

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 3, 2021**

BIAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-19311
(Commission File Number)

33-0112644
(IRS Employer Identification No.)

225 Binney Street, Cambridge, Massachusetts 02142
(Address of principal executive offices; Zip Code)

Registrant's telephone number, including area code: **(617) 679-2000**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0005 par value	BIIB	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- ☐ 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 3, 2021, Biogen Inc. issued a press release announcing its results of operations and financial condition for the fourth quarter and year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The press release is being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that Section, nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The exhibits listed below are furnished as part of this Current Report on Form 8-K.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Biogen's press release dated February 3, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOGEN INC.

By: /s/ Suzanne Murray
Suzanne Murray

Assistant Secretary

Date: February 3, 2021



BIOGEN REPORTS FOURTH QUARTER AND FULL YEAR 2020 RESULTS

Revenue: Fourth quarter \$2,853 million; Full Year \$13,445 million

GAAP diluted EPS: Fourth quarter \$2.32; Full Year \$24.80

Non-GAAP diluted EPS: Fourth quarter \$4.58; Full Year \$33.70

Aducanumab for Alzheimer's disease currently under regulatory review in the U.S., E.U., and Japan; PDUFA date extended to June 7, 2021, in U.S.

Strong progress advancing pipeline: 8 expected mid-to late-stage data readouts in 2021

Collaboration with Sage in depression and movement disorders adds diversification with late-stage assets

Biogen to study potential biomarkers of cognitive health using Apple Watch and iPhone

Cambridge, Mass., February 3, 2021 -- Biogen Inc. (Nasdaq: BIIB) today reported fourth quarter and full year 2020 financial results.

"In 2020 Biogen executed well and maintained leadership across our core businesses in multiple sclerosis (MS), spinal muscular atrophy (SMA), and biosimilars, while simultaneously making significant progress towards building a multi-franchise portfolio through both internal pipeline developments and multiple new strategic collaborations," said Michel Vounatsos, Biogen's Chief Executive Officer.

"Although we expect a financial reset in 2021 primarily due to the entry of TECFIDERA generics, we believe that 2021 has the potential to be a transformative year for our pipeline with an anticipated regulatory decision in the U.S. on aducanumab for Alzheimer's disease in June as well as pivotal trial readouts in postpartum depression, major depressive disorder, ALS, and choroideremia," Vounatsos said. "I'm proud of all that we have achieved in a challenging year, while also accelerating our actions on health and climate as well as diversity and inclusion."

Fourth Quarter 2020 Financial Results

- Fourth quarter total revenues were \$2,853 million, a 22% decrease versus the prior year at both actual and constant currency*.
 - MS revenues, including royalties on sales of OCREVUS®, of \$1,806 million decreased 24% versus the prior year at both actual and constant currency.
 - SPINRAZA® revenues of \$498 million decreased 8% versus the prior year at actual currency and decreased 10% at constant currency.
 - Biosimilars revenues of \$197 million increased 1% versus the prior year at actual currency and decreased 4% at constant currency.
- Fourth quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$358 million and \$2.32, respectively.

- Fourth quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$706 million and \$4.58, respectively.

Full Year 2020 Financial Results

- Full year total revenues were \$13,445 million, a 6% decrease versus the prior year at both actual and constant currency*.
 - MS revenues, including royalties on sales of OCREVUS, of \$8,678 million decreased 6% versus the prior year at actual currency and decreased 5% at constant currency.
 - SPINRAZA revenues of \$2,052 million decreased 2% versus the prior year at actual currency and decreased 1% at constant currency.
 - Biosimilars revenues of \$796 million increased 8% versus the prior year at actual currency and increased 6% at constant currency.
- Full year GAAP net income and diluted EPS attributable to Biogen Inc. were \$4,001 million and \$24.80, respectively.
- Full year Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$5,436 million and \$33.70, respectively.

A reconciliation of GAAP to Non-GAAP financial measures included in this news release can be found in Table 4 at the end of this news release.

