 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 expected to be made by wholesalers and are recorded in the period the related revenue is recognized, resulting in a reduction to product revenues. 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 revenues. To the extent we can demonstrate a separable benefit and fair value for these services we classify these payments in selling, general and administrative expenses.

Revenues from Anti-CD20 Therapeutic Programs

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

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

Revenues from anti-CD20 therapeutic programs consist of:

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

(ii) other revenues from anti-CD20 therapeutic programs, which primarily consist of our share of pre-tax co-promotion profits on RITUXAN in Canada and royalty revenues on sales of OCREVUS.

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

We recognize royalty revenues 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 revenues will be adjusted for in the period in which they become known, which is generally expected to be the following quarter.

For additional information on our relationship with Genentech, please read *Note 18, Collaborative and Other Relationships,* to these consolidated financial statements.

Other Revenues

Royalty Revenues

We recognize royalty revenues related to sales by our licensees of products covered under patents that we own.

Collaborative and Other Relationships

We have a number of significant collaborative and other third-party relationships for revenues 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 revenues, cost of sales

and operating expenses 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, we record our share of the revenues, cost of sales and operating expenses on a net basis in collaborative and other relationships included in other revenues in our consolidated statements of income.

Our development and commercialization arrangements with Genentech 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. Therefore, revenues relating to royalties or profit-sharing amounts received are recognized as the underlying sales occur.

For additional information on our collaboration arrangements with Genentech and Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Other Corporate Revenues

We record other corporate revenues primarily from amounts earned under contract manufacturing agreements. Revenues under contract manufacturing agreements are 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.

Fair Value Measurements

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

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

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

We validate the prices provided by our third-party pricing services by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances. The option pricing valuation models use assumptions within the model, including the term, stock price volatility, constant maturity risk-free interest rate and dividend yield. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2020 and 2019.

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 expenses 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, 2020 and 2019, cash equivalents were comprised of money market funds, commercial paper, overnight reverse repurchase agreements and other debt securities with maturities less than 90 days 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.

In countries where we have experienced a pattern of payments extending beyond our contractual payment term and we expect to collect receivables greater than one year from the time of sale, we have assessed whether the customer has a significant financing component and discounted our receivables and reduced related revenues over the period of time that we estimate those amounts will be paid using the country's market-based borrowing rate for such period. The related receivables are classified at the time of sale as non-current assets. We accrete interest income on these receivables, which is recorded as a component of other income (expense), net in our consolidated statements of income.

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.

Concentration of Credit Risk

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

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

Marketable Securities and Other Investments

Marketable Debt Securities

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

Marketable Equity Securities and Venture Capital Funds

Our marketable equity securities are recorded at fair market value and, beginning January 1, 2018, unrealized gains and losses are included in other income (expense), net in our consolidated statements of income. Prior to January 1, 2018, unrealized gains and losses were included in accumulated other comprehensive income (loss) in equity, net of related tax effects. 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, beginning January 1, 2018, unrealized gains and losses are included in other income (expense), net in our consolidated statements of income. Prior to January 1, 2018, these investments were accounted for under the cost method of accounting. 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 changes in observable prices, depending on our ownership percentage and other factors that suggest we have significant influence. We monitor these investments to evaluate whether any increase or decline in their value has occurred, based on the implied value of recent company financings, public market prices of comparable companies and general market conditions. These investments are included in investments and other assets in our consolidated balance sheets.

Evaluating Marketable Debt Securities for Other-than-Temporary Impairments

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

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

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

Equity Method of Accounting

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

Inventory

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

Capitalization of Inventory Costs

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

inventory upon a change in such judgment, due to, among other potential factors, a denial or significant delay of approval by necessary regulatory bodies.

At December 31, 2020, we capitalized approximately $93.8 million of pre-launch inventory for aducanumab, an anti-amyloid beta antibody candidate for the potential treatment of Alzheimer's disease that we are developing in collaboration with Eisai Co., Ltd. (Eisai). If aducanumab does not receive regulatory approval in the U.S., we would expense this inventory as research and development expense and, under the terms of our collaboration agreement with Eisai to jointly develop and commercialize aducanumab, Eisai would reimburse us for 45.0% of the costs.

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.

Property, Plant and Equipment

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

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

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

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

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

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

Leases

In February 2016 the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, a new standard issued to increase transparency and comparability among organizations related to their leasing activities. This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and lease liabilities on their balance sheet that arise from leases as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*, ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, ASU No. 2018-20, *Narrow-Scope Improvement for Lessors*, and ASU No. 2019-01, *Leases (Topic 842): Codification Improvements*. We adopted these amendments with ASU 2016-02 (collectively, the new leasing standards) effective January 1, 2019.

We adopted the new leasing standards using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, we elected the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within our consolidated balance sheets and to recognize those lease payments on a straight-line basis in our consolidated statements of income over the lease term. Upon adoption of the new leasing standards we recognized an operating lease asset of approximately $463.0 million and a corresponding operating lease liability of approximately $526.0 million, which are included in our consolidated balance sheets. The adoption of the new leasing standards did not have an impact on our consolidated statements of income.

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 we will exercise that option.

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 expenses and other and in long-term operating lease liabilities in our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We also have real estate lease agreements which are subleased to third parties. Operating leases for which we are the sublessor are included in accrued expenses 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 the adoption of the new leasing standards, please read *Note 11, Leases*, to these consolidated financial statements.

Intangible Assets

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

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

Acquired and in-licensed rights and patents primarily relate to our acquisition of all remaining rights to TYSABRI from Elan Pharma International Ltd. (Elan), an affiliate of Elan Corporation, plc. Acquired and in-licensed rights and patents also include other amounts related to our other marketed products and programs acquired through business combinations. Developed technology primarily relates to our AVONEX product, which was recorded in connection with the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in 2003. We amortize the intangible assets related to our TYSABRI, AVONEX, SPINRAZA, VUMERITY and TECFIDERA (rest of world) products using the economic consumption method based on revenues generated from the products underlying the related intangible assets. An analysis of the anticipated lifetime revenues of our TYSABRI, AVONEX, SPINRAZA, VUMERITY and TECFIDERA (rest of world) products is performed annually during our long-range planning cycle and whenever events or changes in circumstances would significantly affect the anticipated lifetime revenues of our TYSABRI, AVONEX, SPINRAZA, VUMERITY and TECFIDERA (rest of world) products.

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

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

Acquired IPR&D represents the fair value assigned to research and development assets that have not reached technological feasibility. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenues from the projects and discounting the net cash flows to present value. The revenues and costs 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 flows to their 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 flows, 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 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. Assets that have been previously impaired, including our vixotrigine (BIIB074) program for the potential treatment of neuropathic pain, such as trigeminal neuralgia (TGN), could become further impaired in the future.

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. Goodwill 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 24, Segment Information,* to these consolidated financial statements, we operate in 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 flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

Contingent Consideration

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

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

Derivative Instruments and Hedging Activities

Cash Flow and Fair Value Derivative Instruments

We recognize all derivative instruments as either assets or liabilities at fair value in our consolidated balance sheets. Changes in the fair value of our derivative instruments are recognized each period in current earnings or accumulated other comprehensive income (loss), depending on whether the derivative instrument is designated as part of a hedge transaction and, if so, the type of hedge transaction. We classify the cash flows from these instruments in the same category as the cash flows 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 flows 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

We are exposed to the impact of foreign exchange fluctuations on our investment in the equity of Samsung Bioepis, which is denominated in a currency other than the U.S. dollar, and could adversely impact the U.S. dollar value of this investment. Using derivative instruments, we have hedged our net investment position to mitigate the effects of foreign exchange fluctuations. We recognize these designated net investment hedges as either assets or liabilities, at fair value, in our consolidated balance sheets. We hedge the changes in the spot exchange rate in accumulated other comprehensive income (loss) and exclude changes to the forward rate and amortize the forward points in other income (expense), net in our consolidated statements of income over the term of the contract. We classify the cash flows from these instruments in the same category as the cash flows from the hedged items.

For additional information on our derivative instruments and hedging activities, please read *Note 9, Derivative Instruments*, to these consolidated financial statements.

Translation of Foreign Currencies

The functional currency for most of our foreign subsidiaries is their local currency. For our non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of the financial statements of our foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of equity. For subsidiaries where the functional currency of the assets and liabilities differ from the local currency, non-monetary assets and liabilities are translated at the rate of exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date. Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other income (expense), net in our consolidated statements of income.

Royalty Cost of Sales

We make royalty payments to a number of third parties under license or purchase agreements associated with our acquisition of intellectual property. These royalty payments are typically calculated as a percentage (royalty rate) of the sales of our products in a particular year. That royalty rate may remain constant, increase or decrease within each year based on the total amount of sales during the annual period. Each quarterly period, we estimate our total royalty obligation for the full year and recognize the proportional amount as cost of sales based on actual quarterly sales as a percentage of full year estimated sales. For example, if the level of net sales in any calendar year increases the royalty rate within the year, we will record our cost of sales at an even rate over the year, based on the estimated blended royalty rate.

Accounting for Share-Based Compensation

Our share-based compensation programs grant awards that have included stock options, restricted stock units that vest based on stock performance known as market stock units (MSUs), performance-vested restricted stock units that settle in cash (CSPUs), time-vested restricted stock units (RSUs), performance-vested restricted stock units that can be settled in cash or shares of our common stock (PUs) at the sole discretion of the Compensation and Management Development Committee of our Board of Directors, performance-vested stock units that settle in stock or cash (PSUs) and shares issued under our employee stock purchase plan (ESPP). Compensation expense is recognized based on the estimated fair value of the awards at grant date. We recognize compensation expense for the number of awards expected to vest after taking into consideration an estimate of award forfeitures over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods (for instance, where a portion of the award vests upon retirement eligibility), we estimate and recognize expense based on the period from the grant date to the date the employee becomes retirement eligible.

The fair values of our MSUs are estimated using a lattice model with a Monte Carlo simulation. We apply an accelerated attribution method to recognize share-based compensation expense over the applicable service period

for our MSUs. The probability of actual shares expected to be earned is considered in the grant date valuation, therefore the expense is not adjusted to reflect the actual units earned.

The fair values of our RSUs are based on the market value of our stock on the date of grant. Compensation expense for RSUs is recognized straight-line over the applicable service period.

We apply an accelerated attribution method to recognize share-based compensation expense when accounting for our CSPUs, PUs and PSUs that settle in cash, and the fair value of the liability is remeasured at the end of each reporting period through expected settlement. Compensation expense associated with CSPUs, PUs and PSUs that settle in cash are based upon the stock price and the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the targeted payout level associated with the performance criteria expected to be achieved. Cumulative adjustments are recorded each quarter to reflect changes in the stock price and estimated outcome of the performance-related conditions until the date results are determined and settled. If performance criteria are not met or not expected to be met, any compensation expense previously recognized to date associated with the awards will be reversed.

The fair values of PSUs that settle in stock are based upon the stock price on the date of grant. Compensation expense is recognized for the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the targeted payout level associated with the performance criteria expected to be achieved. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. If performance criteria are not met or not expected to be met, any compensation expense previously recognized to date associated with the awards will be reversed.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities, which include compensation and benefits, facilities and overhead expenses, clinical trial expenses and fees paid to contract research organizations (CROs), clinical supply and manufacturing expenses, write-offs of inventory that was previously capitalized in anticipation of product launch and determined to no longer be realizable and other outside expenses and upfront fees and milestones paid to third-party collaborators. Research and development expenses are 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 18, Collaborative and Other Relationships,* to these consolidated financial statements. Because an initial indication has been approved for both RITUXAN and GAZYVA, expenses incurred by Genentech in the ongoing development of RITUXAN and GAZYVA are not recorded as research and development expense, but rather reduce our share of profits recorded as a component of revenues from anti-CD20 therapeutic programs.

For collaborations with commercialized products, if we are the principal, we record revenues and the corresponding operating costs in their respective line items in our consolidated statements of income. If we are not the principal, we record operating costs as a reduction of revenue.

Selling, General and Administrative Expenses

Selling, general and administrative expenses are 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 expenses and other general and administrative costs.

Advertising costs are expensed as incurred. For the years ended December 31, 2020, 2019 and 2018, advertising costs totaled $111.8 million, $79.2 million and $90.2 million, respectively.

Income Taxes

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. We evaluate the realizability of our deferred tax assets and establish a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized. We recognize deferred taxes associated with our global intangible low-taxed income (GILTI) tax calculations.

The income tax consequences from the intra-entity transfers of inventory within our consolidated group, both current and deferred, are recorded as a prepaid tax or deferred charge and recognized through our consolidated statements of income when the inventory is sold to a third party.

In October 2016 the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other Than Inventory*. This standard eliminates the deferral of the tax effects of intra-entity asset transfers other than inventory. As a result, the income tax consequences from the intra-entity transfer of an asset other than inventory and associated changes to deferred taxes will be recognized when the transfer occurs.

We adopted this standard on January 1, 2018, using the modified retrospective method, through a cumulative-effect adjustment to retained earnings as of that date. Upon adoption, we recognized additional net deferred tax assets of approximately $0.5 billion, offset by a corresponding net increase to retained earnings of approximately $0.5 billion. In the fourth quarter of 2018, when we elected to begin recognizing deferred taxes on the GILTI tax calculation, we recorded an additional deferred tax liability of $0.4 billion with a corresponding reduction to our retained earnings as these differences are related to intra-entity transactions. We will recognize incremental deferred income tax expense thereafter as these deferred tax assets and liabilities are utilized.

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 expense.

Contingencies

We are currently involved in various claims and legal proceedings. Loss contingency provisions are recorded if the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated or a range of loss can be determined. These accruals represent management's best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. Significant judgment is required in both the determination of probability and as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may change our estimates. Legal costs associated with legal proceedings are expensed when incurred.

Earnings per Share

Basic earnings per share is computed by dividing undistributed net income attributable to Biogen Inc. by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed based on the treasury method by dividing net income by the weighted-average number of common shares outstanding during the period plus potentially dilutive common equivalent shares outstanding.

New Accounting Pronouncements

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

Leases

In February 2016 the FASB issued the new leasing standards to increase transparency and comparability among organizations related to their leasing activities. For additional information on the adoption of the new leasing standards, please read the section titled *Lease* above, and *Note 11, Leases*, to these consolidated financial statements.

Credit Losses

In June 2016 the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2020. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, these standards now require allowances to be recorded instead of reducing the amortized cost of the investment. These standards limit the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases.

Based on the composition of our investment portfolio, accounts receivable and other financial assets, current market conditions and historical credit loss activity, the adoption of these standards did not have a material impact on our consolidated financial position and results of operations and related disclosures.

Debt Securities

In March 2017 the FASB issued ASU No. 2017-08, *Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities*. This standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period to the earliest call date. This standard became effective for us on January 1, 2019, and was adopted using a modified retrospective transition approach. The adoption of this standard did not result in a significant adjustment to our marketable debt securities.

Fair Value Measurements

In August 2018 the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for us on January 1, 2020. The adoption of this standard did not have a material impact on our disclosures.

Derivative Instruments and Hedging Activities

In October 2018 the FASB issued ASU No. 2018-16, *Derivatives and Hedging (Topic 815): Inclusion of the Secured Overnight Financing Rate (SOFR) Overnight Index Swap (OIS) Rate as a Benchmark Interest Rate for Hedge Accounting Purposes.* This standard permits use of the OIS rate based on the SOFR as a U.S. benchmark interest rate for hedge accounting purposes under ASC 815, *Derivatives and Hedging*. This standard became effective for us on January 1, 2019, and did not have an impact on our consolidated results of operations or financial position.

Collaborative Arrangements

In November 2018 the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606.* This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, *Revenue from Contracts with Customers,* when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, *Collaborative Arrangements*, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and

- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for us on January 1, 2020. A retrospective transition approach is required for either all contracts or only for contracts that are not completed at the date of initial application of ASC 606, with a cumulative adjustment to opening retained earnings, as of January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial position, results of operations and related disclosures.

2. Acquisitions

BIIB118 Acquisition

In March 2020 we acquired BIIB118 (CK1 inhibitor), a novel CNS-penetrant small molecule inhibitor of casein kinase 1, for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases from Pfizer Inc. (Pfizer). We are developing BIIB118 for the potential treatment of irregular sleep wake rhythm disorder in Parkinson's disease and plan to develop BIIB118 for the potential treatment of sundowning in Alzheimer's disease.

In connection with this acquisition, we made an upfront payment of $75.0 million to Pfizer, which was accounted for as an asset acquisition and recorded as acquired IPR&D in our consolidated statements of income as BIIB118 has not yet reached technological feasibility. We may also pay Pfizer up to $635.0 million in potential additional development and commercialization milestone payments as well as tiered royalties in the high single digits to sub-teens.

Acquisition of Nightstar Therapeutics plc

In June 2019 we completed our acquisition of all of the outstanding shares of Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. As a result of this acquisition, we added two mid- to late-stage clinical assets, as well as preclinical programs, in ophthalmology. These assets include BIIB111 (timrepigene emparvovec), which is in Phase 3 development for the potential treatment of choroideremia, a rare, degenerative, X-linked inherited retinal disorder that leads to blindness and currently has no approved treatments, and BIIB112 (RPGR gene therapy), which is in Phase 2/3 development for the potential treatment of X-linked retinitis pigmentosa, which is a rare inherited retinal disease with no currently approved treatments.

Under the terms of the acquisition, we paid NST shareholders $25.50 in cash for each issued and outstanding NST share, which totaled $847.6 million. In addition, we paid $4.6 million in cash for equity compensation, which is attributable to pre-combination services and is reflected as a component of the total purchase price paid. The fair value of equity compensation attributable to the post-combination service period was $26.2 million, of which $18.4 million was recognized as a charge to selling, general and administrative expense with the remaining $7.8 million as a charge to research and development expense in our consolidated statements of income. These amounts were associated with the accelerated vesting of stock options previously granted to NST employees and were fully paid in cash as of June 30, 2019. We funded this acquisition through available cash and accounted for it as an acquisition of a business. We finalized purchase accounting for this acquisition in the fourth quarter of 2019.

The fair value of the IPR&D programs acquired was determined through a probability adjusted discounted cash flow analysis utilizing a discount rate of 12.5%. We recorded IPR&D assets for BIIB111 and BIIB112 at their initial fair values of $480.0 million and $220.0 million, respectively. Some of the more significant assumptions utilized in our asset valuations included the estimated net cash flows for each year for each asset or product, including net revenues, cost of sales, research and development and other operating expenses, the potential regulatory and commercial success risks, competitive trends impacting the asset and each cash flow stream as well as other factors. These fair value measurements were based on significant inputs not observable in the market and thus represent Level 3 fair value measurements.

We recognized goodwill in relation to the fair value associated with NST workforce's expertise and early research in retinal disorders. We also recognized goodwill in relation to the establishment of a deferred tax liability for the acquired IPR&D intangible assets, which have no tax basis. This deferred tax liability is net of the related impacts on the deferred taxes for GILTI. Goodwill that is tax deductible for GILTI purposes is approximately $60.9 million as of December 31, 2020.

Pro forma results of operations as a result of this acquisition have not been presented as this acquisition is not material to our consolidated statements of income. Subsequent to June 7, 2019, the acquisition date, our results of operations include the results of operations of NST.

BIIB100 Acquisition

In January 2018 we acquired BIIB100 (XPO1 inhibitor) from Karyopharm Therapeutics Inc. (Karyopharm). BIIB100 is a Phase 1 investigational oral compound for the potential treatment of certain neurological and neurodegenerative diseases, primarily in ALS. BIIB100 is a novel therapeutic candidate that works by inhibiting a protein known as XPO1, with the goal of reducing inflammation and neurotoxicity, along with increasing neuroprotective responses.

We accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of $10.0 million to Karyopharm, which was recorded as acquired IPR&D in our consolidated statements of income as BIIB100 had not yet reached technological feasibility. We may also pay Karyopharm up to $207.0 million in additional milestone payments as well as tiered royalties on potential net commercial sales in the mid-single digit to low-teen percentages.

BIIB104 Acquisition

In April 2018 we acquired BIIB104 (AMPA) from Pfizer. BIIB104 is a first-in-class, Phase 2b ready AMPA receptor potentiator for cognitive impairment associated with schizophrenia. AMPA receptors mediate fast excitatory synaptic transmission in the central nervous system, a process which can be disrupted in a number of neurological and psychiatric diseases, including schizophrenia.

We accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of $75.0 million to Pfizer, which was recorded as acquired IPR&D in our consolidated statements of income as BIIB104 had not yet reached technological feasibility. We may also pay Pfizer up to $515.0 million in total development and commercialization milestone payments as well as tiered royalties on potential net commercial sales in the low to mid-teen percentages.

BIIB110 Acquisition

In July 2018 we acquired BIIB110 (ActRIIA/B ligand trap) and ALG-802 from AliveGen Inc. (AliveGen). BIIB110 and ALG-802 represent novel ways of targeting the myostatin pathway. We initially plan to study BIIB110 in multiple neuromuscular indications, including SMA and ALS.

We accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single asset. In connection with the closing of this transaction, we made an upfront payment of $27.5 million to AliveGen, which was recorded as acquired IPR&D in our consolidated statements of income as BIIB110 had not yet reached technological feasibility. We may also pay AliveGen up to $535.0 million in additional development and commercialization milestones.

3. Divestitures

Divestiture of Hillerød, Denmark Manufacturing Operations

In August 2019 we completed the sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM Corporation (FUJIFILM). Upon the closing of this transaction, we received approximately $881.9 million in cash, which may be adjusted based on other contractual terms, which are discussed below. We determined that the operations disposed of in this transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

As part of this transaction, we provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we do not expect to incur an adverse commitment obligation associated with such guarantees. We may further adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods. We also may be obligated to indemnify FUJIFILM for liabilities that existed relating to certain business activities incurred prior to the closing of this transaction.

In addition, we may earn certain contingent payments based on future manufacturing activities at the Hillerød facility. For the disposition of a business, our policy is to recognize contingent consideration when the consideration is realizable. We currently believe the probability of earning these payments is remote and therefore we did not include these contingent payments in our calculation of the fair value of the operations.

As part of this transaction, we entered into certain manufacturing services agreements with FUJIFILM pursuant to which FUJIFILM will use the Hillerød facility to produce commercial products for us, such as TYSABRI, as well as other third-party products.

For the year ended December 31, 2019, we recognized a total net loss of approximately $124.2 million related to the transaction in our consolidated statements of income. This loss included a pre-tax loss of $55.3 million, which was recorded in loss on divestiture of Hillerød, Denmark manufacturing operations. The loss recognized was based on exchange rates and business conditions on the closing date of this transaction, and included costs to sell our Hillerød, Denmark manufacturing operations of approximately $11.2 million and our estimate of the fair value of adverse commitments of approximately $74.0 million, primarily associated with the guarantee of future minimum batch production at the Hillerød facility. We also recorded a tax expense of $68.9 million related to this transaction.

In addition, upon the closing of this transaction, we sold to FUJIFILM $41.8 million of raw materials that were remaining at the Hillerød facility on the closing date of this transaction. These materials were sold at cost, which approximates fair value.

During the year ended December 31, 2020, we reduced our estimate of the fair value of the adverse commitment associated with the guarantee of future batch production by approximately $62.0 million based on our current manufacturing forecasts. Additionally, we recorded a reduction to our pre-tax loss of approximately $30.5 million due to a refund of interest paid associated with a tax matter.

Our estimate of the fair value of the adverse commitments is a Level 3 measurement and is based on forecasted batch production at the Hillerød facility.

4. Revenues

Product Revenues

Revenues by product are summarized as follows:

	For the Years Ended December 31,								
	2020			2019			2018		
(In millions)	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
Fumarate*	$ 2,742.0	$ 1,163.4	$ 3,905.4	$ 3,312.0	$ 1,126.2	$ 4,438.2	$ 3,253.2	$ 1,020.9	$ 4,274.1
Interferon**	1,273.5	604.0	1,877.5	1,426.6	675.2	2,101.8	1,668.3	694.7	2,363.0
TYSABRI	1,096.8	849.3	1,946.1	1,041.8	850.4	1,892.2	1,025.0	839.0	1,864.0
FAMPYRA	—	103.1	103.1	—	97.1	97.1	—	92.7	92.7
ZINBRYTA	—	—	—	—	—	—	—	1.4	1.4
Subtotal: MS	5,112.3	2,719.8	7,832.1	5,780.4	2,748.9	8,529.3	5,946.5	2,648.7	8,595.2
Spinal Muscular Atrophy:									
SPINRAZA	787.8	1,264.3	2,052.1	933.4	1,163.6	2,097.0	854.0	870.2	1,724.2
Biosimilars:									
BENEPALI	—	481.6	481.6	—	486.2	486.2	—	485.2	485.2
IMRALDI	—	216.3	216.3	—	184.0	184.0	—	16.7	16.7
FLIXABI	—	97.9	97.9	—	68.1	68.1	—	43.2	43.2
Subtotal: Biosimilars	—	795.8	795.8	—	738.3	738.3	—	545.1	545.1
Other:									
FUMADERM	—	12.2	12.2	—	15.2	15.2	—	22.3	22.3
Total product revenues	$ 5,900.1	$ 4,792.1	$ 10,692.2	$ 6,713.8	$ 4,666.0	$ 11,379.8	$ 6,800.5	$ 4,086.3	$ 10,886.8

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.
**Interferon includes AVONEX and PLEGRIDY.

We recognized revenues from two wholesalers accounting for 30.5% and 15.3% of gross product revenues in 2020, 30.0% and 17.2% of gross product revenues in 2019 and 32.0% and 18.4% of gross product revenues in 2018, respectively.

As of December 31, 2020, two wholesale distributors individually accounted for approximately 21.1% and 8.5% of net accounts receivable associated with our product sales, as compared to 24.1% and 13.9% as of December 31, 2019, respectively.

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

	December 31, 2020			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 131.1	$ 1,027.3	$ 40.5	$ 1,198.9
Current provisions relating to sales in current year	774.7	3,308.8	19.0	4,102.5
Adjustments relating to prior years	(1.0)	(54.0)	1.3	(53.7)
Payments/returns relating to sales in current year	(635.1)	(2,426.1)	—	(3,061.2)
Payments/returns relating to sales in prior years	(128.3)	(763.0)	(19.2)	(910.5)
Ending balance	$ 141.4	$ 1,093.0	$ 41.6	$ 1,276.0

	December 31, 2019			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 127.8	$ 888.8	$ 34.7	$ 1,051.3
Current provisions relating to sales in current year	666.2	3,011.5	20.9	3,698.6
Adjustments relating to prior years	0.3	(54.1)	5.5	(48.3)
Payments/returns relating to sales in current year	(535.5)	(2,242.9)	(0.2)	(2,778.6)
Payments/returns relating to sales in prior years	(127.7)	(576.0)	(20.4)	(724.1)
Ending balance	$ 131.1	$ 1,027.3	$ 40.5	$ 1,198.9

	December 31, 2018			
(In millions)	Discounts	Contractual Adjustments	Returns	Total
Beginning balance	$ 109.6	$ 606.0	$ 46.0	$ 761.6
Current provisions relating to sales in current year	679.3	2,686.7	23.1	3,389.1
Adjustments relating to prior years	(0.3)	(10.0)	(1.8)	(12.1)
Payments/returns relating to sales in current year	(551.7)	(1,887.6)	(1.1)	(2,440.4)
Payments/returns relating to sales in prior years	(109.1)	(506.3)	(31.5)	(646.9)
Ending balance	$ 127.8	$ 888.8	$ 34.7	$ 1,051.3

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

	As of December 31,	
(In millions)	2020	2019
Reduction of accounts receivable	$ 195.4	$ 197.8
Component of accrued expenses and other	1,080.6	1,001.1
Total revenue-related reserves	$ 1,276.0	$ 1,198.9

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs are summarized in the table below. For purposes of this footnote, we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

	For the Years Ended December 31,		
(In millions)	2020	2019	2018
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA	$ 1,080.2	$ 1,542.4	$ 1,431.9
Other revenues from anti-CD20 therapeutic programs	897.6	748.0	548.3
Total revenues from anti-CD20 therapeutic programs	$ 1,977.8	$ 2,290.4	$ 1,980.2

Approximately 14.7%, 15.9% and 14.7% of our total revenues in 2020, 2019 and 2018, respectively, were derived from our collaboration arrangements with Genentech. For additional information on our collaboration arrangements with Genentech, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Other Revenues

Other revenues are summarized as follows:

(In millions)	For the Years Ended December 31, 2020	2019	2018
Revenues from collaborative and other relationships:			
Revenues earned under our technical development agreement, manufacturing service agreements and royalty revenues on biosimilar products with Samsung Bioepis	$ 20.9	$ 106.2	$ 96.4
Other revenues from collaborative and other relationships	0.7	—	(8.6)
Other royalty and corporate revenues:			
Royalty	33.9	17.0	38.7
Other corporate	719.1	584.5	459.4
Total other revenues	$ 774.6	$ 707.7	$ 585.9

Other corporate revenues primarily reflect amounts earned under contract manufacturing agreements with our strategic customers, including Bioverativ Inc. (Bioverativ). During the years ended December 31, 2020, 2019 and 2018, we recognized $48.6 million, $383.2 million and $206.7 million, respectively, in revenues under the manufacturing and supply agreement with Bioverativ entered into in connection with the spin-off of our hemophilia business.

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 are entitled to $500.0 million in a series of three payments. The first payment became due upon a regulatory approval of such product and was received during the second quarter of 2020. Subsequent payments are due on the first and second anniversaries of the regulatory approval.

Other corporate revenues for the year ended December 31, 2020, reflect $346.2 million related to the delivery of the license for certain of our manufacturing-related intellectual property under the amended agreement discussed above and the performance of manufacturing product supply services for such customer. We have allocated the remaining $153.8 million of the $500.0 million transaction price to the performance of manufacturing product supply services for the customer, which we expect to perform through 2026. The value allocated to the manufacturing services was based on expected demand for supply and the fair value of comparable manufacturing and development services.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

5. Inventory

The components of inventory are summarized as follows:

(In millions)	As of December 31, 2020	2019
Raw materials	$ 314.9	$ 169.7
Work in process	544.5	460.0
Finished goods	209.2	174.5
Total inventory	$ 1,068.6	$ 804.2

Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons are charged to cost of sales, and totaled $26.6 million, $52.2 million and $41.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Divestiture of Hillerød, Denmark Manufacturing Operations

In August 2019 we completed the sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. This transaction included the sale of $14.0 million of work in process inventory.

In addition, we sold to FUJIFILM approximately $41.8 million of raw materials that were remaining at the Hillerød facility on the closing date of this transaction. These materials were sold at cost, which approximates fair value.

For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to these consolidated financial statements.

6. Intangible Assets and Goodwill

Intangible Assets

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

		As of December 31, 2020			As of December 31, 2019		
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Completed technology	4-28 years	$ 7,394.3	$ (5,136.5)	$ 2,257.8	$ 7,379.3	$ (4,881.4)	$ 2,497.9
In-process research and development	Indefinite until commercialization	762.5	—	762.5	965.5	—	965.5
Trademarks and trade names	Indefinite	64.0	—	64.0	64.0	—	64.0
Total intangible assets		$ 8,220.8	$ (5,136.5)	$ 3,084.3	$ 8,408.8	$ (4,881.4)	$ 3,527.4

Amortization and Impairments

Amortization and impairments of acquired intangible assets totaled $464.8 million, $489.9 million and $747.3 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Amortization of acquired intangible assets, excluding impairment charges, totaled $255.1 million, $274.0 million and $381.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. The decrease in amortization of acquired intangible assets, excluding impairment charges, over the three years was primarily due to a lower rate of amortization for acquired intangible assets.

For the year ended December 31, 2020, amortization and impairment of acquired intangible assets reflects the impact of a $115.0 million impairment charge related to BIIB111, which was obtained as part of our acquisition of NST, a $75.4 million impairment charge related to BIIB054 (cinpanemab) and a $19.3 million impairment charge related to one of our other IPR&D intangible assets.

For the year ended December 31, 2019, amortization and impairments of acquired intangible assets reflects the impact of a $215.9 million impairment charge related to certain IPR&D assets associated with the Phase 2b study of BG00011 (STX-100) for the potential treatment of idiopathic pulmonary fibrosis (IPF), which was discontinued in the third quarter of 2019.

For the year ended December 31, 2018, amortization and impairments of acquired intangible assets reflects the impact of a $189.3 million impairment charge related to certain IPR&D assets associated with our vixotrigine program, as discussed below, and a $176.8 million impairment charge related to our U.S. license to Forward Pharma A/S' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA.

Completed Technology

Completed technology primarily relates to our acquisition of all remaining rights to TYSABRI from Elan as well as other amounts related to our other marketed products and programs acquired through business combinations.

IPR&D Related to Business Combinations

IPR&D represents the fair value assigned to research and development assets that we acquired as part of a business combination and had not yet reached technological feasibility at the date of acquisition. Included in IPR&D balances are adjustments related to foreign currency exchange rate fluctuations. We review amounts capitalized as acquired IPR&D for impairment annually, as of October 31, and whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable. The carrying value associated with our IPR&D assets as of December 31, 2020 and 2019, relates to the various IPR&D programs we acquired in connection with our acquisitions of NST and Convergence Pharmaceuticals Holdings Ltd. (Convergence). The majority of the balance relates to our acquisition of NST in June 2019 whereby we acquired IPR&D programs with an estimated fair value of approximately $585.0 million as of December 31, 2020. For additional information on our acquisition of NST, please read *Note 2, Acquisitions*, to these consolidated financial statements.

BIIB111

During the fourth quarter of 2020 we began experiencing third-party manufacturing delays that may impact our timeline for a potential filing of a Biologics License Application (BLA) for BIIB111 for regulatory approval by up to one year. In addition, we determined that forecasted costs associated with advancing the BIIB111 program through Phase 3 development and potential commercialization will exceed our original estimates. We reassessed the fair value of the program based on these changes in assumptions and determined that the program was partially impaired. We recognized an impairment charge of $115.0 million during the fourth quarter of 2020, which resulted in a reduction of the IPR&D asset from $480.0 million to $365.0 million.

BIIB054

In February 2021 we announced that we discontinued development of BIIB054 as a potential treatment of Parkinson's disease as our Phase 2 SPARK study did not meet its primary or secondary endpoints. Although we made this determination in February 2021, it was based on conditions that existed as of December 31, 2020. As a result, we recognized an impairment charge of approximately $75.4 million during the fourth quarter of 2020 to reduce the fair value of the related IPR&D intangible asset to zero.

The IPR&D impairment charges were included in amortization and impairment of acquired intangible assets and the gain resulting from the remeasurement of our contingent consideration obligation was recorded in (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of income. The fair value of the intangible assets and contingent consideration obligations were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenues, costs and probabilities of success.

Vixotrigine

In the periods since we acquired vixotrigine, there have been numerous delays in the initiation of Phase 3 studies for the potential treatment of TGN as we engaged with the U.S. Food and Drug Administration (FDA) regarding the design of the Phase 3 studies and awaited data and insights from mid-stage clinical trials of vixotrigine in other indications that have since been completed. The fair value of the TGN asset is not significantly in excess of carrying value. As of December 31, 2020, the carrying value associated with our vixotrigine IPR&D assets was $177.5 million.

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, 2020
2021	$ 205.0
2022	215.0
2023	215.0
2024	225.0
2025	220.0

Goodwill

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

(In millions)	As of December 31, 2020	As of December 31, 2019
Goodwill, beginning of year	$ 5,757.8	$ 5,706.4
Increase to goodwill	—	117.5
Elimination of goodwill allocated to Hillerød, Denmark manufacturing operations	—	(69.5)
Other	4.3	3.4
Goodwill, end of year	$ 5,762.1	$ 5,757.8

As of December 31, 2020, we had no accumulated impairment losses related to goodwill. Other includes adjustments related to foreign currency exchange rate fluctuations.

7. Fair Value Measurements

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

(In millions)	As of December 31, 2020 Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 626.9	$ —	$ 626.9	$ —
Marketable debt securities:				
Corporate debt securities	1,301.5	—	1,301.5	—
Government securities	627.1	—	627.1	—
Mortgage and other asset backed securities	122.4	—	122.4	—
Marketable equity securities	1,974.3	271.1	1,703.2	—
Derivative contracts	20.5	—	20.5	—
Plan assets for deferred compensation	28.2	—	28.2	—
Total	$ 4,700.9	$ 271.1	$ 4,429.8	$ —
Liabilities:				
Derivative contracts	$ 217.2	$ —	$ 217.2	$ —
Contingent consideration obligations	259.8	—	—	259.8
Total	$ 477.0	$ —	$ 217.2	$ 259.8

	As of December 31, 2019			
(In millions)	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 2,541.1	$ —	$ 2,541.1	$ —
Marketable debt securities:				
Corporate debt securities	1,695.1	—	1,695.1	—
Government securities	1,013.9	—	1,013.9	—
Mortgage and other asset backed securities	261.3	—	261.3	—
Marketable equity securities	337.5	7.9	329.6	—
Derivative contracts	43.8	—	43.8	—
Plan assets for deferred compensation	27.7	—	27.7	—
Total	$ 5,920.4	$ 7.9	$ 5,912.5	$ —
Liabilities:				
Derivative contracts	$ 8.3	$ —	$ 8.3	$ —
Contingent consideration obligations	346.1	—	—	346.1
Total	$ 354.4	$ —	$ 8.3	$ 346.1

There have been no material impairments of our assets measured and carried at fair value during the years ended December 31, 2020 and 2019. In addition, there have been no changes in valuation techniques during the years ended December 31, 2020 and 2019. The fair value of Level 2 instruments classified as cash equivalents and marketable debt securities was determined through third-party pricing services. The fair value of Level 2 instruments classified as marketable equity securities represents our investments in Sangamo Therapeutics, Inc. (Sangamo) common stock, Denali Therapeutics Inc. (Denali) common stock and Sage Therapeutics, Inc. (Sage) common stock and are valued using an option pricing valuation model as the investments are each subject to certain holding period restrictions. For additional information on our investments in Sangamo, Denali and Sage common stock, please read *Note 8, Financial Instruments*, to these consolidated financial statements.