* Percentage changes in revenue growth at constant currency are presented excluding the impact of changes in foreign currency exchange rates and hedging gains or losses. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

Expense Highlights

(In millions)	Q4 '20	Q4 '19	Q4 '20 v. Q4 '19	FY '20	FY '19	FY '20 v. FY '19
GAAP cost of sales	\$ 491	\$ 447	(10%)	\$ 1,805	\$ 1,955	8%
Non-GAAP cost of sales	\$ 491	\$ 447	(10%)	\$ 1,805	\$ 1,955	8%
GAAP R&D	\$ 1,726	\$ 692	(150%)	\$ 3,991	\$ 2,281	(75%)
Non-GAAP R&D	\$ 642	\$ 692	7%	\$ 2,097	\$ 2,273	8%
GAAP SG&A	\$ 806	\$ 665	(21%)	\$ 2,505	\$ 2,376	(5%)
Non-GAAP SG&A	\$ 793	\$ 662	(20%)	\$ 2,482	\$ 2,325	(7%)

Note: Percent changes represented as favorable/(unfavorable)

- GAAP R&D expense in the fourth quarter of 2020 included a \$1,084 million charge related to Biogen's collaboration with Sage Therapeutics, Inc. (Sage), comprising an \$875 million upfront payment and a \$209 million premium paid on Sage common stock purchased. These amounts are excluded from Non-GAAP R&D expense.
- GAAP and Non-GAAP R&D expense in the fourth quarter of 2020 included a total of \$68 million in upfront payments related to collaboration agreements with Scribe Therapeutics Inc., Atalanta Therapeutics (Atalanta), and ViGeneron GmbH (ViGeneron).

- Fourth quarter 2020 GAAP amortization and impairment of acquired intangible assets was \$249 million and included a \$115 million impairment charge related to timrepigene emparvovec (BIIB111), which was obtained as part of our acquisition of Nightstar Therapeutics plc. During the fourth quarter of 2020 we began experiencing third-party manufacturing delays for BIIB111 and determined that forecasted costs associated with advancing the program through development and commercialization will exceed our original estimates. We also recognized a GAAP impairment charge of approximately \$75 million during the fourth quarter of 2020 related to the discontinuation of BIIB054 (cinpanemab) in Parkinson's disease based on data from the Phase 2 SPARK study, which did not meet its primary or secondary endpoints. Full year 2020 GAAP amortization and impairment of acquired intangible assets was \$465 million. These amounts are excluded from Non-GAAP results.
- Fourth quarter 2020 GAAP gain on fair value remeasurement of contingent consideration was \$63 million, including \$51 million related to BIIB054. Full year 2020 GAAP gain on fair value remeasurement of contingent consideration was \$86 million. These amounts are excluded from Non-GAAP results.
- Fourth quarter 2020 GAAP and Non-GAAP net expense related to collaboration profit sharing was \$66 million. Full year 2020 GAAP and Non-GAAP net expense related to collaboration profit sharing was \$233 million.

Other Financial Highlights

- Fourth quarter 2020 GAAP other income was \$684 million, primarily driven by gains on strategic equity investments of \$734 million partially offset by \$52 million of net interest expense. Fourth quarter 2020 Non-GAAP other expense was \$51 million, primarily driven by \$52 million of net interest expense. Full year 2020 GAAP other income was \$497 million, primarily driven by gains on strategic equity investments of \$694 million partially offset by \$181 million of net interest expense. Full year 2020 Non-GAAP other expense was \$187 million, primarily driven by \$171 million of net interest expense.
- Fourth quarter 2020 effective GAAP and Non-GAAP tax rates were 3.8% and 15.9%, respectively. Full year 2020 effective GAAP and Non-GAAP tax rates were 19.7% and 17.9%, respectively. The fourth quarter 2020 effective GAAP tax rate was impacted by the effective settlement of certain tax matters during the quarter.
- In the fourth quarter of 2020 Biogen repurchased approximately 1.6 million shares of the Company's common stock for a total value of \$400 million. Throughout 2020 Biogen repurchased approximately 22.4 million shares of the Company's common stock for a total value of \$6,679 million. As of December 31, 2020, there was \$4,600 million remaining under the share repurchase program authorized in October 2020.
- For the fourth quarter of 2020 the Company's weighted average diluted shares were 154 million. For 2020 the Company's full year weighted average diluted shares were 161 million.
- Fourth quarter 2020 net cash outflow from operations was \$367 million. Capital expenditures were \$86 million, and free cash flow, defined as net cash flow from operations less capital expenditures, was a net cash outflow of \$453 million. Fourth quarter cash flow was negatively impacted by the upfront payments to Denali Therapeutics Inc. (Denali) and Sage and the equity premium paid to Sage.
- Full year 2020 net cash flow from operations was \$4,230 million. Capital expenditures were \$425 million, and free cash flow, defined as net cash flow from operations less capital expenditures, was \$3,805 million. Full year cash flow was negatively impacted by the upfront payments and equity premiums paid to Sangamo Therapeutics, Inc., Denali, and Sage.