Our investments in marketable equity securities also include shares of Ionis Pharmaceuticals, Inc. (Ionis) common stock acquired in June 2018. Our shares of Ionis common stock were initially subject to certain holding period restrictions that have since expired. The fair value of this investment was a Level 1 measurement as of December 31, 2020. For additional information on our collaboration arrangements with Ionis, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

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

The following table summarizes the significant unobservable inputs in the fair value measurement of our contingent consideration obligations as of December 31, 2020:

	As of December 31, 2020				
(In millions)	Fair Value	Valuation Technique	Unobservable Input	Range	Weighted Average
Liabilities:					
Contingent consideration obligation	$259.8	Discounted cash flow	Discount rate	0.60%	0.60%
			Expected timing of achievement of development milestones	2021 to 2025	—

The weighted average discount rate was calculated based on the relative fair value of our contingent consideration obligations. In addition, we apply various probabilities of technological and regulatory success, ranging from 39.9% to certain probability, to the valuation models to estimate the fair values of our contingent consideration obligations.

Nonrecurring Fair Value Measurements

In addition to assets and liabilities that are recorded at fair value on a recurring basis, we record assets and liabilities at fair value on a nonrecurring basis as required by accounting principles generally accepted in the U.S. (U.S. GAAP). Generally, assets are recorded at fair value on a nonrecurring basis as a result of impairment charges.

The gains or losses on assets measured at fair value on a nonrecurring basis, are summarized as follows:

	As of December 31, 2020		
(In millions)	**Beginning Book Value**	**Impairment**	**Ending Book Value**
BIIB111 intangible asset	$ 480.0	$ (115.0)	$ 365.0

For the year ended December 31, 2020, we recorded a partial impairment charge of $115.0 million related to BIIB111. For additional information, please read *Note 6, Intangible Assets and Goodwill*, to these consolidated financial statements.

Debt Instruments

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

	As of December 31,	
(In millions)	**2020**	**2019**
2.900% Senior Notes due September 15, 2020[1]	$ —	$ 1,509.6
3.625% Senior Notes due September 15, 2022	1,054.1	1,038.9
4.050% Senior Notes due September 15, 2025	2,003.1	1,897.2
2.250% Senior Notes due May 1, 2030	1,557.2	—
5.200% Senior Notes due September 15, 2045	2,365.1	2,107.9
3.150% Senior Notes due May 1, 2050	1,536.4	—
Total	$ 8,515.9	$ 6,553.6

[1] Our 2.900% Senior Notes due September 15, 2020, were redeemed in full in May 2020 using the net proceeds from the issuance on April 30, 2020, of our senior unsecured notes for an aggregate principal amount of $3.0 billion. For additional information, please read *Note 12, 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. For additional information related to our Senior Notes, please read *Note 12, Indebtedness*, to these consolidated financial statements.

Contingent Consideration Obligations

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

	As of December 31,	
(In millions)	**2020**	**2019**
Fair value, beginning of year	$ 346.1	$ 409.8
Changes in fair value	(86.3)	(63.7)
Payments and other	—	—
Fair value, end of year	$ 259.8	$ 346.1

As of December 31, 2020 and 2019, approximately $110.3 million and $197.7 million, respectively, of the fair value of our total contingent consideration obligations was reflected as a component of other long-term liabilities in our consolidated balance sheets with the remaining balance reflected as a component of accrued expenses and other.

For the year ended December 31, 2020, changes in the fair value of our contingent consideration obligations were primarily due to our discontinuing development of BIIB054 for the potential treatment of Parkinson's disease, resulting in a reduction of our contingent consideration obligations of $51.0 million as well as other changes in the

probability and the expected timing of the achievement of certain remaining developmental milestones, changes in the interest rates used to revalue our contingent consideration liabilities and the passage of time.

For the year ended December 31, 2019, changes in the fair value of our contingent consideration obligations were primarily due to the discontinuation of the Phase 2b study of BG00011 for the potential treatment of IPF resulting in a reduction of our contingent consideration obligations of $61.2 million as well as other changes in the probability and expected timing of achievement of certain developmental milestones, a decrease in interest rates used to revalue our contingent consideration liabilities and the passage of time.

The fair values of the contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs. For additional information on the valuation techniques and inputs utilized in the valuation of our financial assets and liabilities, please read *Note 1, Summary of Significant Accounting Policies,* to these consolidated financial statements.

Convergence Pharmaceuticals Holdings Limited

In connection with our acquisition of Convergence in February 2015 we recorded a contingent consideration obligation of $274.5 million. As of December 31, 2020 and 2019, the fair value of this contingent consideration obligation was $259.8 million and $244.6 million, respectively. Our most recent valuation was determined based upon net cash flow projections of $400.0 million, probability weighted and discounted using a rate of 0.6%, which is a measure of the credit risk associated with settling the liability.

Biogen International Neuroscience GmbH

In connection with our acquisition of BIN in December 2010 we recorded a contingent consideration obligation of $81.2 million. We discontinued further development of BIIB054 for the potential treatment of Parkinson's disease based on the results of a Phase 2 study of BIIB054. Additionally, during the third and fourth quarters of 2020 we discontinued other programs related to our acquisition of BIN for which we had immaterial contingent consideration obligations. As a result, the fair value of the contingent consideration obligations related to our acquisition of BIN has been adjusted to zero, resulting in a gain of $101.5 million for the year ended December 31, 2020.

Acquired IPR&D

The fair values of the acquired IPR&D assets were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements and inputs including estimated revenues and probabilities of success. These assets are tested for impairment annually until commercialization, after which time the acquired IPR&D will be amortized over its estimated useful life using the economic consumption method. In connection with our acquisition of BIN, we recognized a $110.9 million acquired IPR&D intangible asset. We discontinued further development of BIIB054 for the potential treatment of Parkinson's disease and recognized an impairment charge of $75.4 million during the fourth quarter of 2020 to reduce the fair value of the IPR&D intangible asset to zero. In connection with our acquisition of Stromedix Inc., we recognized a $219.2 million acquired IPR&D intangible asset. During the third quarter of 2019 we discontinued the Phase 2b study of BG00011 for the potential treatment of IPF and recognized an impairment charge of $215.9 million to reduce the fair value of the IPR&D intangible asset to zero. In connection with our acquisition of Convergence, we recognized a $424.6 million acquired IPR&D intangible asset. During the third quarter of 2018 we recognized impairment charges related to certain IPR&D assets associated with our vixotrigine program totaling $189.3 million. For additional information on our IPR&D intangible assets, including a discussion of our most significant assumptions, please read *Note 6, Intangible Assets and Goodwill*, to these consolidated financial statements.

8. Financial Instruments

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

	As of December 31,	
(In millions)	2020	2019
Commercial paper	$ 61.1	$ 384.4
Overnight reverse repurchase agreements	37.4	368.8
Money market funds	505.1	1,628.5
Short-term debt securities	23.3	159.4
Total	$ 626.9	$ 2,541.1

The carrying values of our commercial paper, including accrued interest, overnight reverse repurchase agreements, money market funds and our short-term debt securities approximate fair value due to their short-term maturities.

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

	As of December 31, 2020			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities				
Current	$ 897.8	$ 0.4	$ (0.2)	$ 898.0
Non-current	402.5	1.1	(0.1)	403.5
Government securities				
Current	380.6	0.1	—	380.7
Non-current	245.9	0.5	—	246.4
Mortgage and other asset backed securities				
Current	0.2	—	—	0.2
Non-current	122.1	0.2	(0.1)	122.2
Total marketable debt securities	$ 2,049.1	$ 2.3	$ (0.4)	$ 2,051.0
Marketable equity securities, current	$ 70.6	$ 15.9	$ —	$ 86.5
Marketable equity securities, non-current	$ 1,168.9	$ 733.8	$ (14.9)	$ 1,887.8

	As of December 31, 2019			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities				
Current	$ 1,057.2	$ 1.0	$ —	$ 1,058.2
Non-current	633.9	3.0	—	636.9
Government securities				
Current	502.9	0.4	—	503.3
Non-current	510.1	0.8	(0.3)	510.6
Mortgage and other asset backed securities				
Current	0.7	—	—	0.7
Non-current	260.2	0.8	(0.4)	260.6
Total marketable debt securities	$ 2,965.0	$ 6.0	$ (0.7)	$ 2,970.3
Marketable equity securities, non-current	$ 218.4	$ 132.1	$ (13.0)	$ 337.5

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

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

	As of December 31, 2020		As of December 31, 2019	
(In millions)	Estimated Fair Value	Amortized Cost	Estimated Fair Value	Amortized Cost
Due in one year or less	$ 1,278.9	$ 1,278.6	$ 1,562.2	$ 1,560.8
Due after one year through five years	722.6	721.3	1,234.5	1,230.4
Due after five years	49.5	49.2	173.6	173.8
Total marketable debt securities	$ 2,051.0	$ 2,049.1	$ 2,970.3	$ 2,965.0

The average maturity of our marketable debt securities available-for-sale as of December 31, 2020 and 2019, was approximately 11 months and 14 months, respectively.

Proceeds from Marketable Debt Securities

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

	For the Years Ended December 31,		
(In millions)	2020	2019	2018
Proceeds from maturities and sales	$ 7,299.4	$ 6,007.0	$ 9,173.7
Realized gains	17.7	6.0	3.2
Realized losses	26.0	1.5	11.7

Realized losses for the year ended December 31, 2020, 2019 and 2018, primarily relate to sales of corporate bonds, agency mortgage-backed securities and other asset-backed securities.

Strategic Investments

As of December 31, 2020 and 2019, our strategic investment portfolio was comprised of investments totaling $2,024.6 million and $393.9 million, respectively, which are included in investments and other assets in our consolidated balance sheets.

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

The increase in our strategic investment portfolio for the year ended December 31, 2020, was primarily due to our purchases of Sage, Denali and Sangamo common stock, as discussed below. These purchases were reflected as net cash flows used in investing activities within the consolidated statement of cash flows.

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage. In connection with the closing of this collaboration in December 2020 we purchased approximately 6.2 million shares of Sage common stock. This investment is classified as a Level 2 marketable equity security due to certain holding period restrictions and is remeasured each reporting period and carried at fair value. The effects of certain holding period restrictions on the investment are estimated using an option pricing valuation model. The most significant assumptions within the model are the term of the restrictions and the stock price volatility, which is based upon historical volatility of similar companies. We also use a constant maturity risk free-interest rate to match the remaining term of the restrictions on our investment in Sage common stock and a dividend yield of zero based upon the fact that Sage and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration agreement with Sage, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali. As part of this collaboration we purchased approximately 13 million shares of Denali common stock in September 2020. This investment is classified as a Level 2 marketable equity security due to certain holding period restrictions and is remeasured each reporting period and carried at fair value. The effects of certain holding period restrictions on the investment are estimated using an option pricing valuation model. The most significant assumptions within the model are the term of the restrictions and the stock price volatility, which is based upon historical volatility of similar companies. We also use a constant maturity risk free-interest rate to match the remaining term of the restrictions on our investment in Denali common stock and a dividend yield of zero based upon the fact that Denali and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration agreement with Denali, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Sangamo Therapeutics, Inc.

In February 2020 we entered into a collaboration and license agreement with Sangamo. In connection with the closing of this transaction in April 2020 we purchased approximately 24 million shares of Sangamo common stock. This equity method investment will be remeasured each reporting period and carried at fair value due to our election of the fair value option. The effects of certain holding period restrictions on the investment are estimated using an option pricing valuation model. The most significant assumptions within the model are the term of the restrictions and the stock price volatility, which is based upon historical volatility of similar companies. We also use a constant maturity risk free-interest rate to match the remaining term of the restrictions on our investment in Sangamo common stock and a dividend yield of zero based upon the fact that Sangamo and similar companies generally have not historically granted cash dividends.

For additional information on our collaboration agreement with Sangamo, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Samsung Bioepis

In June 2018 we exercised our option under our joint venture agreement with Samsung BioLogics to increase our ownership percentage in Samsung Bioepis from approximately 5.0% to approximately 49.9%. The share purchase transaction was completed in November 2018 and, upon closing, we paid 759.5 billion South Korean won ($676.6 million) to Samsung BioLogics.

As of December 31, 2020 and 2019, the carrying value of our investment in Samsung Bioepis totaled 673.8 billion South Korean won ($620.2 million) and 670.8 billion South Korean won ($580.2 million), respectively, which is classified as a component of investments and other assets within our consolidated balance sheets.

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

9. Derivative Instruments

Foreign Currency Forward Contracts - Hedging Instruments

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

Foreign currency forward contracts in effect as of December 31, 2020 and 2019, had durations of 1 to 24 months and 1 to 15 months, respectively. These contracts have been designated as cash flow hedges and unrealized gains or losses on the portion of these foreign currency forward contracts that are included in the effectiveness test are reported in accumulated other comprehensive income (loss) (referred to as AOCI in the table below). Realized gains and losses of such contracts are recognized in revenues when the sale of product in the currency being hedged is recognized and in operating expenses when the expense in the currency being hedged is recorded. We recognize all cash flow hedge reclassifications from accumulated other comprehensive income (loss)

and fair value changes of excluded portions in the same line item in our consolidated statements of income that has been impacted by the hedged item.

The notional value of foreign currency forward contracts that were entered into to hedge forecasted revenues and operating expenses is summarized as follows:

	Notional Amount As of December 31,	
(In millions)	2020	2019
Euro	$ 2,979.1	$ 1,892.4
British pound	250.6	—
Total foreign currency forward contracts	$ 3,229.7	$ 1,892.4

The pre-tax portion of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net losses of $212.5 million as of December 31, 2020, net gains of $0.5 million as of December 31, 2019, and net gains of $27.3 million as of December 31, 2018. We expect the net losses of $212.5 million to be settled over the next 24 months, of which $175.2 million of these losses are expected to be settled over the next 12 months, with any amounts in accumulated other comprehensive income (loss) to be reported as an adjustment to revenues or operating expenses. 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, 2020 and 2019, credit risk did not materially change the fair value of our foreign currency forward contracts.

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

	For the Years Ended December 31,					
	Net Gains/(Losses) Reclassified from AOCI into Operating Income (in millions)			Net Gains/(Losses) Recognized in Operating Income (in millions)		
Location	2020	2019	2018	Location	2020	2019	2018
Revenues	$ 18.3	$ 118.6	$ (42.5)	Revenues	$ (9.9)	$ 2.9	$ 10.8
Operating expenses	3.3	(3.3)	0.2	Operating expenses	—	0.2	(0.1)

Interest Rate Contracts - Hedging Instruments

We have entered into interest rate lock contracts or interest rate swap contracts on certain borrowing transactions to manage our exposure to interest rate changes and to reduce our overall cost of borrowing.

Interest Rate Swap Contracts

In connection with the issuance of our 2.90% Senior Notes due September 15, 2020, we entered into interest rate swaps with an aggregate notional amount of $675.0 million, which were set to expire on September 15, 2020. The interest rate swap contracts were designated as hedges of the fair value changes in our 2.90% Senior Notes attributable to changes in interest rates. The carrying value of our 2.90% Senior Notes as of December 31, 2019, included approximately $2.3 million related to changes in the fair value of these interest rate swap contracts. In May 2020 we settled our interest rate swap contracts, in conjunction with our early redemption of our 2.90% Senior Notes, resulting in a gain of approximately $3.3 million for the year ended December 31, 2020, which was recorded as a component of interest expense in our consolidated statements of income.

Net Investment Hedges - Hedging Instruments

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

In order to mitigate these currency fluctuations between the U.S. dollar and South Korean won, we have entered into foreign currency forward contracts. Foreign currency forward contracts in effect as of December 31, 2020, had remaining durations of 10 months. These contracts have been designated as net investment hedges. We recognize changes in the spot exchange rate in accumulated other comprehensive income (loss). The pre-tax portion

of the fair value of these foreign currency forward contracts that were included in accumulated other comprehensive income (loss) in total equity reflected net losses of $21.2 million and $1.5 million as of December 31, 2020 and 2019, respectively. We exclude fair value changes related to the forward rate from our hedging relationship and will amortize the forward points in other income (expense), net in our consolidated statements of income over the term of the contract. The pre-tax portion of the fair value of the forward points that were included in accumulated other comprehensive income (loss) in total equity reflected gains of $0.2 million and $2.9 million as of December 31, 2020 and 2019, respectively.

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

	For the Years Ended December 31,								
	Net Gains/(Losses) Recognized in Other Comprehensive Income (Effective Portion) (in millions)			Net Gains/(Losses) Recognized in Other Comprehensive Income (Amounts Excluded from Effectiveness Testing) (in millions)			Net Gains/(Losses) Recognized in Net Income (Amounts Excluded from Effectiveness Testing) (in millions)		
Location	2020	2019	2018	Location	2020	2019	2018	Location	2020	2019	2018
Gains (losses) on net investment hedge	$ (35.1)	$ 25.3	$ (3.8)	Gains (losses) on net investment hedge	$ 4.5	$ 3.3	$ —	Other income (expense)	$ 2.9	$ 7.0	$ 1.5

For additional information on our collaboration arrangements with Samsung Bioepis, please read *Note 18, 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 contracts was $1,158.0 million and $793.8 million as of December 31, 2020 and 2019, respectively. Net gains of $30.1 million, net losses of $5.9 million and net gains of $2.0 million related to these contracts were recorded as a component of other income (expense), net for the years ended December 31, 2020, 2019 and 2018, 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:

		As of December 31,	
(In millions)	Balance Sheet Location	2020	2019
Cash Flow Hedging Instruments:			
Asset derivative instruments	Other current assets	$ —	$ 33.8
Liability derivative instruments	Accrued expenses and other	157.1	2.0
	Other long-term liabilities	35.7	1.7
Net Investment Hedging Instruments:			
Asset derivative instruments	Other current assets	—	2.0
Liability derivative instruments	Accrued expenses and other	19.7	—
Fair Value Hedging Instruments			
Liability derivative instruments	Accrued expenses and other	—	2.3
Other Derivative Instruments:			
Asset derivative instruments	Other current assets	20.5	8.0
Liability derivative instruments	Accrued expenses and other	4.7	2.4

10. 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, 2020	2019
Land	$ 119.8	$ 118.1
Buildings	1,025.3	835.0
Leasehold improvements	104.6	99.5
Machinery and equipment	1,027.8	844.5
Computer software and hardware	903.0	798.4
Furniture and fixtures	62.5	58.3
Construction in progress	1,950.8	2,084.4
Total cost	5,193.8	4,838.2
Less: accumulated depreciation	(1,782.3)	(1,590.9)
Total property, plant and equipment, net	$ 3,411.5	$ 3,247.3

Depreciation expense totaled $201.9 million, $190.6 million and $269.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

For the years ended December 31, 2020, 2019 and 2018, we capitalized interest costs related to construction in progress totaling approximately $65.2 million, $68.8 million and $54.0 million, respectively.

Solothurn, Switzerland Manufacturing Facility

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially operational during the first half of 2021. Upon completion, this facility will include 393,000 square feet related to a large-scale biologics manufacturing facility, 290,000 square feet of warehouse, utilities and support space and 51,000 square feet of administrative space. As of December 31, 2020 and 2019, we had approximately $1.8 billion and $1.9 billion, respectively, capitalized as construction in progress related to this facility. For the year ended December 31, 2020, we placed approximately $256.8 million of fixed assets in service related to this facility.

Divestiture of Hillerød, Denmark Manufacturing Operations

In August 2019 we completed the sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. This transaction included $631.5 million of property, plant and equipment, which was primarily comprised of $312.5 million for buildings and $287.3 million for machinery and equipment. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to these consolidated financial statements.

11. 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 ten years. Certain leases include one or more options to renew, exercised at our sole discretion, with renewal terms that can extend the lease term from one year to six years.

In addition, we sublease certain real estate to third parties. Our sublease portfolio consists of operating leases, with remaining lease terms ranging from four years to eight years. Our subleases do not include an option to renew as they are coterminous with our operating leases.

All of our leases qualify as operating leases. The following table summarizes the presentation in our consolidated balance sheets of our operating leases:

(In millions)	Balance sheet location	As of December 31, 2020	As of December 31, 2019
Assets:			
Operating lease assets	Operating lease assets	$ 433.3	$ 427.0
Liabilities			
Current operating lease liabilities	Accrued expenses and other	$ 83.2	$ 73.6
Non-current operating lease liabilities	Long-term operating lease liabilities	402.0	412.7
Total operating lease liabilities		$ 485.2	$ 486.3

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, 2020	For the Years Ended December 31, 2019
Operating lease cost	Research and development	$ 5.2	$ 6.7
	Selling, general and administrative	93.1	84.6
Variable lease cost	Research and development	1.1	1.2
	Selling, general and administrative	21.1	23.7
Sublease income	Selling, general and administrative	(24.2)	(25.6)
	Other (income) expense, net	(3.9)	(3.9)
Net lease cost		$ 92.4	$ 86.7

Variable lease cost primarily related to operating expenses, taxes and insurance associated with our operating leases. As these costs are generally variable in nature, they are not included in the measurement of the operating lease asset and related lease liability.

The minimum lease payments for the next five years and thereafter is expected to be as follows:

(In millions)	As of December 31, 2020
2021	$ 95.8
2022	93.5
2023	82.0
2024	75.0
2025	56.9
Thereafter	129.8
Total lease payments	$ 533.0
Less: interest	47.8
Present value of operating lease liabilities	$ 485.2

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

	As of December 31, 2020	As of December 31, 2019
Weighted average remaining lease term in years	6.30	7.07
Weighted average discount rate	2.9 %	3.2 %

Supplemental disclosure of cash flow information related to our operating leases included in cash flows provided by operating activities in our consolidated statements of cash flows is as follows:

	As of December 31,	
(In millions)	2020	2019
Cash paid for amounts included in the measurement of lease liabilities	$ 100.2	$ 93.8
Operating lease assets obtained in exchange for lease obligations	59.0	35.9

12. Indebtedness

Our indebtedness is summarized as follows:

	As of December 31,	
(In millions)	2020	2019
Current portion:		
2.900% Senior Notes due September 15, 2020[1]	$ —	$ 1,495.8
Current portion of notes payable	$ —	$ 1,495.8
Non-current portion:		
3.625% Senior Notes due September 15, 2022	$ 997.9	$ 996.6
4.050% Senior Notes due September 15, 2025	1,741.2	1,739.5
2.250% Senior Notes due May 1, 2030	1,491.1	—
5.200% Senior Notes due September 15, 2045	1,723.4	1,722.9
3.150% Senior Notes due May 1, 2050	1,472.6	—
Non-current portion of notes payable	$ 7,426.2	$ 4,459.0

[1] Our 2.900% Senior Notes due September 15, 2020, were redeemed in full in May 2020 using the net proceeds from the issuance on April 30, 2020, of our senior unsecured notes for an aggregate principal amount of $3.0 billion, as discussed below.

2020 Senior Notes

On April 30, 2020, we issued senior unsecured notes for an aggregate principal amount of $3.0 billion (2020 Senior Notes) as of December 31, 2020, consisting of the following:

- $1.5 billion aggregate principal amount of 2.25% Senior Notes due May 1, 2030, valued at 99.973% of par; and
- $1.5 billion aggregate principal amount of 3.15% Senior Notes due May 1, 2050, valued at 99.174% of par.

Our 2020 Senior Notes are senior unsecured obligations and may be redeemed at our option at any time at 100.0% of the principal amount plus accrued interest and, until a specified period before maturity, a specified make-whole amount. Our 2020 Senior Notes contain a change-of-control provision that, under certain circumstances, may require us to purchase our 2020 Senior Notes at a price equal to 101.0% of the principal amount plus accrued and unpaid interest to the date of repurchase.

We incurred approximately $24.4 million of costs associated with this offering which have been recorded as a reduction to the carrying amount of the debt on our consolidated balance sheet. These costs will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. The discounts will be amortized as additional interest expense over the period from issuance through maturity using the effective interest rate method. Interest on our 2020 Senior Notes is payable May 1 and November 1 of each year, commencing November 1, 2020.

2015 Senior Notes

The following is a summary of our currently outstanding senior secured notes issued in 2015 (the 2015 Senior Notes) as of December 31, 2020:

- $1.0 billion aggregate principal amount of 3.625% Senior Notes due September 15, 2022, valued at 99.920% of par;

- $1.75 billion aggregate principal amount of 4.05% Senior Notes due September 15, 2025, valued at 99.764% of par; and
- $1.75 billion aggregate principal amount of 5.20% Senior Notes due September 15, 2045, valued at 99.294% of par.

The original costs associated with this offering of approximately $47.5 million have been recorded as a reduction to the carrying amount of the debt in our consolidated balance sheets. These costs along with the discounts will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity.

Our 2015 Senior Notes are senior unsecured obligations and may be redeemed at our option at any time at 100.0% of the principal amount plus accrued interest and a specified make-whole amount. Our 2015 Senior Notes contain a change of control provision that may require us to purchase the notes at a price equal to 101.0% of the principal amount plus accrued and unpaid interest to the date of purchase under certain circumstances.

On September 15, 2015, we issued $1.5 billion aggregate principal amount of 2.90% Senior Notes due September 15, 2020, at 99.792% of par. Our 2.90% Senior Notes were senior unsecured obligations. In connection with the 2.90% Senior Notes, we entered into interest rate swap contracts where we received a fixed rate and paid a variable rate. In May 2020 we used the net proceeds from the sale of our 2020 Senior Notes to redeem our 2.90% Senior Notes prior to their maturity and recognized a net pre-tax charge of $9.4 million upon the extinguishment of these notes. This charge, which was recognized in interest expense in other income (expense), net in our consolidated statements of income for the year ended December 31, 2020, reflects the payment of a $12.7 million early call premium and the write off of remaining unamortized original debt issuance costs and discount balances, partially offset by a $3.3 million gain related to the settlement of the associated interest rate swap contracts. For additional information on our interest rate contracts, please read *Note 9, Derivative Instruments,* to these consolidated financial statements.

2020 Credit Facility

In January 2020 we entered into a $1.0 billion, five-year senior unsecured revolving credit facility under which we are permitted to draw funds for working capital and general corporate purposes. The terms of the revolving credit facility include a financial covenant that requires us not to exceed a maximum consolidated leverage ratio. This revolving credit facility replaced the revolving credit facility that we entered into in August 2015. As of December 31, 2020, we had no outstanding borrowings and were in compliance with all covenants under this facility.

Debt Maturity

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

(In millions)	As of December 31, 2020
2021	$ —
2022	1,000.0
2023	—
2024	—
2025	1,750.0
2026 and thereafter	4,750.0
Total	$ 7,500.0

The fair value of our debt is disclosed in *Note 7, Fair Value Measurements,* to these consolidated financial statements.

13. 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 2020, 2019 and 2018.

Common Stock

The following table describes the number of shares authorized, issued and outstanding of our common stock as of December 31, 2020, 2019 and 2018:

	As of December 31, 2020			As of December 31, 2019			As of December 31, 2018		
(In millions)	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding	Authorized	Issued	Outstanding
Common stock	1,000.0	176.2	152.4	1,000.0	198.0	174.2	1,000.0	221.0	197.2

Share Repurchases

In October 2020 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2020 Share Repurchase Program). Our 2020 Share Repurchase Program does not have an expiration date. All share repurchases under our 2020 Share Repurchase Program will be retired. Under our 2020 Share Repurchase Program, we repurchased and retired approximately 1.6 million shares of our common stock at a cost of approximately $400.0 million during the year ended December 31, 2020.

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

In March 2019 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (March 2019 Share Repurchase Program), which was completed as of March 31, 2020. All shares repurchased under our March 2019 Share Repurchase Program were retired. Under our March 2019 Share Repurchase Program, we repurchased and retired approximately 4.1 million and 14.7 million shares of our common stock at a cost of approximately $1.3 billion and $3.7 billion during the years ended December 31, 2020 and 2019, respectively.

In August 2018 our Board of Directors authorized a program to repurchase up to $3.5 billion of our common stock (2018 Share Repurchase Program), which was completed as of June 30, 2019. All share repurchases under our 2018 Share Repurchase Program were retired. Under our 2018 Share Repurchase Program, we repurchased and retired approximately 8.9 million and 4.3 million shares of our common stock at a cost of approximately $2.1 billion and $1.4 billion during the years ended December 31, 2019 and 2018, respectively.

In July 2016 our Board of Directors authorized a program to repurchase up to $5.0 billion of our common stock (2016 Share Repurchase Program), which was completed as of June 30, 2018. All share repurchases under our 2016 Share Repurchase Program were retired. Under our 2016 Share Repurchase Program, we repurchased and retired approximately 10.5 million shares of common stock at a cost of approximately $3.0 billion during the year ended December 31, 2018.

Amounts paid to repurchase shares in excess of their par value are allocated between additional paid-in capital and retained earnings, with payments in excess of our additional paid-in-capital balance recorded as a reduction to retained earnings.

Accumulated Other Comprehensive Income (Loss)

The following tables summarize the changes in accumulated other comprehensive income (loss), net of tax by component:

	December 31, 2020					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, net of tax	Unrealized Gains (Losses) on Cash Flow Hedges, net of tax	Gains (Losses) on Net Investment Hedge, Net of Tax	Unfunded Status of Postretirement Benefit Plans, net of tax	Currency Translation Adjustments	Total
Balance, December 31, 2019	$ 4.2	$ 7.8	$ 25.1	$ (32.8)	$ (139.5)	$ (135.2)
Other comprehensive income (loss) before reclassifications	(9.3)	(165.0)	(30.7)	(33.5)	92.9	(145.6)
Amounts reclassified from accumulated other comprehensive income (loss)	6.5	(21.8)	(2.9)	—	—	(18.2)
Net current period other comprehensive income (loss)	(2.8)	(186.8)	(33.6)	(33.5)	92.9	(163.8)
Balance, December 31, 2020	$ 1.4	$ (179.0)	$ (8.5)	$ (66.3)	$ (46.6)	$ (299.0)

	December 31, 2019					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, net of tax	Unrealized Gains (Losses) on Cash Flow Hedges, net of tax	Gains (Losses) on Net Investment Hedge, Net of Tax	Unfunded Status of Postretirement Benefit Plans, net of tax	Currency Translation Adjustments	Total
Balance, December 31, 2018	$ (4.0)	$ 34.7	$ 3.5	$ (31.3)	$ (243.3)	$ (240.4)
Other comprehensive income (loss) before reclassifications	11.8	88.1	28.6	(1.5)	103.8	230.8
Amounts reclassified from accumulated other comprehensive income (loss)	(3.6)	(115.0)	(7.0)	—	—	(125.6)
Net current period other comprehensive income (loss)	8.2	(26.9)	21.6	(1.5)	103.8	105.2
Balance, December 31, 2019	$ 4.2	$ 7.8	$ 25.1	$ (32.8)	$ (139.5)	$ (135.2)

	December 31, 2018					
(In millions)	Unrealized Gains (Losses) on Securities Available for Sale, net of tax	Unrealized Gains (Losses) on Cash Flow Hedges, net of tax	Gains (Losses) on Net Investment Hedge, Net of Tax	Unfunded Status of Postretirement Benefit Plans, net of tax	Currency Translation Adjustments	Total
Balance, December 31, 2017	$ (1.6)	$ (104.5)	$ —	$ (36.8)	$ (175.5)	$ (318.4)
Amount reclassified, net of tax, upon adoption of ASU 2016-01	1.5	—	—	—	—	1.5
Balance, January 1, 2018	(0.1)	(104.5)	—	(36.8)	(175.5)	(316.9)
Other comprehensive income (loss) before reclassifications	(10.6)	97.4	5.0	5.5	(67.8)	29.5
Amounts reclassified from accumulated other comprehensive income (loss)	6.7	41.8	(1.5)	—	—	47.0
Net current period other comprehensive income (loss)	(3.9)	139.2	3.5	5.5	(67.8)	76.5
Balance, December 31, 2018	$ (4.0)	$ 34.7	$ 3.5	$ (31.3)	$ (243.3)	$ (240.4)

The following table summarizes the amounts reclassified from accumulated other comprehensive income:

		Amounts Reclassified from Accumulated Other Comprehensive Income		
		For the Years Ended December 31,		
(In millions)	Income Statement Location	2020	2019	2018
Gains (losses) on securities available for sale	Other income (expense)	$ (8.2)	$ 4.5	$ (8.5)
	Income tax benefit (expense)	1.7	(0.9)	1.8
Gains (losses) on cash flow hedges	Revenues	18.3	118.6	(42.5)
	Operating expenses	3.3	(3.3)	0.2
	Other income (expense)	0.3	0.3	0.3
	Income tax benefit (expense)	(0.1)	(0.6)	0.2
Gains (losses) on net investment hedge	Other Income (expense)	2.9	7.0	1.5
Total reclassifications, net of tax		$ 18.2	$ 125.6	$ (47.0)

14. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

	For the Years Ended December 31,		
(In millions)	2020	2019	2018
Numerator:			
Net income attributable to Biogen Inc.	$ 4,000.6	$ 5,888.5	$ 4,430.7
Denominator:			
Weighted average number of common shares outstanding	160.9	187.1	204.9
Effect of dilutive securities:			
Time-vested restricted stock units	0.2	0.2	0.3
Market stock units	0.1	0.1	0.1
Performance stock units settled in stock	0.1	—	—
Dilutive potential common shares	0.4	0.3	0.4
Shares used in calculating diluted earnings per share	161.3	187.4	205.3

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

Earnings per share for the years ended December 31, 2020, 2019 and 2018, reflects the repurchase of approximately 22.4 million shares, 23.6 million shares and 14.8 million shares of our common stock, respectively, under our share repurchase programs. For additional information on our share repurchase programs, please read *Note 13, Equity*, to these consolidated financial statements.

15. Share-Based Payments

Share-Based Compensation Expense

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

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Research and development	$ 80.0	$ 77.1	$ 75.8
Selling, general and administrative	131.3	148.3	105.8
Subtotal	211.3	225.4	181.6
Capitalized share-based compensation costs	(6.2)	(8.9)	(11.5)
Share-based compensation expense included in total cost and expenses	205.1	216.5	170.1
Income tax effect	(33.5)	(35.7)	(27.5)
Share-based compensation expense included in net income attributable to Biogen Inc.	$ 171.6	$ 180.8	$ 142.6

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

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Market stock units	$ 40.5	$ 30.4	$ 27.2
Time-vested restricted stock units	142.6	134.0	126.6
Cash settled performance units	(1.7)	0.7	7.8
Performance units	(0.1)	1.6	3.1
Performance stock units settled in stock	7.9	15.5	4.7
Performance stock units settled in cash	8.6	5.5	1.7
Employee stock purchase plan	13.5	11.5	10.5
NST stock options	—	26.2	—
Subtotal	211.3	225.4	181.6
Capitalized share-based compensation costs	(6.2)	(8.9)	(11.5)
Share-based compensation expense included in total cost and expenses	$ 205.1	$ 216.5	$ 170.1

As of December 31, 2020, unrecognized compensation cost related to unvested share-based compensation was approximately $207.6 million, net of estimated forfeitures. We expect to recognize the cost of these unvested awards over a weighted-average period of 1.9 years.

Share-Based Compensation Plans

We have three share-based compensation plans pursuant to which awards are currently being made: (i) the Biogen Inc. 2006 Non-Employee Directors Equity Plan (2006 Directors Plan); (ii) the Biogen Inc. 2017 Omnibus Equity Plan (2017 Omnibus Equity Plan); and (iii) the Biogen Inc. 2015 Employee Stock Purchase Plan (2015 ESPP).

Directors Plan

In May 2006 our shareholders approved the 2006 Directors Plan for share-based awards to our directors. Awards granted from the 2006 Directors Plan may include stock options, shares of restricted stock, RSUs, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the 2006 Directors Plan. We have reserved a total of 1.6 million shares of common stock for issuance under the 2006 Directors Plan. The 2006 Directors Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares reserved under the plan in a 1.5-to-1 ratio. In June 2015 our shareholders approved an amendment to extend the term of the 2006 Directors Plan until June 2025.

Omnibus Plan

In June 2017 our shareholders approved the 2017 Omnibus Equity Plan for share-based awards to our employees. Awards granted from the 2017 Omnibus Equity Plan may include stock options, shares of restricted stock, RSUs, performance shares, stock appreciation rights and other awards in such amounts and with such terms and conditions as may be determined by a committee of our Board of Directors, subject to the provisions of the 2017 Omnibus Equity Plan. Shares of common stock available for grant under the 2017 Omnibus Equity Plan consist of 8.0 million shares reserved for this purpose, plus shares of common stock that remained available for grant under the Biogen Idec Inc. 2008 Omnibus Equity Plan (2008 Omnibus Equity Plan) as of June 7, 2017, or that could again become available for grant if outstanding awards under the 2008 Omnibus Equity Plan as of June 7, 2017, are cancelled, surrendered or terminated in whole or in part. The 2017 Omnibus Equity Plan provides that awards other than stock options and stock appreciation rights will be counted against the total number of shares available under the plan in a 1.5-to-1 ratio.