- As of December 31, 2020, Biogen had \$7,426 million in total debt, and cash, cash equivalents, and marketable securities totaling \$3,382 million, resulting in net debt of \$4,044 million.

2021 Financial Guidance

Biogen expects full year 2021 revenue to be between \$10.45 billion and \$10.75 billion, Non-GAAP diluted EPS to be between \$17.00 and \$18.50, and capital expenditures to be between \$375 million and \$425 million.

This financial guidance assumes aducanumab, an investigational treatment for Alzheimer's disease, will be approved in the U.S. by June 7, 2021, although uncertainty remains on the U.S. Food and Drug Administration's (FDA) decision. If aducanumab is approved in the U.S., Biogen expects an immediate launch with only modest revenue in 2021, ramping thereafter. This financial guidance further assumes there will be a sharp decline of TECFIDERA in the U.S. during the first half of 2021. Biogen also expects that there will be significant erosion of RITUXAN in the U.S.

Non-GAAP R&D expense is expected to be between \$2.35 billion and \$2.45 billion, and Non-GAAP SG&A expense is expected to be between \$2.6 billion and \$2.7 billion. This Non-GAAP SG&A expense estimate includes approximately \$600 million in support of the potential launch of aducanumab, approximately \$200 million of which would be reimbursable by Eisai Co., Ltd. (Eisai) and reflected on the collaboration profit sharing line post-commercialization. The Non-GAAP tax rate for 2021 is expected to be between 16% and 17%.

In addition, this financial guidance assumes that we will utilize a portion of the remaining share repurchase authorization of \$4.6 billion throughout 2021, and that foreign exchange rates as of December 31, 2020, will remain in effect for the year, net of hedging activities.

This financial guidance does not include any impact from potential acquisitions or large business development transactions, as both are hard to predict, or any impact of potential tax or healthcare reform.

Biogen may incur charges, realize gains or losses, or experience other events or circumstances in 2021 that could cause any of these assumptions to change and/or actual results to vary from this financial guidance.

Biogen does not provide guidance for GAAP reported financial measures (other than revenue) or a reconciliation of forward-looking Non-GAAP financial measures to the most directly comparable GAAP reported financial measures because the Company is unable to predict with reasonable certainty the financial impact of items such as the transaction, integration, and certain other costs related to acquisitions or large business development transactions; unusual gains and losses; potential future asset impairments; gains and losses from our equity security investments; and the ultimate outcome of pending significant litigation without unreasonable effort. These items are uncertain, depend on various factors, and could have a material impact on GAAP reported results for the guidance period. For the same reasons, the Company is unable to address the significance of the unavailable information, which could be material to future results.

Recent Events

- In January 2021 the FDA extended the review period by three months for the Biologics License Application (BLA) for aducanumab. The updated Prescription Drug User Fee Act (PDUFA) action date is June 7, 2021. As part of the ongoing review, Biogen 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. Biogen is collaborating with Eisai on the development of aducanumab.
- In January 2021 Biogen announced that the FDA approved a new intramuscular (IM) injection route of administration for PLEGRIDY® for the treatment of relapsing forms of MS. The new IM

administration of PLEGRIDY provides the well-characterized efficacy and safety of the platform injectable along with the potential for reduced injection site reactions. This FDA approval follows approval by the European Commission in December 2020.