We have not made any awards pursuant to the 2008 Omnibus Equity Plan since our shareholders approved the 2017 Omnibus Equity Plan, and do not intend to make any awards pursuant to the 2008 Omnibus Equity Plan in the future, except that unused shares under the 2008 Omnibus Equity Plan have been carried over for use under the 2017 Omnibus Equity Plan.

Stock Options

We currently do not grant stock options to our employees or directors. Outstanding stock options previously granted to our employees and directors generally have a 10-year term and vest over a period of between one and four years, provided the individual continues to serve at Biogen through the vesting dates. Options granted under all plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. As of December 31, 2020, all outstanding options were exercisable.

The following table summarizes our stock option activity:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	12,000	$ 58.46
Granted	—	—
Exercised	(12,000)	58.46
Cancelled	—	—
Outstanding at December 31, 2020	—	$ —

The total intrinsic values of options exercised in 2020, 2019 and 2018 totaled $2.9 million, $4.2 million and $4.0 million, respectively.

The following table summarizes the amount of tax benefit realized for stock options and cash received from the exercise of stock options:

	For the Years Ended December 31,		
(In millions)	2020	2019	2018
Tax benefit realized for stock options	$ 2.9	$ 2.5	$ 2.2
Cash received from the exercise of stock options	0.7	0.4	0.8

Market Stock Units (MSUs)

MSUs awarded to employees prior to 2014 vested in four equal annual increments beginning on the first anniversary of the grant date. Participants may ultimately earn between zero and 150.0% of the target number of units granted based on actual stock performance.

MSUs awarded to employees in 2014 and thereafter vest in three equal annual increments beginning on the first anniversary of the grant date, and participants may ultimately earn between zero and 200.0% of the target number of units granted based on actual stock performance.

The vesting of these awards is subject to the respective employee's continued employment. The number of MSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain market-based criteria involving our stock price. The number of MSUs earned is calculated at each annual

anniversary from the date of grant over the respective vesting periods, resulting in multiple performance periods. Accordingly, additional MSUs may be issued or currently outstanding MSUs may be cancelled upon final determination of the number of awards earned.

The following table summarizes our MSU activity:

	December 31, 2020	
	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	183,000	$ 378.09
Granted [1]	133,000	398.61
Vested	(82,000)	375.42
Forfeited	(33,000)	402.62
Unvested at December 31, 2020	201,000	$ 388.98

[1] MSUs granted during 2020 include awards granted in conjunction with our annual awards made in February 2020 and MSUs 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. MSUs granted in 2020 also reflect an adjustment based upon the final performance multiplier in relation to shares granted in 2019, 2018 and 2017.

We value grants of MSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, the 30 calendar day average closing stock price on the date of grant for MSUs, expected volatility of our stock price, risk-free rates of return and expected dividend yield.

The assumptions used in our valuation are summarized as follows:

	For the Years Ended December 31,		
	2020	2019	2018
Expected dividend yield	—%	—%	—%
Range of expected stock price volatility	37.8% - 44.1%	31.2% - 33.6%	27.5% - 32.4%
Range of risk-free interest rates	1.41% - 1.48%	2.46% - 2.53%	1.9% - 2.3%
30 calendar day average stock price on grant date	$257.83 - $325.40	$228.59 - $331.18	$279.47 - $346.76
Weighted-average per share grant date fair value	$398.61	$378.08	$378.85

The fair values of MSUs vested in 2020, 2019 and 2018 totaled $26.9 million, $32.5 million and $26.9 million, respectively.

Cash Settled Performance Units (CSPUs)

CSPUs awarded to employees vest in three equal annual increments beginning on the first anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment with such awards settled in cash. The number of CSPUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between zero and 200.0% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional CSPUs may be issued or currently outstanding CSPUs may be cancelled upon final determination of the number of units earned. CSPUs are classified as liability awards and will be settled in cash based on the 30 calendar day average closing stock price through each vesting date, once the actual vested and earned number of units is known. Since no shares are issued, these awards do not dilute equity.

The following table summarizes our CSPU activity:

	Shares
Unvested at December 31, 2019	13,000
Granted	—
Vested	(13,000)
Forfeited	—
Unvested at December 31, 2020	—

The cash paid in settlement of CSPUs vested in 2020, 2019 and 2018 totaled $3.8 million, $10.6 million and $15.1 million, respectively.

Performance-vested Restricted Stock Units (PUs)

PUs are granted to certain employees in the form of RSUs that may be settled in cash or shares of our common stock at the sole discretion of the Compensation and Management Development Committee of our Board of Directors. These awards are structured and accounted for the same way as the CSPUs, and vest in three equal annual increments beginning on the first anniversary of the grant date. The number of PUs granted represents the target number of units that are eligible to be earned based on the attainment of certain performance measures established at the beginning of the performance period, which ends on December 31 of each year. Participants may ultimately earn between zero and 200.0% of the target number of units granted based on the degree of actual performance metric achievement. Accordingly, additional PUs may be issued or currently outstanding PUs may be cancelled upon final determination of the number of units earned. PUs settling in cash are based on the 30 calendar day average closing stock price through each vesting date once the actual vested and earned number of units is known.

The following table summarizes our PU activity:

	Shares
Unvested at December 31, 2019	11,000
Granted	—
Vested	(11,000)
Forfeited	—
Unvested at December 31, 2020	—

All PUs that vested in 2020, 2019 and 2018 were settled in cash totaling $3.4 million, $10.4 million and $17.0 million, respectively.

Performance Stock Units (PSUs)

PSUs Settled in Stock

During the first quarter of 2018 we began granting awards for performance-vested RSUs that will settle in stock. PSUs awarded to employees have a three-year performance period and vest on the third anniversary of the grant date. The vesting of these awards is subject to the respective employee's continued employment. The number of PSUs granted represents the target number of units that are eligible to be earned based on the achievement of cumulative three-year performance measures established at the beginning of the performance period, which ends on December 31 of the third year of the performance period.

Participants may ultimately earn between zero and 200.0% of the target number of PSUs granted based on the degree of achievement of the applicable performance metric. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned.

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

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	111,000	$ 316.39
Granted [1]	73,000	293.35
Vested	—	—
Forfeited	(29,000)	323.42
Unvested at December 31, 2020	155,000	$ 304.19

[1] PSUs settled in stock granted in 2020 include awards granted in conjunction with our annual awards made in February 2020 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 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.

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

	Shares
Unvested at December 31, 2019	82,000
Granted [1]	63,000
Vested	(2,000)
Forfeited	(23,000)
Unvested at December 31, 2020	120,000

[1] PSUs settled in cash granted in 2020 include awards granted in conjunction with our annual awards made in February 2020 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.

Time-Vested Restricted Stock Units (RSUs)

RSUs awarded to employees generally vest no sooner than one-third per year over three years on the anniversary of the date of grant, or upon the third anniversary of the date of the grant, provided the employee remains continuously employed with us, except as otherwise provided in the plan. Shares of our common stock will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. RSUs awarded to directors for service on our Board of Directors vest on the first anniversary of the date of grant, provided in each case that the director continues to serve on our Board of Directors through the vesting date. Shares of our common stock will be delivered to the director upon vesting and are not subject to any withholding taxes.

The following table summarizes our RSU activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	938,000	$ 306.55
Granted [1]	620,000	318.87
Vested	(440,000)	304.45
Forfeited	(100,000)	314.46
Unvested at December 31, 2020	1,018,000	$ 314.46

[1] RSUs granted in 2020 primarily represent RSUs granted in conjunction with our annual awards made in February 2020 and awards made in conjunction with the hiring of new employees. RSUs granted in 2020 also include approximately 10,000 RSUs granted to our Board of Directors.

RSUs granted in 2019 and 2018 had weighted average grant date fair values of $304.44 and $316.32, respectively.

The fair values of RSUs vested in 2020, 2019 and 2018 totaled $140.5 million, $131.5 million and $111.7 million, respectively.

Employee Stock Purchase Plan (ESPP)

In June 2015 our shareholders approved the 2015 ESPP. The maximum aggregate number of shares of our common stock that may be purchased under the 2015 ESPP is 6.2 million.

The following table summarizes our ESPP activity:

(In millions, except share amounts)	For the Years Ended December 31, 2020	2019	2018
Shares issued under the 2015 ESPP	212,000	204,000	170,000
Cash received under the 2015 ESPP	$ 48.6	$ 40.4	$ 40.5

16. Income Taxes

Income Tax Expense

Income before income tax expense and the income tax expense consist of the following:

(In millions)	For the Years Ended December 31, 2020	2019	2018
Income before income taxes (benefit):			
Domestic	$ 3,290.0	$ 4,725.3	$ 3,877.0
Foreign	1,757.5	2,400.6	2,022.6
Total	$ 5,047.5	$ 7,125.9	$ 5,899.6
Income tax expense (benefit):			
Current:			
Federal	$ 647.0	$ 947.4	$ 1,131.8
State	41.2	59.1	45.5
Foreign	155.1	84.4	140.0
Total	843.3	1,090.9	1,317.3
Deferred:			
Federal	$ (1,749.9)	$ 1,143.9	$ (62.0)
State	(6.8)	(2.3)	(7.4)
Foreign	1,905.7	(1,074.5)	177.7
Total	149.0	67.1	108.3
Total income tax expense	$ 992.3	$ 1,158.0	$ 1,425.6

2017 Tax Act

The Tax Cuts and Jobs Act of 2017 (2017 Tax Act) resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35.0% to 21.0%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system, which has the effect of subjecting certain earnings of our foreign subsidiaries and collaborations to immediate U.S. taxation as GILTI or Subpart F income, includes a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and base erosion prevention measures on U.S. earnings and reduces the effective tax rate on income that comes from U.S. exports, called Foreign Derived Intangible Income. These changes became effective in 2018.

During the year ended December 31, 2018, we recognized a net reduction of $34.6 million in our estimated Transition Toll Tax, an expense of $12.7 million to remeasure our deferred tax balances, an expense of $135.8 million related to establishing deferred taxes for GILTI and an expense of $11.0 million to reflect other aspects of the 2017 Tax Act.

Transition Toll Tax

The 2017 Tax Act eliminated the deferral of U.S. income tax on the historical unrepatriated earnings by imposing the Transition Toll Tax. The Transition Toll Tax was assessed on our share of our foreign corporations' accumulated foreign earnings that were not previously taxed. Earnings in the form of cash and cash equivalents were taxed at a rate of 15.5% and all other earnings were taxed at a rate of 8.0%.

As of December 31, 2020 and 2019, we have accrued income tax liabilities of $697.0 million under the Transition Toll Tax. Of the amounts accrued as of December 31, 2020, $62.0 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight-year period, which started in 2018, and does not accrue

interest.

Unremitted Earnings

At December 31, 2020, 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, 2020, 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, 2020. The residual U.S. tax liability, if these differences reverse, would be between $300.0 million and $400.0 million as of December 31, 2020.

Coronavirus Aid, Relief and Economic Security Act

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law in the U.S. in March 2020. The CARES Act adjusted a number of provisions of the tax code, including the calculation and eligibility of certain deductions and the treatment of net operating losses and tax credits. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the year ended December 31, 2020, or to our net deferred tax assets as of December 31, 2020.

TECFIDERA

In June 2020 and September 2020 judgments were entered in favor of the defendants in the patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in West Virginia and Delaware. We have appealed the judgments in both actions. For additional information, please read *Note 20, Litigation*, to these consolidated financial statements.

Multiple TECFIDERA generic entrants are now in the U.S. market and have deeply discounted prices compared to TECFIDERA. The generic competition for TECFIDERA significantly reduced our TECFIDERA revenues during the year ended December 31, 2020, and is expected to have a substantial negative impact on our TECFIDERA revenues for as long as there is generic competition.

As of December 31, 2020, we have assessed the realizability of our deferred tax assets that are dependent on future expected sales of TECFIDERA in the U.S. and reduced the net value of certain deferred tax assets by approximately $1.7 billion and reduced the net value of deferred tax liabilities associated with GILTI and tax credits by approximately $1.6 billion. For the year ended December 31, 2020, the income tax expense associated with these reductions was approximately $90.3 million.

Deferred Tax Assets and Liabilities

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

	As of December 31,	
(In millions)	**2020**	**2019**
Deferred tax assets:		
Tax credits	$ 113.4	$ 106.6
Inventory, other reserves and accruals	165.9	162.0
Intangibles, net	1,546.0	3,380.0
Net operating loss	2,080.3	130.4
Share-based compensation	23.3	23.8
Other	103.1	103.7
Valuation allowance	(1,753.9)	(1.1)
Total deferred tax assets	$ 2,278.1	$ 3,905.4
Deferred tax liabilities:		
Purchased intangible assets	$ (396.2)	$ (350.3)
GILTI	(1,143.7)	(1,381.6)
Tax credits	(174.6)	(1,617.2)
Depreciation, amortization and other	(227.0)	(135.0)
Total deferred tax liabilities	$ (1,941.5)	$ (3,484.1)

The change in the valuation allowance between December 31, 2020 and 2019, was primarily related to the establishment of a valuation allowance against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S., as discussed above.

In addition to deferred tax assets and liabilities, we have recorded deferred charges related to intra-entity sales of inventory. As of December 31, 2020 and 2019, the total deferred charges were $142.2 million and $243.8 million, respectively.

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,		
	2020	**2019**	**2018**
Statutory rate	21.0%	21.0%	21.0%
State taxes	0.7	0.8	0.6
Taxes on foreign earnings	(3.3)	(4.5)	(1.9)
Credits and net operating loss utilization	(1.2)	(1.1)	(0.9)
Purchased intangible assets	0.7	0.4	1.2
Divestiture of Denmark manufacturing operations	(0.4)	1.0	—
Internal reorganization of certain intellectual property rights	—	(2.1)	—
TECFIDERA impairment	1.8	—	—
GILTI	1.3	1.5	1.6
U.S. tax reform	—	—	2.1
Swiss tax reform	—	(0.8)	—
Other	(0.9)	0.1	0.5
Effective tax rate	19.7%	16.3%	24.2%

Changes in Tax Rate

For the year ended December 31, 2020, our effective tax rate was primarily increased by the income tax expense related to the establishment of a valuation allowance against certain deferred tax assets, the realization of which is dependent on future sales of TECFIDERA in the U.S., as discussed above, and partially offset by the benefit recognized on the effective settlement of certain tax matters. Additionally, our 2019 effective tax rate benefited from

an internal reorganization of certain intellectual property rights and the enactment of a new taxing regime in the country and certain cantons of Switzerland, which we refer to as Swiss Tax Reform, partially offset by tax expense related to the divestiture of our Hillerød, Denmark manufacturing operations. Although we recognized a loss on the divestiture of our Hillerød, Denmark manufacturing operations, the divestiture required us to write-off certain deferred tax assets and resulted in a taxable gain in certain jurisdictions. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to these consolidated financial statements.

As a result of the 2019 internal reorganization of certain intellectual property rights, we recorded a deferred tax asset of $754.1 million and a deferred tax liability of $603.3 million as of December 31, 2019.

For the year ended December 31, 2019, as compared to 2018, the decrease in our effective tax rate was primarily due to the combination of the internal reorganization of certain intellectual property rights and the impact of the Swiss Tax Reform. This decrease was partially offset by a $68.9 million tax expense related to the divestiture of our subsidiary that owned our Hillerød, Denmark manufacturing operations. We also had a higher effective tax rate in 2018 resulting from the unfavorable effects of the 2017 Tax Act and our sale of inventory, the tax effect of which had been included within prepaid taxes at January 1, 2018, at a higher effective tax rate than the 2018 statutory tax rate.

Tax Attributes

As of December 31, 2020, we had net operating losses and general business credit carry forwards for U.S. federal income tax purposes of approximately $0.6 million and $1.3 million, respectively, which begin to expire in 2026. For U.S. state income tax purposes, we had research and investment credit carry forwards of approximately $142.4 million that begin to expire in 2022. For foreign income tax purposes, we had $18.0 billion of Swiss federal net operating loss carryforwards that begin to expire in 2025 and $16.8 billion of Swiss cantonal net operating loss carryforwards that begin to expire in 2025.

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)	2020	2019	2018
Beginning balance at January 1,	$ 129.9	$ 114.2	$ 66.8
Additions based on tax positions related to the current period	1.5	5.3	0.5
Additions for tax positions of prior periods	51.7	17.2	58.7
Reductions for tax positions of prior periods	(63.6)	(10.3)	(13.6)
Statute expirations	(7.9)	(0.1)	(2.9)
Settlement refund (payment)	(35.9)	3.6	4.7
Ending balance ar December 31,	$ 75.7	$ 129.9	$ 114.2

Our 2020 activity reflects the impact of the effective settlement of certain tax matters. We and our subsidiaries are routinely examined by various taxing authorities. We file income tax returns in various U.S. states and in U.S. federal and other foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal tax examination for years before 2017 or state, local or non-U.S. income tax examinations for years before 2012.

The U.S. Internal Revenue Service and other national tax authorities routinely examine our intercompany transfer pricing with respect to intellectual property related transactions and it is possible that they may disagree with one or more positions we have taken with respect to such valuations.

Included in the balance of unrecognized tax benefits as of December 31, 2020, 2019 and 2018, are $68.8 million, $122.7 million and $109.1 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in future periods.

We recognize potential interest and penalties related to unrecognized tax benefits in income tax expense. In 2020, 2019 and 2018 we recognized a net interest and penalty expense of $1.0 million, $4.7 million and $2.2 million, respectively. We have accrued $21.2 million and $20.0 million for the payment of interest and penalties as of December 31, 2020 and 2019, respectively.

Federal and State Uncertain Tax Positions

It is reasonably possible that we will adjust the value of our uncertain tax positions related to certain transfer pricing, collaboration matters and other issues as we receive additional information from various taxing authorities, including reaching settlements with such authorities.

We estimate that it is reasonably possible that our gross unrecognized tax benefits, exclusive of interest, could decrease by up to approximately $25.0 million in the next 12 months as a result of various audit closures, settlements and expiration of the statute of limitations.

Accounting for Bioverativ Spin-off

On February 1, 2017, in connection with the spin-off of our hemophilia business, we distributed all of the then outstanding shares of Bioverativ common stock to Biogen shareholders pursuant to a separation agreement. In March 2018 Bioverativ was acquired by Sanofi S.A. (Sanofi) and is now an indirect wholly-owned subsidiary of Sanofi. The spin-off of our hemophilia business was intended to qualify for tax-free treatment to Biogen and its shareholders under the Internal Revenue Code. Our 2017 tax return position remains open to audit. Bioverativ and Sanofi agreed to indemnify us for certain potential liabilities that may arise.

17. Other Consolidated Financial Statement Detail

Supplemental Cash Flow Information

Supplemental disclosure of cash flow information for the years ended December 31, 2020, 2019 and 2018, is as follows:

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Cash paid during the year for:			
Interest	$ 272.7	$ 244.2	$ 243.2
Income taxes	906.7	1,064.5	1,007.1

Non-cash Operating, Investing and Financing Activity

In the fourth quarter of 2018 we accrued $300.0 million upon reaching $20.0 billion in total cumulative sales of FUMADERM and TECFIDERA (together, the Fumapharm Products), which was paid in the first quarter of 2019. These amounts, net of tax benefit, were accounted for as increases to goodwill in accordance with the accounting standard applicable to business combinations when we acquired Fumapharm AG.

In connection with the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland, we accrued charges related to processing equipment and engineering services of approximately $12.4 million and $50.0 million in our consolidated balance sheets as of December 31, 2020 and 2019, respectively. For additional information on the construction of our manufacturing facility in Solothurn, Switzerland, please read *Note 10, Property, Plant and Equipment,* to these consolidated financial statements.

Other Income (Expense), Net

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

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Interest income	$ 42.0	$ 120.0	$ 112.5
Interest expense	(222.5)	(187.4)	(200.6)
Gain (loss) on investments, net	685.7	204.7	119.5
Foreign exchange gains (losses), net	(10.7)	(7.0)	(9.9)
Other, net	2.9	(47.0)	(10.5)
Total other income (expense), net	$ 497.4	$ 83.3	$ 11.0

Gain (loss) 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.

For the year ended December 31, 2020, net unrealized and realized gains on our holdings in equity securities were approximately $681.8 million and $12.1 million, respectively, compared to net unrealized and realized gains of $150.1 million and $50.0 million in 2019. The net unrealized gains recognized during the year ended December 31, 2020, primarily reflects an increase in the fair value of Denali and Sangamo common stock of approximately $703.9 million.

The following table summarizes our gain (loss) on investments, net that relates to our equity securities held as of December 31, 2020, 2019 and 2018:

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Net gains (losses) recognized during the period on equity securities	$ 693.9	$ 200.1	$ 127.9
Less: Net gains (losses) recognized on equity securities sold during the period and on capital distributions	12.1	50.0	(0.6)
Unrealized gains (losses) recognized during the period on equity securities	$ 681.8	$ 150.1	$ 128.5

Accrued Expenses and Other

Accrued expenses and other consists of the following:

	As of December 31,	
(In millions)	**2020**	**2019**
Revenue-related reserves for discounts and allowances	$ 1,080.6	$ 1,001.1
Collaboration expenses	389.9	281.6
Employee compensation and benefits	333.8	309.1
Royalties and licensing fees	218.5	220.9
Derivative liabilities	181.5	6.7
Current portion of contingent consideration obligations	149.6	148.4
Other	791.4	798.0
Total accrued expenses and other	$ 3,145.3	$ 2,765.8

Other Long-term Liabilities

Other long-term liabilities were $1,329.6 million and $1,348.9 million as of December 31, 2020 and 2019, respectively, and include accrued income taxes totaling $709.9 million and $803.3 million, respectively.

18. 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; and other potential anti-CD20 therapies pursuant to our collaboration arrangements with Genentech, a wholly-owned member of the Roche Group. For purposes of this footnote, we refer to RITUXAN and RITUXAN HYCELA collectively as RITUXAN.

Our collaboration arrangements will continue in effect until we mutually agree to terminate the collaboration, except that 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 OCREVUS and any other collaboration anti-CD20 products in development in exchange for a royalty as well as our rights to GAZYVA in exchange for the compensation described in the collaboration arrangement. 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. We recognize our share of the development and commercialization expenses of GAZYVA as a reduction of our share of pre-tax profits in revenues from anti-CD20 therapeutic programs.

Commercialization of GAZYVA impacts our percentage of the co-promotion profits for RITUXAN, as summarized in the table below.

OCREVUS

In March 2017 the FDA approved OCREVUS for the treatment of RMS and PPMS. Pursuant to the terms of our collaboration arrangements with Genentech, we receive a tiered royalty on U.S. net sales from 13.5% and increasing up to 24.0% if annual net sales exceed $900.0 million. There will be a 50.0% reduction to these royalties if a biosimilar to OCREVUS is approved in the U.S.

In addition, we receive a gross 3.0% royalty on net sales of OCREVUS outside the U.S., with the royalty period lasting 11 years from the first commercial sale of OCREVUS on a country-by-country basis. OCREVUS has been approved for the treatment of RMS and PPMS in the E.U. and certain other countries.

The commercialization of OCREVUS does not impact the percentage of the co-promotion profits we receive for RITUXAN or GAZYVA. Genentech is solely responsible for development and commercialization of OCREVUS and funding future costs. Genentech cannot develop OCREVUS in CLL, non-Hodgkin's lymphoma or rheumatoid arthritis. OCREVUS royalty revenues were 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 revenues will be adjusted for in the period in which they become known, which is generally expected to be the following quarter.

Profit-sharing Formulas

RITUXAN Profit Share

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

Until GAZYVA First Non-CLL FDA Approval	40.0 %
After GAZYVA First Non-CLL FDA Approval until First GAZYVA Threshold Date	39.0 %
After First GAZYVA Threshold Date until Second GAZYVA Threshold Date	37.5 %
After Second GAZYVA Threshold Date	35.0 %

First Non-CLL GAZYVA FDA Approval means the FDA's first approval of GAZYVA in an indication other than CLL.

First GAZYVA Threshold Date means the earlier of (i) the date of the First Non-CLL GAZYVA FDA approval if U.S. gross sales of GAZYVA for the preceding consecutive 12-month period were at least $150.0 million or (ii) the first day of the calendar quarter after the date of the First Non-CLL GAZYVA FDA Approval that U.S. gross sales of GAZYVA within any consecutive 12-month period have reached $150.0 million.

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

Our share of RITUXAN pre-tax profits in the U.S. in excess of $50.0 million for the years ended December 31, 2020, 2019 and 2018, was 37.5%.

In addition, should the FDA approve an anti-CD20 product other than OCREVUS or GAZYVA that is acquired or developed by Genentech and subject to the collaboration agreement, our share of the co-promotion operating profits would be between 30.0% and 37.5% based on certain events.

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 profits in excess of $50.0 million varies, as summarized in the table below, upon the following events:

Until First GAZYVA Threshold Date	39.0 %
After First GAZYVA Threshold Date until Second GAZYVA Threshold Date	37.5 %
After Second GAZYVA Threshold Date	35.0 %

Our share of GAZYVA pre-tax profits in excess of $50.0 million for the years ended December 31, 2020, 2019 and 2018, was 37.5%.

In November 2017 the FDA approved GAZYVA in combination with chemotherapy, followed by GAZYVA alone, for people with previously untreated advanced follicular lymphoma.

Revenues from Anti-CD20 Therapeutic Programs

Revenues from anti-CD20 therapeutic programs are summarized as follows:

	For the Years Ended December 31,		
(In millions)	2020	2019	2018
Biogen's share of pre-tax profits in the U.S. for RITUXAN and GAZYVA, including the reimbursement of selling and development expenses	$ 1,080.2	$ 1,542.4	$ 1,431.9
Other revenues from anti-CD20 therapeutic programs	897.6	748.0	548.3
Total revenues from anti-CD20 therapeutic programs	$ 1,977.8	$ 2,290.4	$ 1,980.2

Prior to regulatory approval, we record our share of the expenses incurred by the collaboration for the development of anti-CD20 products in research and development expense in our consolidated statements of income.

After an anti-CD20 product is approved, we record our share of the development expenses related to that product as a reduction of our share of pre-tax profits in revenues 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, 2020, 2019 and 2018, totaled $286.6 million, $293.0 million and $238.0 million, respectively.

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.

Upon entering into this agreement, we made an upfront payment of $30.0 million to Ionis and agreed to make potential additional payments, prior to licensing, of up to $10.0 million based on the development of the selected product candidate as well as a mark-up of the cost estimate of the Phase 1 and Phase 2 trials. During 2015 we recognized this $10.0 million developmental milestone upon the selection of BIIB080 (tau ASO), which is currently in Phase 1 development for the potential treatment of Alzheimer's disease.

In December 2019 we exercised our option with Ionis and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB080. In connection with the option exercise, we made a payment of $45.0 million to Ionis, which was recorded as research and development expense in our consolidated statements of income. Future payments may include additional milestone payments of up to $155.0 million and royalties on future sales in the low- to mid-teens if we successfully develop the product candidate after option exercise.

2018 Ionis Agreement

In June 2018 we closed a 10-year exclusive collaboration agreement with Ionis to develop novel antisense oligonucleotide (ASO) drug candidates for a broad range of neurological diseases (2018 Ionis Agreement) for a total payment of $1.0 billion, consisting of an upfront payment of $375.0 million and the purchase of approximately 11.5 million shares of Ionis common stock at a cost of $625.0 million.

Upon closing, we recorded $50.9 million of the $375.0 million upfront payment as prepaid services in our consolidated balance sheets and recognized the remaining $324.1 million as research and development expense in our consolidated statements of income. The amount recorded as prepaid services represented the value of the employee resources committed to the arrangement to provide research and discovery services over the term of the agreement.

The 11.5 million shares of Ionis common stock were purchased at a premium to their fair value at the transaction closing date. The premium consisted of acquiring the shares at a price above the fair value based on the trailing 10-day weighted-average close price prior to entering into the 2018 Ionis Agreement in April 2018 and the effect of certain holding period restrictions. We recorded an asset of $462.9 million in investments and other assets in our consolidated balance sheets reflecting the fair value of the Ionis common stock as of the purchase date and a charge of $162.1 million to research and development expense in our consolidated statements of income in the second quarter of 2018 reflecting the premium paid for the Ionis common stock.

Our investment in Ionis common stock is remeasured each reporting period. Changes in the fair value of our investment in Ionis common stock, including the effect of the holding period restrictions, are reflected in other income (expense), net in our consolidated statements of income. For additional information on the fair value of our investment in Ionis common stock, please read *Note 7, Fair Value Measurements*, to these consolidated financial statements.

We have the option to license therapies arising out of the 2018 Ionis Agreement and will be responsible for the development and commercialization of such therapies. We may pay development milestones to Ionis of up to $125.0 million or $270.0 million for each program, depending on the indication plus an annual license fee, as well as royalties on potential net commercial sales.

During the years ended December 31, 2020 and 2019, we incurred milestones of $11.3 million and $30.0 million, respectively, related to the advancement of neurological targets identified under the 2018 Ionis Agreement.

2017 SMA Collaboration Agreement

In December 2017 we entered into a collaboration agreement with Ionis to identify new ASO drug candidates for the potential treatment of SMA. Under this agreement, we have the option to license therapies arising out of this collaboration and will be responsible for their development and commercialization of such therapies.

Upon entering into this agreement, we made a $25.0 million upfront payment to Ionis and we may pay Ionis up to $260.0 million in additional development and regulatory milestone payments if new drug candidates advance to marketing approval. Upon commercialization, we may also pay Ionis up to $800.0 million in additional performance-based milestone payments and tiered royalties on potential net sales of such therapies.

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 BIIB067 (tofersen), an investigational treatment for ALS with superoxide dismutase 1 (SOD1) mutations. In connection with the option exercise, we made a payment of $35.0 million to Ionis, which was recorded as research and development in our consolidated statements of income. Future payments may include potential post-licensing milestone payments of up to $55.0 million and royalties in the low- to mid-teen percentages on potential annual worldwide net sales. We are solely responsible for the costs and expenses related to the development, manufacturing and commercialization of tofersen following the option exercise.

During the years ending December 31, 2020, 2019 and 2018, we incurred milestones of $28.0 million, $20.0 million and $18.0 million, respectively, related to the advancement of programs under this agreement, which were recorded as research and development expense in our consolidated statements of income.

Eisai Co., Ltd.

BAN2401 Collaboration

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

Eisai serves as the global operational and regulatory lead for BAN2401 and all costs, including research, development, sales and marketing expenses, are shared equally between us and Eisai. If BAN2401 receives marketing approval, we and Eisai will co-promote BAN2401 and share profits equally. In addition, the BAN2401 Collaboration provides both parties with certain rights and obligations in the event of a change in control of either party.

The BAN2401 Collaboration also provided Eisai with an option to jointly develop and commercialize aducanumab (Aducanumab 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 Aducanumab Option and we entered into a new collaboration agreement for the joint development and commercialization of aducanumab (the Aducanumab Collaboration Agreement).

Eisai may exercise the Anti-Tau Option after completion of the Phase 1 clinical trial of such anti-tau monoclonal antibody. If Eisai exercises its Anti-Tau Option, we will receive an upfront payment from Eisai and will be entitled to additional development and commercial milestone payments. Eisai has not yet exercised its Anti-Tau Option.

A summary of development and sales and marketing expenses related to the BAN2401 Collaboration is as follows:

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Total development expense incurred by the collaboration related to the advancement of BAN2401 and elenbecestat	$ 219.3	$ 348.7	$ 232.0
Biogen's share of BAN2401 and elenbecestat development expense reflected in research and development expense in our consolidated statements of income	109.6	174.3	116.0
Total sales and marketing expense incurred by the collaboration	9.8	32.4	10.7
Biogen's share of BAN2401 and elenbecestat sales and marketing expense reflected in selling, general and administrative expense in our consolidated statements of income	4.9	16.2	5.4

Aducanumab Collaboration Agreement

Under the Aducanumab Collaboration Agreement, we and Eisai will co-promote aducanumab with a region-based profit split and we lead the ongoing development of aducanumab.

In March 2019, based on a pre-specified futility analysis, we discontinued the global Phase 3 trials, EMERGE and ENGAGE, designed to evaluate the efficacy and safety of aducanumab in patients with early Alzheimer's disease. A new analysis of a larger dataset from these trials, conducted in scientific collaboration with the FDA, showed that the Phase 3 EMERGE study met its pre-specified primary and secondary endpoints. In the first quarter of 2019, as a result of the decision to discontinue the Phase 3 EMERGE and ENGAGE trials following the futility analysis, we accrued and subsequently paid approximately $45.0 million related to the termination of various clinical trials and research and development contracts net of the expected 45.0% Eisai reimbursement of development costs incurred under the Aducanumab Collaboration Agreement. In October 2019 we and Eisai announced that we plan to pursue regulatory approval for aducanumab in the U.S. In July 2020 we completed the submission of a BLA for the approval of aducanumab to the FDA.

For the period through March 31, 2018, we were responsible for 100.0% of development costs incurred by the collaboration for the advancement of aducanumab (aducanumab development expense). For the period April 1, 2018 through December 31, 2018, Eisai reimbursed us for 15.0% of aducanumab development expense incurred and beginning January 1, 2019, is reimbursing us for 45.0% of aducanumab development expense incurred.

For the year ended December 31, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone expense related to the submission of the BLA for the approval of aducanumab to the FDA.

Upon commercialization, both companies will co-promote aducanumab with a region-based profit split. We will receive a 55.0% share of the potential profits (losses) in the U.S., a 68.5% share of the potential profits (losses) in the European Union (E.U.) and a 20.0% share of the potential profits (losses) in Japan and Asia, excluding China and South Korea. The two companies will continue to share equally in the potential profits (losses) in rest of world markets. Sales and marketing expense incurred before commercialization are shared in proportion to the same region-based profit split that will be utilized to co-promote aducanumab.

A summary of development, sales and marketing and milestone expense related to the Aducanumab Collaboration Agreement is as follows:

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Total aducanumab development expense	$ 152.0	$ 179.4	$ 264.8
Biogen's share of aducanumab development expense reflected in research and development expense in our consolidated statements of income	83.6	98.7	234.6
Total aducanumab sales and marketing expense incurred by the collaboration	353.0	27.4	50.6
Biogen's share of aducanumab sales and marketing expense reflected in selling, general and administrative expense in our consolidated statements of income	193.7	15.1	27.3
Total aducanumab collaboration third party milestone expense	75.0	—	—
Eisai's share of aducanumab milestone expense reflected in collaboration profit sharing in our consolidated statements of income	33.8	—	—

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

UCB Pharma S.A.

We have a collaboration agreement with UCB Pharma S.A. (UCB) to jointly develop and commercialize dapirolizumab pegol, an anti-CD40L pegylated Fab, for the potential treatment of systemic lupus erythematosus and other future agreed indications. Either we or UCB may propose development of dapirolizumab pegol in additional indications. If the parties do not agree to add an indication as an agreed indication to the collaboration, we or UCB may, at the sole expense of the applicable party, pursue development in such excluded indication(s), subject to an opt-in right of the non-pursuing party after proof of clinical activity.

All costs incurred for agreed indications, including research, development, sales and marketing expenses, are shared equally between us and UCB. Upon marketing approval, we and UCB will co-promote dapirolizumab pegol and share profits equally. A summary of development expense related to the UCB collaboration agreement is as follows:

	For the Years Ended December 31,		
(In millions)	**2020**	**2019**	**2018**
Total UCB development expense	$ 58.3	$ 31.9	$ 29.7
Biogen's share of UCB development expense reflected in research and development expense in our consolidated statements of income	29.2	16.0	14.9

Alkermes

In November 2017 we entered into an exclusive license and collaboration agreement with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc (Alkermes), for VUMERITY, a novel fumarate for the treatment of RMS. In October 2019 the FDA approved VUMERITY in the U.S. for the treatment of RMS. In November 2019 VUMERITY became commercially available in the U.S.

Under this agreement, we received an exclusive, worldwide license to develop and commercialize VUMERITY and we pay Alkermes a royalty of 15.0% on worldwide net commercial sales of VUMERITY. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval.

Alkermes is eligible to receive royalties in the high-single digits to sub-teen double digits of annual net commercial sales upon successful development and commercialization of new product candidates, other than VUMERITY, developed under the exclusive license from Alkermes.

During the fourth quarter of 2019, following the FDA's approval of VUMERITY, we paid Alkermes $155.0 million in milestone payments, which were recorded in intangible assets in our consolidated balance sheets and will be amortized over the useful life of the product. For the years ended December 31, 2020, 2019 and 2018, we recorded $32.4 million, $53.5 million and $68.7 million, respectively, in research and development expense in our consolidated statements of income related to this collaboration.

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

Bristol-Myers Squibb Company

In June 2017 we completed an exclusive license agreement with Bristol-Myers Squibb Company (BMS) for the development and potential commercialization of BIIB092 (gosuranemab), an antibody targeting tau, the protein that forms the deposits, or tangles, in the brain associated with Alzheimer's disease.

Under this agreement, we received worldwide rights to gosuranemab and are responsible for the full development and potential commercialization of gosuranemab in Alzheimer's disease and progressive supranuclear palsy (PSP).