- In January 2021 Biogen announced a new virtual research study, in collaboration with Apple, to investigate the role Apple Watch and iPhone could play in monitoring cognitive performance and screening for decline in cognitive health including mild cognitive impairment, an early indicator of certain forms of dementia such as Alzheimer's disease.
- In January 2021 Biogen announced first patient treated in a global clinical study, RESPOND. The Phase 4 study will examine the clinical benefit and assess the safety of SPINRAZA in infants and children with SMA who still have unmet clinical needs following treatment with gene therapy Zolgensma® (onasemnogene abeparvovec). RESPOND will be conducted at approximately 20 sites worldwide and aims to enroll up to 60 children with SMA.
- In the fourth quarter of 2020 Biogen entered into a global collaboration and licensing agreement with ViGeneron, a gene therapy company, to develop and commercialize gene therapy products based on adeno-associated virus (AAV) vectors to treat inherited eye diseases. The companies will use ViGeneron's proprietary vgAAV, novel engineered AAV capsids, to efficiently transduce retinal cells via intravitreal injections. ViGeneron will be eligible to receive milestone payments as well as tiered royalties on net commercial sales of products arising from the collaboration.
- In the fourth quarter of 2020 Biogen submitted a Japanese New Drug Application to the Ministry of Health, Labor and Welfare for aducanumab. The Japanese regulatory authority will review the application through the standard review process.
- In the fourth quarter of 2020 Biogen and Sage announced a global collaboration and license agreement to jointly develop and commercialize zuranolone (SAGE-217) for major depressive disorder, postpartum depression, and other psychiatric disorders and SAGE-324 for essential tremor and other neurological disorders. Under the agreement, Biogen made an \$875 million upfront payment and an equity investment of \$650 million and may pay up to \$1.6 billion in potential milestone payments as well as potential profit sharing and royalties.
- In the fourth quarter of 2020 Samsung Bioepis Co., Ltd. and Biogen announced that the FDA accepted for review the BLA for SB11, a proposed biosimilar referencing Lucentis® (ranibizumab). Ranibizumab is an anti-VEGF (vascular endothelial growth factor) therapy for retinal vascular disorders, which are a leading cause of blindness in the U.S.
- In the fourth quarter of 2020 Biogen was ranked the number one biotechnology company on the Dow Jones Sustainability World Index (DJSI World Index) for the fifth time, more than any other biotechnology company. The DJSI World Index recognizes the top 10% of companies in the S&P Global Broad Market Index for performance on environmental, social, and governance issues, which S&P Global considers key to generating long-term stakeholder value.
- In the fourth quarter of 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. FDA advisory committees provide non-binding recommendations for consideration by the FDA.
- In the fourth quarter of 2020 Biogen entered into strategic collaboration with Atalanta, a biotechnology company pioneering new treatment options for neurodegenerative disease, to develop RNAi therapeutics for multiple CNS targets for neurodegenerative diseases, including Parkinson's

disease and Alzheimer's disease. Atalanta will be eligible to receive development and milestone payments on these programs as well as potential royalty payments.

Conference Call and Webcast

The Company's earnings conference call for the fourth quarter will be broadcast via the internet at 8:00 a.m. ET on February 3, 2021, and will be accessible through the Investors section of Biogen's website, www.biogen.com. Supplemental information in the form of a slide presentation is also accessible at the same location on the internet and will be subsequently available on the website for at least one month.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics, and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology, and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; 2021 financial guidance; and plans relating to share repurchases. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, and other third

parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; failure to obtain, protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; risks relating to technology failures or breaches; risks relating to management and key personnel changes, including attracting and retaining key personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; fluctuations in our effective tax rate; fluctuations in our operating results; risks related to investment in properties; the market, interest and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements.

Biogen Investor Contact: Biogen Media Contact:

Mike Hencke David Caouette

Biogen Inc. Biogen Inc.

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TABLE 1

BIAGEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF INCOME
(unaudited, in millions, except per share amounts)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Product, net	\$ 2,301.6	\$ 2,924.8	\$ 10,692.2	\$ 11,379.8
Revenues from anti-CD20 therapeutic programs	419.0	600.8	1,977.8	2,290.4
Other	132.0	145.7	774.6	707.7
Total revenues	2,852.6	3,671.3	13,444.6	14,377.9
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	490.6	447.1	1,805.2	1,955.4
Research and development	1,726.0	691.7	3,990.9	2,280.6
Selling, general and administrative	806.3	664.9	2,504.5	2,374.7
Amortization and impairment of acquired intangible assets	249.2	67.7	464.8	489.9
Collaboration profit (loss) sharing	66.4	59.8	232.9	241.6
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations	(92.5)	(40.2)	(92.5)	55.3
(Gain) loss on fair value remeasurement of contingent consideration	(62.8)	2.6	(86.3)	(63.7)
Restructuring charges	—	—	—	1.5
Acquired in-process research and development	—	—	75.0	—
Total cost and expenses	3,183.2	1,893.6	8,894.5	7,335.3
Income from operations	(330.6)	1,777.7	4,550.1	7,042.6
Other income (expense), net	683.5	(49.3)	497.4	83.3
Income before income tax expense and equity in loss of investee, net of tax	352.9	1,728.4	5,047.5	7,125.9
Income tax expense	13.3	276.1	992.3	1,158.0
Equity in loss of investee, net of tax	(18.0)	12.6	(5.3)	79.4
Net income	357.6	1,439.7	4,060.5	5,888.5
Net income (loss) attributable to noncontrolling interests, net of tax	(0.3)	—	59.9	—
Net income attributable to Biogen Inc.	\$ 357.9	\$ 1,439.7	\$ 4,000.6	\$ 5,888.5
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 2.33	\$ 8.10	\$ 24.86	\$ 31.47
Diluted earnings per share attributable to Biogen Inc.	\$ 2.32	\$ 8.08	\$ 24.80	\$ 31.42
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	153.7	177.8	160.9	187.1
Diluted earnings per share attributable to Biogen Inc.	154.0	178.2	161.3	187.4

TABLE 2

BIAGEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in millions)

	As of December 31, 2020	As of December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	\$ 2,610.1	\$ 4,475.9
Accounts receivable, net	1,913.8	1,880.5
Inventory	1,068.6	804.2
Other current assets	1,294.6	1,221.2
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
Investments and other assets	4,268.5	4,484.9
TOTAL ASSETS	\$ 24,618.9	\$ 27,234.3
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ —	\$ 1,495.8
Other current liabilities	3,742.2	3,368.0
Total current liabilities	3,742.2	4,863.8
Notes payable	7,426.2	4,459.0
Long-term operating lease liabilities	402.0	412.7
Other long-term liabilities	2,362.4	4,159.7
Equity	10,686.1	13,339.1
TOTAL LIABILITIES AND EQUITY	\$ 24,618.9	\$ 27,234.3

TABLE 3

BIOGEN INC. AND SUBSIDIARIES
PRODUCT REVENUES & TOTAL REVENUES
(unaudited, in millions)

For the Three Months Ended December 31,						
	2020			2019		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 319.7	\$ 288.2	\$ 607.9	\$ 877.0	\$ 284.4	\$ 1,161.4
VUMERITY*	38.9	—	38.9	5.5	—	5.5
Total Fumarate	358.6	288.2	646.8	882.5	284.4	1,166.9
AVONEX	259.9	96.5	356.4	303.1	107.8	410.9
PLEGRIDY	48.1	51.5	99.6	56.1	49.4	105.5
Total Interferon	308.0	148.0	456.0	359.2	157.2	516.4
TYSABRI	270.7	204.5	475.2	269.5	203.4	472.9
FAMPYRA	—	25.1	25.1	—	25.9	25.9
Spinal Muscular Atrophy:						
SPINRAZA	159.5	338.5	498.0	242.8	300.4	543.2
Biosimilars:						
BENEPALI	—	117.6	117.6	—	126.0	126.0
FLIXABI	—	26.1	26.1	—	18.2	18.2
IMRALDI	—	53.7	53.7	—	51.7	51.7
Other Product Revenues:						
FUMADERM	—	3.1	3.1	—	3.6	3.6
Total product revenues	\$ 1,096.8	\$ 1,204.8	\$ 2,301.6	\$ 1,754.0	\$ 1,170.8	\$ 2,924.8

For the Twelve Months Ended December 31,						
	2020			2019		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 2,677.7	\$ 1,163.4	\$ 3,841.1	\$ 3,306.5	\$ 1,126.2	\$ 4,432.7
VUMERITY*	64.3	—	64.3	5.5	—	5.5
Total Fumarate	2,742.0	1,163.4	3,905.4	3,312.0	1,126.2	4,438.2
AVONEX	1,083.4	408.5	1,491.9	1,202.1	463.8	1,665.9
PLEGRIDY	190.1	195.5	385.6	224.5	211.4	435.9
Total Interferon	1,273.5	604.0	1,877.5	1,426.6	675.2	2,101.8
TYSABRI	1,096.8	849.3	1,946.1	1,041.8	850.4	1,892.2
FAMPYRA	—	103.1	103.1	—	97.1	97.1
Spinal Muscular Atrophy:						
SPINRAZA	787.8	1,264.3	2,052.1	933.4	1,163.6	2,097.0
Biosimilars:						
BENEPALI	—	481.6	481.6	—	486.2	486.2
FLIXABI	—	97.9	97.9	—	68.1	68.1
IMRALDI	—	216.3	216.3	—	184.0	184.0
Other Product Revenues:						
FUMADERM	—	12.2	12.2	—	15.2	15.2
Total product revenues	\$ 5,900.1	\$ 4,792.1	\$ 10,692.2	\$ 6,713.8	\$ 4,666.0	\$ 11,379.8

*VUMERITY became commercially available in the U.S. in November 2019.