In December 2019 we announced that the Phase 2 PASSPORT study investigating gosuranemab in individuals with PSP did not meet its primary endpoint. Based on these results, we discontinued development of gosuranemab in PSP and other primary tauopathies. We will continue our ongoing Phase 2 TANGO study of gosuranemab for mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease, given differences in disease pathology.

Upon entering into this agreement, we made an upfront payment of $300.0 million to BMS and assumed all remaining obligations to the former shareholders of iPierian, Inc. (iPierian) related to BMS's acquisition of iPierian in 2014. We may pay BMS up to $360.0 million in additional milestone payments, and potential royalties, and we may pay the former shareholders of iPierian up to $370.0 million in remaining milestone payments as well as potential royalties on net commercial sales.

For the years ended December 31, 2020, 2019 and 2018, we recorded $62.4 million, $144.0 million and $97.0 million, respectively, in research and development expense in our consolidated statements of income related to this agreement.

Acorda Therapeutics, Inc.

In June 2009 we entered into a collaboration and license agreement with Acorda Therapeutics, Inc. (Acorda) to develop and commercialize products containing fampridine, such as FAMPYRA, in markets outside the U.S. We are responsible for all regulatory activities and the future clinical development of related products in those markets.

Under this agreement, we pay tiered royalties based on the level of ex-U.S. net sales and we may pay potential milestone payments based on the successful achievement of certain regulatory and commercial milestones, which would be capitalized as intangible assets upon achievement of the milestones and amortized utilizing an economic consumption model. The next expected milestone of $15.0 million, due if ex-U.S. net sales reach $100.0 million over a period of four consecutive quarters, was recognized during the third quarter of 2020 and capitalized within intangible assets, net in our consolidated balance sheet. Royalty payments are recognized in cost of sales within our consolidated statements of income.

In connection with the collaboration and license agreement, we also entered into a supply agreement with Acorda for the commercial supply of FAMPYRA. This agreement is a sublicense arrangement of an existing agreement between Acorda and Alkermes Inc., who acquired Elan Drug Technologies, the original party to the license with Acorda.

For the years ending December 31, 2020, 2019 and 2018, total cost of sales related to royalties and commercial supply of FAMPYRA reflected in our consolidated statements of income were $44.5 million, $42.0 million and $36.5 million, respectively.

Sage Therapeutics, Inc.

In November 2020 we entered into a global collaboration and license agreement with Sage to jointly develop and commercialize zuranolone (SAGE-217) for the potential treatment of major depressive disorder, postpartum depression and other psychiatric disorders and SAGE-324 for the potential treatment of essential tremor and other neurological disorders.

In connection of 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 are subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Sage common stock acquired and a charge of approximately $209.0 million to research and development expense in our consolidated statements of income to reflect the premium paid for the Sage common stock. We also made an upfront payment of $875.0 million that was recorded as research and development expense.

We may also pay Sage development and commercial milestone payments that could total up to approximately $1.6 billion if all the specified milestones set forth in this agreement are achieved. Both companies will share equal responsibility and costs for development as well as profits and losses for commercialization in the U.S. Outside of the U.S., we are responsible for development and commercialization, excluding Japan, Taiwan and South Korea, with respect to zuranolone and will pay Sage potential tiered royalties in the high teens to low twenties.

Denali Therapeutics Inc.

In August 2020 we entered into a collaboration and license agreement with Denali to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease. In addition to the LRRK2 program, we also have an exclusive option to license two preclinical programs from Denali's Transport Vehicle platform, including its Antibody Transport Vehicle (ATV): ATV enabled anti-amyloid beta program and a second program utilizing its Transport Vehicle technology. Further, we have a right of first negotiation on two additional Transport Vehicle-enabled therapeutics, should Denali decide to seek a collaboration for such programs.

As part of this collaboration we purchased approximately $465.0 million of Denali common stock in September 2020, or approximately 13 million shares at approximately $34.94 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Denali common stock acquired and a charge of approximately $41.3 million to research and development expense in our consolidated statements of income to reflect the premium paid for the Denali common stock. We also made an upfront payment of $560.0 million that was recorded as research and development expense.

We may also pay Denali development and commercial milestone payments that could total up to approximately $1.1 billion if the milestones related to the LRRK2 program are achieved. Under this agreement, both companies share responsibility and costs for global development based on specified percentages and we are responsible for commercialization and will pay Denali potential tiered royalties.

For the year ended December 31, 2020, we recorded $8.8 million in research and development expense in our consolidated statements of income related to this collaboration.

Sangamo Therapeutics, Inc.

In February 2020 we entered into a collaboration and license agreement with Sangamo to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. The companies are leveraging Sangamo's proprietary zinc finger protein technology delivered via adeno-associated virus to modulate the expression of key genes involved in neurological diseases.

In connection with the closing of this transaction in April 2020 we purchased $225.0 million of Sangamo common stock, or approximately 24 million shares at approximately $9.21 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately $83.0 million to research

and development expense in our consolidated statements of income to reflect the premium paid for the Sangamo common stock. We also made an upfront payment of $125.0 million that was recorded as research and development expense.

We may also pay Sangamo research, development, regulatory and commercial milestone payments that could total up to approximately $2.4 billion if we select all of the targets allowed under this agreement and all the specified milestones set forth in this agreement are achieved. Of this amount, up to $80.0 million relates to the selection of targets, $1.9 billion relates to the achievement of specified research, clinical development, regulatory and first commercial sale milestones and $380.0 million relates to the achievement of specified sales-based milestones if annual worldwide net sales of licensed products reach specified levels. In addition, we will pay Sangamo tiered royalties on potential net commercial sales of any products developed under this collaboration in the high single digit to double digit sub-teen percentages.

For the year ended December 31, 2020, we recorded $6.4 million in research and development expense in our consolidated statements of income related to this collaboration.

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, 2020, 2019 and 2018, we recorded $92.1 million, $77.0 million and $48.6 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. As of December 31, 2020, our ownership percentage remained at approximately 49.9%.

We recognize our share of the results of operations related to our investment in Samsung Bioepis under the equity method of accounting one quarter in arrears when the results of the entity become available, which is reflected as equity in income (loss) of investee, net of tax in our consolidated statements of income. During 2015, as our share of losses exceeded the carrying value of our initial investment, we suspended recognizing additional losses. In the first quarter of 2019 we restarted recognizing our share of Samsung Bioepis' income (losses), and we began recognizing amortization on certain basis differences resulting from our November 2018 investment.

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

The former chief executive officer (the incumbent chairman of the board) and the chief financial officer of our joint venture partner, Samsung BioLogics, is currently subject to ongoing criminal proceedings that we continue to monitor. While these proceedings could impact the operations of Samsung Bioepis and its business, we have assessed the value of our investment in Samsung Bioepis and continue to believe that the fair value of the investment is in excess of its net book value.

For the year ended December 31, 2020, we recognized net income on our investment of $5.3 million, reflecting our share of income totaling $45.3 million offset by amortization of basis differences totaling $40.0 million.

For the year ended December 31, 2019, we recognized net losses on our investment of $79.4 million, reflecting our share of losses totaling $1.2 million and amortization of basis differences totaling $78.2 million.

As of December 31, 2020 and 2019, the carrying value of our investment in Samsung Bioepis totaled 673.8 billion South Korean won ($620.2 million) and 670.8 billion South Korean won ($580.2 million), respectively, which is classified as a component of investments and other assets within our consolidated balance sheets.

2019 Transaction

In December 2019 we completed a transaction with Samsung Bioepis and secured the exclusive rights to commercialize two potential ophthalmology biosimilar products, SB11, a proposed ranibizumab biosimilar referencing LUCENTIS, and SB15, a proposed aflibercept biosimilar referencing EYLEA, in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. Samsung Bioepis will be responsible for development and will supply both products to us.

In connection with this transaction, we made an upfront payment of $100.0 million to Samsung Bioepis in January 2020, of which $63.0 million was recorded as research and development expense in 2019 and $37.0 million was recorded as an intangible asset in 2019. Additionally, during the third quarter of 2020, we paid Samsung Bioepis a $15.0 million development milestone, which was included in research and development expense in our consolidated statements of income. We may pay Samsung Bioepis up to $195.0 million in additional development, regulatory and sales-based milestones.

We also acquired an option to extend the term of our 2013 commercial agreement for BENEPALI, IMRALDI and FLIXABI by an additional five years, subject to payment of an option exercise fee of $60.0 million, and obtained an option to acquire exclusive rights to commercialize these products in China.

2013 Commercial Agreement

In December 2013 we entered into an agreement with Samsung Bioepis to commercialize, over a 10-year term, 3 anti-tumor necrosis factor (TNF) biosimilar product candidates in Europe and in the case of BENEPALI, Japan. As discussed above, we have an option to extend this agreement by an additional five years. Under this agreement, we have made upfront and clinical development milestone payments totaling $46.0 million, which were recorded as research and development expense in our consolidated statements of income as the programs they relate to had not achieved regulatory approval. We also agreed to make additional milestone payments of $25.0 million upon regulatory approval in the E.U. for each of the three anti-TNF biosimilar product candidates. IMRALDI, an adalimumab biosimilar referencing HUMIRA, FLIXABI, an infliximab biosimilar referencing REMICADE, and BENEPALI, an etanercept biosimilar referencing ENBREL, received regulatory approval in the E.U. in August 2017, May 2016 and January 2016, respectively, and we capitalized the related milestone payments totaling $75.0 million as intangible assets, net in our consolidated balance sheets.

In April 2018 we and Samsung Bioepis announced an agreement with AbbVie Inc. (AbbVie) related to the commercialization of IMRALDI. Under the terms of the agreement, AbbVie granted us and Samsung Bioepis patent licenses for the use and sale of IMRALDI in Europe, on a country-by-country basis, and we make royalty payments to AbbVie on behalf of Samsung Bioepis. We began to recognize revenues on sales of IMRALDI to third parties in Europe in the fourth quarter of 2018.

We reflect revenues on sales of BENEPALI, IMRALDI and FLIXABI to third parties in product revenues, net in our consolidated statements of income and record the related cost of revenues and sales and marketing expenses 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% of the profit or loss related to our commercial agreement with Samsung Bioepis, which is recognized in collaboration profit (loss) sharing in our consolidated statements of income. For the years ended December 31, 2020, 2019 and 2018, we recognized a net profit-sharing expense of $266.5 million, $241.6 million and $187.4 million, respectively, to reflect Samsung Bioepis' 50% sharing of the net collaboration profits.

Other Services

Simultaneous with the formation of Samsung Bioepis, we also entered into a technical development services agreement, a manufacturing agreement and a license agreement with Samsung Bioepis.

Under the technical development services agreement, we provided Samsung Bioepis technical development and technology transfer services, which included, but were not limited to, cell culture development, purification process development, formulation development and analytical development.

Under the manufacturing agreement, we manufacture clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis pursuant to contractual terms.

Following the divestiture of our Hillerød, Denmark manufacturing operations in August 2019, FUJIFILM assumed responsibility for the manufacture of clinical and commercial quantities of bulk drug substance of biosimilar products for Samsung Bioepis. We no longer recognize revenues for the manufacturing completed after the divestiture date under the manufacturing agreements with Samsung Bioepis. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to these consolidated financial statements.

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

For the years ended December 31, 2020, 2019 and 2018, we recognized $20.9 million, $106.2 million and $96.4 million, respectively, in revenues under the license, technical development services and manufacturing agreements, which is reflected in revenues from collaborative and other relationships, as a component of other revenues in our consolidated statements of income.

Amounts receivable from Samsung Bioepis related to the agreements discussed above were $5.1 million and $85.0 million as of December 31, 2020 and 2019, respectively. Amounts payable to Samsung Bioepis as of December 31, 2020, were $99.0 million. Amounts payable to Samsung Bioepis as of December 31, 2019, consisted of the $100.0 million upfront payment related to the transaction we completed in December 2019, as discussed above.

19. Investments in Variable Interest Entities

Consolidated Variable Interest Entities

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

Neurimmune SubOne AG

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

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

In October 2017 we amended the terms of the Neurimmune Agreement and made a $150.0 million payment to Neurimmune in exchange for a 15.0% reduction in the previously negotiated royalty rates payable on products developed under the Neurimmune Agreement, including royalties payable on potential commercial sales of aducanumab. In May 2018 we made an additional $50.0 million payment to Neurimmune to further reduce the previously negotiated royalty rates payable on products developed under the Neurimmune Agreement, including

royalties payable on potential commercial sales of aducanumab, by an additional 5.0%. Our royalty rates payable on products developed under the Neurimmune Agreement, including royalty rates payable on potential commercial sales of aducanumab, now range from the high single digits to sub-teens. As we consolidate the results of Neurimmune, we treated these payments as distributions and recognized them as charges to noncontrolling interests in the fourth quarter of 2017 and the second quarter of 2018, as applicable.

Under the terms of the Neurimmune Agreement, we were required to pay Neurimmune a milestone payment of $75.0 million upon the regulatory filing with the FDA for the approval of aducanumab. During the second quarter of 2020, we paid Neurimmune $75.0 million upon the completed submission of the BLA for the approval of aducanumab to the FDA, which was recognized as a charge to noncontrolling interests for the year ended December 31, 2020. In addition, for the year ended December 31, 2020, we recognized net profit-sharing income of $33.8 million to reflect Eisai's 45.0% share of the $75.0 million milestone expense.

Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay up to approximately $200.0 million in milestones to Neurimmune in 2021, which includes $100.0 million if launched in the U.S., $50.0 million if launched in three or more countries within the E.U. and $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the Aducanumab Collaboration Agreement with Eisai.

Research and development costs for which we reimburse Neurimmune are reflected in research and development expense in our consolidated statements of income. During the years ending December 31, 2020, 2019 and 2018, amounts reimbursed were immaterial.

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.

Under the Aducanumab Collaboration Agreement, Eisai had an option to share in the benefit and cost associated with the royalty reductions discussed above; however, Eisai did not elect to share in the benefit and cost with respect to either the October 2017 or May 2018 royalty reductions, which will impact the amount of profits (losses) on potential commercial sales of aducanumab to be shared with Eisai.

For additional information on our collaboration arrangements with Eisai, please read *Note 18, 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, 2020 and 2019, the carrying value of our investments in certain biotechnology companies representing potential unconsolidated variable interest entities totaled $12.8 million and $22.7 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 previously contractually required amounts.

20. Litigation

We are currently involved in various claims and legal proceedings, including the matters described below. For information as to our accounting policies relating to claims and legal proceedings, including use of estimates and contingencies, please read *Note 1, Summary of Significant Accounting Policies*, to these consolidated financial statements.

With respect to some loss contingencies, an estimate of the possible loss or range of loss cannot be made until management has further information, including, for example, (i) which claims, if any, will survive dispositive

motion practice; (ii) information to be obtained through discovery; (iii) information as to the parties' damages claims and supporting evidence; (iv) the parties' legal theories; and (v) the parties' settlement positions.

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

Aducanumab Securities Litigation

We and certain current and former officers are named as defendants in an action filed by a shareholder on November 13, 2020, in the U.S. District Court for the Central District of California and an action filed by a shareholder on January 5, 2021, in the U.S. District Court for the District of Massachusetts. Both actions allege violations of federal securities laws under 15 U.S.C §78j(b) and §78t(a) and 17 C.F.R. §240.10b-5 and are seeking a declaration of the action as a class action and an award of damages, interest and attorneys' fees. An estimate of the possible loss or range of loss cannot be made at this time. No trial date has been set.

IMRALDI Patent Litigation

In September 2018 Fresenius Kabi Deutschland GmbH (Fresenius Kabi) commenced proceedings for damages and injunctive relief against Biogen France SAS in the Tribunal de Grande Instance de Paris, alleging that IMRALDI, the adalimumab biosimilar product of Samsung Bioepis UK Limited that Biogen has commercialized in Europe, infringes the French counterpart of European Patent No. 3 148 510 (the '510 Patent), which was issued in June 2018 and expires in May 2035. No hearing has been scheduled.

In October 2018 Fresenius Kabi commenced preliminary injunction proceedings against Biogen (Denmark) Manufacturing ApS and Biogen Denmark A/S in Denmark's Maritime and Commercial High Court alleging infringement of Danish Utility Models. In June 2019 the Danish court denied Fresenius Kabi's request for a preliminary injunction. Fresenius Kabi has appealed that decision and was permitted to add a claim of infringement of the Danish counterpart of the '510 patent, and the appeal is pending. In July 2020 the Danish Patent Board of Appeal revoked the Danish Utility Models that were the subject of Fresenius Kabi's October 2018 request for a preliminary injunction and Fresenius Kabi has appealed those revocations to Denmark's Maritime and Commercial High Court. No hearing has been scheduled in that appeal.

In June 2020 Fresenius Kabi commenced preliminary injunction proceedings against Biogen (Denmark) Manufacturing ApS and Biogen (Denmark) A/S in Denmark's Maritime and Commercial High Court alleging infringement of another Danish Utility Model. A hearing has been scheduled for May 2021.

In November 2018 Fresenius Kabi commenced infringement proceedings for damages and injunctive relief against Biogen GmbH in the Düsseldorf Regional Court relating to the German counterpart of the '510 Patent. A hearing has been set for August 2021.

In July 2019 Gedeon Richter PLC (Gedeon Richter) commenced proceedings against Biogen GmbH in the Düsseldorf Regional Court alleging infringement of the German counterpart of European Patent No. 3 212 667 (the '667 Patent), which was issued in September 2018 and expires in October 2035, and seeking damages and injunctive relief. A hearing has been set for November 2021.

An estimate of the possible loss or range of loss in the IMRALDI patent litigation described above cannot be made at this time.

Qui Tam Litigation

In July 2015 a qui tam action filed by Michael Bawduniak on behalf of the U.S. and certain states was unsealed by the U.S. District Court for the District of Massachusetts. The action alleges sales and promotional activities in violation of the federal False Claims Act and state law counterparts and seeks single and treble damages, civil penalties, interest, attorneys' fees and costs. No trial date has been set. The U.S. has not made an intervention decision. An estimate of the possible loss or range of loss cannot be made at this time.

Dispute with Former Convergence Shareholders

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

Dispute with Jacobs Switzerland GmbH

Jacobs Switzerland GmbH, the general contractor for the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland, claimed additional payments were due for construction costs. We have reached an agreement in principle to resolve the claim.

Other Matters

Petition for Inter Partes Review

In July 2018 Mylan Pharmaceuticals, Inc. (Mylan) filed a petition that was granted by the U.S. Patent Trial and Appeal Board (PTAB) for *inter partes* review of our U.S. Patent No. 8,399,514 (the '514 Patent). The '514 Patent includes claims covering treatment of MS with 480 mg of dimethyl fumarate per day as provided for in our TECFIDERA label. In February 2020 the PTAB issued a final written decision upholding the patentability of the '514 Patent and in April 2020 Mylan filed an appeal in the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit), which is pending.

Hatch-Waxman Act Litigation relating to TECFIDERA Orange-Book Listed Patents

In 2017 to 2020, we filed patent infringement proceedings relating to TECFIDERA Orange-Book listed patents pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (the Delaware Actions), against Accord Healthcare Inc., Alkem Laboratories Ltd., Amneal Pharmaceuticals LLC, Cipla Limited, Graviti Pharmaceuticals Pvt. Ltd., Hetero USA, Inc., Lupin Atlantis Holdings SA, Macleods Pharmaceuticals, Ltd., MSN Laboratories Pvt. Ltd., Pharmathen S.A., Prinston Pharmaceutical Inc., Sandoz Inc., Shilpa Medicare Limited, Slayback Pharma LLC, Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., Sun Pharma Global FZE, Torrent Pharmaceuticals Ltd., TWi Pharmaceuticals, Inc., Windlas Healthcare Pvt. Ltd. and Zydus Pharmaceuticals (USA) Inc. (collectively, the Delaware Defendants) in the U.S. District Court for the District of Delaware (the Delaware Court) and against Mylan in the U.S. District Court for the Northern District of West Virginia (the West Virginia Court).

On June 22, 2020, the West Virginia Court entered judgment for Mylan that the asserted claims of the '514 Patent are invalid for lack of written description. We appealed the judgment to the Federal Circuit and the appeal is pending.

The Delaware Court entered judgment for the Delaware Defendants on the grounds that the judgment of the West Virginia Court applies to the Delaware Actions under principles of collateral estoppel. We have appealed the judgments and the appeal is pending.

European Patent Office Oppositions

In 2016 the European Patent Office (EPO) revoked our European Patent No. 2 137 537, which covers the treatment of MS with 480 mg of dimethyl fumarate as provided for in our TECFIDERA label. We have appealed to the Technical Boards of Appeal of the EPO and a hearing date has been set for January 2022.

In March 2018 the EPO revoked Forward Pharma's European Patent No. 2 801 355, which expires in October 2025. Forward Pharma has filed an appeal to the Technical Boards of Appeal of the EPO and a hearing has been set for September 2021.

TYSABRI Patent Revocation Matters

In November 2017 Bioeq GMBH, affiliated with the Polpharma Group, brought an action in the Polish Patent Office seeking to revoke Polish Patent No. 215263 (the Polish '263 Patent), which corresponds to our European Patent No. 1 485 127 (the E.U. '127 Patent) and covers administration of natalizumab (TYSABRI) to treat MS. The Polish '263 Patent expires in February 2023. A hearing was held in January 2021 and a decision is pending. In August 2020 a related entity, Polpharma Biologics S.A., also brought an action seeking to revoke the Polish '263 Patent. No hearing has been set in this matter.

Swiss Pharma International AG, also affiliated with the Polpharma Group, filed actions in the District Court of the Hague, Netherlands (January 2016), the German Patents Court (March 2016) and the Commercial Court of Rome (November 2017) seeking to invalidate the Dutch, German and Italian counterparts, respectively, of the E.U. '127 Patent, which also cover administration of natalizumab (TYSABRI) to treat MS and expire in February 2023. The Dutch and German counterparts were ruled invalid. The decision in the Dutch action was affirmed on appeal and the German appeal has been withdrawn. No hearing has been set in the Italian action.

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

Pharmaceutical Works Polpharma SA (Polpharma) and Mylan Ireland Ltd. (Mylan Ireland) have each filed applications in the General Court of the European Union (Polpharma in October 2018 and Mylan Ireland in November 2020) seeking to annul decisions of the European Medicines Agency (EMA) refusing to validate Polpharma's and Mylan Ireland's respective applications to market a generic version of TECFIDERA. The EMA's refusals were on the grounds that TECFIDERA benefits from regulatory data protection. Biogen and the European Commission were granted leave to intervene in support of the EMA in the case brought by Polpharma. That case was heard in July 2020 and we are awaiting a decision. We intend to seek leave to intervene in support of the EMA in the case brought by Mylan Ireland. No hearing has been set in that matter.

Product Liability and Other Legal Proceedings

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

21. Commitments and Contingencies

Royalty Payments

TYSABRI

In 2013 we acquired from Elan full ownership of all remaining rights to TYSABRI that we did not already own or control. Under the acquisition agreement, we are obligated to make contingent payments to Elan of 18.0% on annual worldwide net commercial sales up to $2.0 billion and 25.0% on annual worldwide net commercial sales that exceed $2.0 billion. Royalty payments to Elan and other third parties are recognized as cost of sales in our consolidated statements of income. Elan was acquired by Perrigo Company plc (Perrigo) in December 2013 and Perrigo subsequently sold its rights to these payments to a third-party effective January 2017.

SPINRAZA

In 2016 we exercised our option to develop and commercialize SPINRAZA from Ionis. Under our agreement with Ionis, we make royalty payments to Ionis on annual worldwide net commercial sales of SPINRAZA using a tiered royalty rate between 11.0% and 15.0%, which are recorded as cost of sales in our consolidated statements of income. For additional information on our collaboration arrangements with Ionis, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

VUMERITY

In October 2019 the FDA approved VUMERITY for the treatment of RMS. Under our agreement with Alkermes, we make royalty payments to Alkermes on worldwide net commercial sales of VUMERITY using a royalty rate of 15.0%, which are recorded as cost of sales in our consolidated statements of income. Royalties payable on net commercial sales of VUMERITY are subject, under certain circumstances, to tiered minimum annual payment requirements for a period of five years following FDA approval. For additional information on our collaboration arrangement with Alkermes, please read *Note 18, Collaborative and Other Relationships*, to these consolidated financial statements.

Contingent Consideration related to Business Combinations

In connection with our acquisition of Convergence, we agreed to make additional payments based upon the achievement of certain milestone events.

As the acquisition of Convergence occurred after January 1, 2009, we recognized the contingent consideration liabilities associated with this transaction at their fair value on the acquisition date and revalue the remaining obligations each reporting period. We may pay up to approximately $400.0 million in remaining milestones related to these acquisitions.

Fumapharm AG

In 2006 we acquired Fumapharm AG. As part of this acquisition we acquired the Fumapharm Products. We were required to make contingent payments to former shareholders of Fumapharm AG and holders of their rights based on the attainment of certain cumulative sales levels of Fumapharm Products and the level of total net sales of Fumapharm Products in the prior 12-month period, as defined in the acquisition agreement, until such time as the cumulative sales level reached $20.0 billion, at which time no further contingent payments were due. During the first quarter of 2019 we paid the final $300.0 million contingent payment as we achieved the $20.0 billion cumulative sales levels related to the Fumapharm Products in the fourth quarter of 2018.

Contingent Development, Regulatory and Commercial Milestone Payments

Based on our development plans as of December 31, 2020, we could trigger potential future milestone payments to third parties of up to approximately $10.2 billion, including approximately $1.9 billion in development milestones, approximately $1.3 billion in regulatory milestones and approximately $7.0 billion in commercial milestones, as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or commercial milestones. Because the achievement of these milestones was not considered probable as of December 31, 2020, 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 $86.2 million in milestones in 2021 under our current agreements. Additionally, if aducanumab receives regulatory approval in the jurisdictions where we have submitted filings, we may pay up to $200.0 million in milestones to Neurimmune in 2021, which includes $100.0 million if launched in the U.S., $50.0 million if launched in three or more countries within the E.U. and $50.0 million if launched in Japan. Milestones payable to Neurimmune are shared expenses under the Aducanumab Collaboration Agreement with Eisai.

During the second quarter of 2020 we paid Neurimmune $75.0 million upon the completed submission of the BLA for the approval of aducanumab to the FDA, which was recognized as a charge to noncontrolling interests for the year ended December 31, 2020.

Other Funding Commitments

As of December 31, 2020, 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 expenses of approximately $21.7 million in our consolidated balance sheet for expenditures incurred by CROs as of December 31, 2020. We have approximately $593.0 million in cancellable future commitments based on existing CRO contracts as of December 31, 2020.

As part of the sale of our Hillerød, Denmark manufacturing operations to FUJIFILM, we provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we do not expect to incur an adverse commitment obligation associated with such guarantees. We developed this estimate using a probability-weighted estimate of future manufacturing activity and may further adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods.

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, 2020, we have approximately $79.6 million of liabilities associated with uncertain tax positions.

As of December 31, 2020 and 2019, we have accrued income tax liabilities of $697.0 million, respectively, under the Transition Toll Tax. Of the amounts accrued as of December 31, 2020, $62.0 million is expected to be paid within one year. The Transition Toll Tax will be paid over an eight–year period, which started in 2018, and does not accrue interest. For additional information on the Transition Toll Tax, please read *Note 16, Income Taxes*, to these consolidated financial statements.

Solothurn, Switzerland Manufacturing Facility

In order to support our future growth and drug development pipeline, we are building a large-scale biologics manufacturing facility in Solothurn, Switzerland. We expect this facility to be partially operational during the first half of 2021. As of December 31, 2020, we had contractual commitments of approximately $9.3 million related to the construction of this facility.

22. Guarantees

As of December 31, 2020 and 2019, 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, 2020 and 2019.

23. Employee Benefit Plans

We sponsor various retirement and pension plans. Our estimates of liabilities and expenses for these plans incorporate a number of assumptions, including expected rates of return on plan assets and interest rates used to discount future benefits.

401(k) Savings Plan

We maintain a 401(k) Savings Plan, which is available to substantially all regular employees in the U.S. over the age of 21. Participants may make voluntary contributions. We make matching contributions according to the 401(k) Savings Plan's matching formula. All matching contributions and participant contributions vest immediately. The 401(k) Savings Plan also holds certain transition contributions on behalf of participants who previously participated in the Biogen, Inc. Retirement Plan. The expense related to our 401(k) Savings Plan primarily consists of our matching contributions.

Expense related to our 401(k) Savings Plan totaled $44.3 million, $44.8 million and $42.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Deferred Compensation Plan

We maintain a non-qualified deferred compensation plan, known as the Supplemental Savings Plan (SSP), which allows a select group of management employees in the U.S. to defer a portion of their compensation. The SSP also provides certain credits to highly compensated U.S. employees that are paid by the company. These credits are known as the Restoration Match. The deferred compensation amounts are accrued when earned. Such deferred compensation is distributable in cash in accordance with the rules of the SSP. Deferred compensation amounts under such plan as of December 31, 2020 and 2019, totaled approximately $120.0 million and $114.6 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 2020, 2019 and 2018. 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, 2020 and 2019, the Swiss plan had an unfunded net pension obligation of $75.7 million and $42.9 million, respectively, and plan assets that totaled $170.0 million and $127.1 million, respectively. In 2020, 2019 and 2018 we recognized expense totaling $15.5 million, $14.7 million and $14.8 million, respectively, related to our Swiss plan, of which $2.6 million, $1.2 million and $1.3 million, respectively, was included in other income (expense), net.

The obligations under the German plans are unfunded and totaled $75.5 million and $59.6 million as of December 31, 2020 and 2019, respectively. Net periodic pension cost related to the German plans totaled $6.2 million, $5.1 million and $5.3 million for the years ended December 31, 2020, 2019 and 2018, respectively, of which $2.0 million, $1.4 million and $1.5 million, respectively, was included in other income (expense), net.

24. Segment Information

We operate as one operating segment, focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Our Chief Executive Officer (CEO), as the chief operating decision-maker, manages and allocates resources to the operations of our company on a total company basis. Our research and development organization is responsible for the research and discovery of new product candidates and supports development and registration efforts for potential future products. Our pharmaceutical, operations and technology organization manages the development of the manufacturing processes, clinical trial supply, commercial product supply, distribution, buildings and facilities. Our commercial organization is responsible for U.S. and international development of our commercial products. The company is also supported by corporate staff functions. Managing and allocating resources on a total company basis enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

Enterprise-wide disclosures about product revenues, other revenues and long-lived assets by geographic area are presented below. Revenues are 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, 2020				
(In millions)	**U.S.**	**Europe**	**Asia**	**Other**	**Total**
Product revenues from external customers	$ 5,900.1	$ 3,656.4	$ 596.7	$ 539.0	$ 10,692.2
Revenues from anti-CD20 therapeutic programs	1,897.4	0.1	—	80.3	1,977.8
Other revenues from external customers	733.6	8.1	32.9	—	774.6
Long-lived assets	1,496.3	2,321.4	16.2	10.9	3,844.8

	December 31, 2019				
(In millions)	**U.S.**	**Europe**	**Asia**	**Other**	**Total**
Product revenues from external customers	$ 6,713.8	$ 3,794.5	$ 320.3	$ 551.2	$ 11,379.8
Revenues from anti-CD20 therapeutic programs	2,211.9	0.2	—	78.3	2,290.4
Other revenues from external customers	585.8	9.7	112.2	—	707.7
Long-lived assets	1,493.2	2,162.9	6.2	12.0	3,674.3

	December 31, 2018				
(In millions)	**U.S.**	**Europe**	**Asia**	**Other**	**Total**
Product revenues from external customers	$ 6,800.5	$ 3,370.3	$ 281.2	$ 434.8	$ 10,886.8
Revenues from anti-CD20 therapeutic programs	1,903.4	0.2	—	76.6	1,980.2
Other revenues from external customers	457.0	32.7	96.2	—	585.9
Long-lived assets	1,152.7	2,442.8	3.9	1.8	3,601.2

Other

As of December 31, 2020, 2019 and 2018, approximately $2,180.6 million, $2,028.8 million and $1,748.5 million, respectively, of our long-lived assets were related to the construction of our large-scale biologics manufacturing facility in Solothurn, Switzerland.

In August 2019 we completed the sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM. As of December 31, 2018, approximately $646.5 million of our long-lived assets were related to our manufacturing facility in Hillerød, Denmark.

For additional information on our large-scale biologics manufacturing facility in Solothurn, Switzerland, please read *Note 10, Property, Plant and Equipment,* to these consolidated financial statements. For additional information on the divestiture of our Hillerød, Denmark manufacturing operations, please read *Note 3, Divestitures*, to these consolidated financial statements.

25. Quarterly Financial Data (Unaudited)

(In millions, except per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
2020					
Product revenues, net	$ 2,904.6	$ 2,795.7	$ 2,690.3	$ 2,301.6	$ 10,692.2
Revenues from anti-CD20 therapeutic programs	$ 520.4	$ 478.3	$ 560.1	$ 419.0	$ 1,977.8
Other revenues	$ 109.3	$ 407.6	$ 125.7	$ 132.0	$ 774.6
Total revenues	$ 3,534.3	$ 3,681.6	$ 3,376.1	$ 2,852.6	$ 13,444.6
Gross profit [1]	$ 3,080.0	$ 3,270.5	$ 2,927.0	$ 2,361.9	$ 11,639.4
Net income	$ 1,392.6	$ 1,606.5	$ 703.9	$ 357.6	$ 4,060.5
Net income attributable to Biogen Inc.	$ 1,399.1	$ 1,542.1	$ 701.5	$ 357.9	$ 4,000.6
Net income per share:					
Basic earnings per share attributable to Biogen Inc.	$ 8.10	$ 9.60	$ 4.47	$ 2.33	$ 24.86
Diluted earnings per share attributable to Biogen Inc.	$ 8.08	$ 9.59	$ 4.46	$ 2.32	$ 24.80
Weighted-average shares used in calculating:					
Basic earnings per share attributable to Biogen Inc.	172.8	160.6	156.9	153.7	160.9
Diluted earnings per share attributable to Biogen Inc.	173.1	160.9	157.2	154.0	161.3

(In millions, except per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
2019					
Product revenues, net	$ 2,680.0	$ 2,880.3	$ 2,894.7	$ 2,924.8	$ 11,379.8
Revenues from anti-CD20 therapeutic programs	$ 517.4	$ 576.4	$ 595.8	$ 600.8	$ 2,290.4
Other revenues	$ 292.4	$ 160.0	$ 109.6	$ 145.7	$ 707.7
Total revenues	$ 3,489.8	$ 3,616.7	$ 3,600.1	$ 3,671.3	$ 14,377.9
Gross profit [1]	$ 2,887.8	$ 3,140.4	$ 3,170.1	$ 3,224.2	$ 12,422.5
Net income	$ 1,408.8	$ 1,494.1	$ 1,545.9	$ 1,439.7	$ 5,888.5
Net income attributable to Biogen Inc.	$ 1,408.8	$ 1,494.1	$ 1,545.9	$ 1,439.7	$ 5,888.5
Net income per share:					
Basic earnings per share attributable to Biogen Inc.	$ 7.17	$ 7.85	$ 8.40	$ 8.10	$ 31.47
Diluted earnings per share attributable to Biogen Inc.	$ 7.15	$ 7.85	$ 8.39	$ 8.08	$ 31.42
Weighted-average shares used in calculating:					
Basic earnings per share attributable to Biogen Inc.	196.6	190.3	184.0	177.8	187.1
Diluted earnings per share attributable to Biogen Inc.	197.0	190.4	184.2	178.2	187.4

[1] Gross profit is calculated as total revenues less cost of sales, excluding amortization and impairment of acquired intangible assets.

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, 2020 and 2019, and the related consolidated statements of income, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Changes in Accounting Principles

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019 and the manner in which it accounts for income taxes for intra-entity transfers of assets other than inventory in 2018.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance

with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Reserves for Medicaid and Managed Care Rebates

As described in Notes 1 and 4 to the consolidated financial statements, the Company recognized revenue from product sales net of reserves, including Medicaid and managed care rebates. Within Accrued expenses and other, total contractual adjustments amounted to $1,093.0 million as of December 31, 2020. This balance primarily includes provisions for Medicaid and managed care rebates in the US. Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end. Managed care rebates represent the Company's estimated obligations to third parties, primarily pharmacy benefit managers. 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 expenses and other current liabilities. 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 customer's buying coverage patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period. As disclosed by management, the Medicaid and managed care estimates reflect historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

The principal considerations for our determination that performing procedures relating to reserves for Medicaid and managed care rebates is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing these reserves, as the reserves are based on assumptions developed using historical experience, current contractual requirements, specific known market events and payment patterns, which in turn led to a high degree of auditor judgment, subjectivity and effort in applying procedures related to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the reserves for Medicaid and managed care rebates, including controls over the assumptions used to estimate these rebate reserves. These procedures also included, among others, (i) developing an independent estimate of the rebate reserves by utilizing third-party data related to product demand, data related to price changes, the terms of the specific rebate programs, the historical trend of actual rebate claims paid and consideration of contractual requirement changes and market events; (ii) comparing the independent estimate to management's estimate, and (iii) testing rebate claims paid by the Company, including evaluating the claims for consistency with the contractual terms of the Company's rebate agreements.

/s/PricewaterhouseCoopers LLP
Boston, Massachusetts
February 3, 2021

We have served as the Company's auditor since 2003.