(In millions)	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
Total Product Revenues:	\$ 2,301.6	\$ 2,924.8	\$ 10,692.2	\$ 11,379.8
OCREVUS Royalties	202.4	205.4	845.4	687.5
RITUXAN®/GAZYVA® Revenues	216.5	395.5	1,132.4	1,602.9
Other Revenues	132.1	145.6	774.6	707.7
Total Revenues	\$ 2,852.6	\$ 3,671.3	\$ 13,444.6	\$ 14,377.9

TABLE 4

BIAGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION:
DILUTED EARNINGS PER SHARE, NET INCOME ATTRIBUTABLE TO BIAGEN INC., REVENUE GROWTH AT
CONSTANT CURRENCY AND FREE CASH FLOW
(unaudited, in millions, except per share amounts)

An itemized reconciliation between diluted earnings per share on a GAAP and Non-GAAP basis is as follows:

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
GAAP earnings per share - Diluted	\$ 2.32	\$ 8.08	\$ 24.80	\$ 31.42
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	2.26	0.26	8.90	2.15
Non-GAAP earnings per share - Diluted	<u>\$ 4.58</u>	<u>\$ 8.34</u>	<u>\$ 33.70</u>	<u>\$ 33.57</u>

An itemized reconciliation between net income attributable to Biogen Inc. on a GAAP and Non-GAAP basis is as follows:

	For the Three Months Ended December 31,	
	2020	2019
GAAP net income attributable to Biogen Inc.	\$ 357.9	\$ 1,439.7
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets ^A	249.2	67.7
(Gain) loss on fair value remeasurement of contingent consideration ^A	(62.8)	2.6
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations ^B	(92.5)	(40.2)
Acquisition-related transaction and integration costs	10.1	4.5
Subtotal: Acquisition and divestiture related costs	104.0	34.6
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation	—	0.5
Other cost saving initiatives	2.8	—
Subtotal: Restructuring, business transformation and other cost saving initiatives	2.8	0.5
(Gain) loss on equity security investments	(734.2)	(2.9)
Sage upfront payment and premium paid on the purchase of Sage common stock ^C	1,084.0	—
Premium paid on early debt redemption	—	—
Valuation allowance associated with deferred tax assets ^D	1.0	—
Income tax effect related to reconciling items	(116.6)	(6.9)
Amortization included in equity in loss of investee, net of tax	6.8	20.6
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 705.7</u>	<u>\$ 1,485.6</u>

	For the Twelve Months Ended December 31,	
	2020*	2019
GAAP net income attributable to Biogen Inc.	\$ 4,000.6	\$ 5,888.5
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets ^A	464.8	489.9
Acquired in-process research and development	75.0	—
(Gain) loss on fair value remeasurement of contingent consideration ^A	(86.3)	(63.7)
(Gain) loss on divestiture of Hillerød, Denmark manufacturing operations ^B	(92.5)	55.3
Net distribution to noncontrolling interests	0.3	—
Stock option expense related to acquisition of Nightstar Therapeutics plc	—	26.2
Acquisition-related transaction and integration costs	19.5	27.9
Accelerated share-based compensation expense	—	6.7
Subtotal: Acquisition and divestiture related costs	380.8	542.3
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation	—	3.5
Restructuring charges	—	1.5
Other cost saving initiatives	2.8	—
Subtotal: Restructuring, business transformation and other cost saving initiatives	2.8	5.0
(Gain) loss on equity security investments	(693.9)	(200.2)
Sangamo upfront payment and premium paid on the purchase of Sangamo common stock ^E	208.2	—
Denali upfront payment and premium paid on the purchase of Denali common stock ^F	601.3	—
Sage upfront payment and premium paid on the purchase of Sage common stock ^G	1,084.0	—
Premium paid on early debt redemption	9.4	—
Valuation allowance associated with deferred tax assets ^D	90.3	—
Income tax effect related to reconciling items	(287.9)	31.3
Swiss tax reform ^G	—	(54.3)
Amortization included in equity in loss of investee, net of tax	40.0	78.2
Non-GAAP net income attributable to Biogen Inc.	\$ 5,435.6	\$ 6,290.8

*Beginning in the third quarter of 2020 material upfront payments associated with significant collaboration and licensing arrangements are excluded from Non-GAAP R&D expense in order to better reflect the Company's core operating performance. Full year Non-GAAP results reflect this change as the \$125.0 million upfront payment related to the collaboration with Sangamo Therapeutics, Inc. in the second quarter of 2020 has been excluded from Non-GAAP R&D expense.

A reconciliation between total revenue growth and revenue growth at constant currency is as follows:

	For the Three Months Ended December 31, 2020	For the Year Ended December 31, 2020
Total Revenues		
Revenue growth, as reported	(22.3)%	(6.5)%
Less impact of foreign currency translation and hedging (gains) losses	— %	0.7 %
Revenue growth at constant currency^	(22.3)%	(5.8)%
Total MS Revenues (including OCREVUS royalties)		
Revenue growth, as reported	(24.4)%	(5.9)%
Less impact of foreign currency translation and hedging (gains) losses	0.8 %	1.1 %
Revenue growth at constant currency^	(23.6)%	(4.8)%
Total SPINRAZA Revenues		
Revenue growth, as reported	(8.3)%	(2.1)%
Less impact of foreign currency translation and hedging (gains) losses	(1.8)%	1.0 %
Revenue growth at constant currency^	(10.1)%	(1.1)%
Total Biosimilars Revenues		
Revenue growth, as reported	0.8 %	7.8 %
Less impact of foreign currency translation and hedging (gains) losses	(5.2)%	(1.8)%
Revenue growth at constant currency^	(4.4)%	6.0 %

^ Percentage changes in revenue growth at constant currency are presented excluding the impact of changes in foreign currency exchange rates and hedging gains or losses. The current period's foreign currency revenue values are converted into U.S. dollars using the average exchange rates from the prior period.

A reconciliation between net cash flow from operations and free cash flow is as follows:

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
Net cash flow (outflow) from operating activities	\$ (367.1)	\$ 1,960.2	\$ 4,229.8	\$ 7,078.6
Purchases of property, plant, and equipment	(86.0)	(110.4)	(424.8)	(514.5)
Free cash flow^	\$ (453.1)	\$ 1,849.8	\$ 3,805.0	\$ 6,564.1

^ Free cash flow is defined as net cash flow from operations less capital expenditures.

Notes to GAAP to Non-GAAP Reconciliation

^A Amortization and impairment of acquired intangible assets for the three months ended December 31, 2020, compared to the same period in 2019, increased primarily due to the impact of an impairment charge related to timrepigene emparvovec (BIIB111), which was obtained as part of the Nightstar Therapeutics plc acquisition. During the fourth quarter of 2020 we began experiencing third-party manufacturing delays for BIIB111 and determined that forecasted costs associated with advancing the program through development and 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 approximately \$115.0 million during the fourth quarter of 2020.

In February 2021 we announced that we discontinued development of BIIB054 (cinpanemab) for the 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 in-process research and development (IPR&D) intangible asset to zero. We also adjusted the value of our contingent consideration obligation related to BIIB054 resulting in a gain of \$51.0 million in the fourth quarter of 2020.

For the twelve months ended December 31, 2020, amortization and impairment of acquired intangible assets reflects the impact of the BIIB111 and BIIB054 impairment charges as well as a \$19.3 million impairment charge related to one of our IPR&D intangible assets. Amortization and impairment of acquired intangible assets for the twelve months ended December 31, 2019, 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, which was discontinued during the third quarter of 2019. We also adjusted the value of our contingent consideration obligations related to BG00011 resulting in a gain of \$61.2 million in the third quarter of 2019.

^B 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. 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.

In connection with this transaction we recognized a total net loss of approximately \$164.4 million in our consolidated statements of income. This loss included a pre-tax loss of \$95.5 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 an adverse commitment of approximately \$114.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. We also recorded a tax expense of \$68.9 million related to this transaction. During the fourth quarter of 2019 we recorded a \$40.2 million reduction in our estimate of the future minimum batch commitment utilizing our current manufacturing forecast, which reflects the impact of forecasted batches of aducanumab, an investigational treatment for Alzheimer's disease, resulting in a reduction in the pre-tax loss on divestiture from \$95.5 million to \$55.3 million.

During the fourth quarter of 2020 we reduced our estimate of the fair value of the adverse commitment 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. As of December 31, 2020, the cumulative loss on the divestiture of the Hillerød, Denmark manufacturing operations was \$33.2 million.

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. Consistent with our assessment as of the transaction date, 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.

^C In November 2020 we entered into 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 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 \$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.

^D Income tax expense for the three and twelve months ended December 31, 2020, included \$1.0 million and \$90.3 million, respectively, in income tax expense related to a net valuation allowance against certain deferred tax assets, due to the decisions of the U.S. District Court of the Northern District of West Virginia and the U.S. District Court of the District of Delaware that the asserted claims of our U.S. patent No. 8,399,514, which cover the treatment of multiple sclerosis with 480 mg of dimethyl fumarate per day as provided for in our TECFIDERA label, are invalid.

^E In February 2020 we entered into 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. 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 \$9.21 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately \$83.2 million to research and development expense in our condensed 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.

^F In August 2020 we entered into a collaboration and license agreement with Denali Therapeutics Inc. (Denali) to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich kinase 2 (LRRK2) for Parkinson's disease. As part of this collaboration, we purchased approximately \$465.0 million of Denali common stock in September 2020, or approximately 13 million shares at \$34.94 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed 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 condensed 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.

^G During the third quarter of 2019 a new taxing regime in the country and certain cantons of Switzerland was enacted, which we refer to as Swiss Tax Reform. As a result of the impact of Swiss Tax Reform, we recorded an income tax benefit of approximately \$54.3 million resulting from a remeasurement of our deferred tax assets and liabilities in the twelve months ended December 31, 2019.

Use of Non-GAAP Financial Measures

We supplement our GAAP consolidated financial statements and GAAP financial measures with other financial measures, such as adjusted net income, adjusted diluted earnings per share, revenue growth at constant currency, which excludes the impact of changes in foreign exchange rates and hedging gains or losses, and free cash flow, which is defined as net flow from operations less capital expenditures. We believe that these and other Non-GAAP financial measures provide additional insight into the ongoing economics of our business and reflect how we manage our business internally, set operational goals and form the basis of our management incentive programs. Non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

Our “Non-GAAP net income attributable to Biogen Inc.” and “Non-GAAP earnings per share - Diluted” financial measures exclude the following items from “GAAP net income attributable to Biogen Inc.” and “GAAP earnings per share - Diluted”:

1. Acquisitions, divestitures and significant collaboration and licensing arrangements

We exclude transaction, integration and certain other costs related to the acquisition and divestiture of businesses, the acquisitions of assets, significant collaboration and licensing arrangements and items associated with the initial consolidation or deconsolidation of variable interest entities. These adjustments include, but are not limited to, upfront payments in significant collaborations and licensing arrangements, charges for in-process research and development and certain milestones, the amortization and impairment of intangible assets, charges or credits from the fair value remeasurement of our contingent consideration obligations and losses on assets and liabilities held for sale.

2. Restructuring, business transformation and other cost saving initiatives

We exclude costs associated with our execution of certain strategies and initiatives to streamline operations, achieve targeted cost reductions, rationalize manufacturing facilities or refocus research and development activities. These costs may include employee separation costs, retention bonuses, facility closing and exit costs, asset impairment charges or additional depreciation when the expected useful life of certain assets have been shortened due to changes in anticipated usage and other costs or credits that management believes do not have a direct correlation to our ongoing or future business operations.

3. (Gain) loss on equity security investments

We exclude unrealized and realized gains and losses and discounts or premiums on our equity security investments as we do not believe that these components of income or expense have a direct correlation to our ongoing or future business operations.

4. Other items

We evaluate other items of income and expense on an individual basis and consider both the quantitative and qualitative aspects of the item, including (i) its size and nature, (ii) whether or not it relates to our ongoing business operations and (iii) whether or not we expect it to occur as part of our normal business on a regular basis. We also include an adjustment to reflect the related tax effect of all reconciling items within our reconciliation of our GAAP to Non-GAAP net income attributable to Biogen Inc. and earnings per share - diluted.