

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): **October 20, 2021**

**BIOGEN 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
<b>Common Stock, \$0.0005 par value</b>	<b>BIIB</b>	<b>The Nasdaq Global Select Market</b>

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 October 20, 2021, Biogen Inc. issued a press release announcing its results of operations and financial condition for the third quarter ended September 30, 2021. 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	<a href="#">Biogen's press release dated October 20, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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## BIOGEN REPORTS THIRD QUARTER 2021 RESULTS

*Third quarter revenue \$2,779 million; GAAP diluted EPS \$2.22;  
Non-GAAP diluted EPS \$4.77*

*Rolling submission initiated for lecanemab (BAN2401) in the U.S. and new data presented for aducanumab and BIIB080 (tau ASO)*

*Phase 3 data reported for tofersen in SOD1 ALS*

*Announced plans to submit U.S. New Drug Application of zuranolone for depression*

*BYOOVIZ™, a biosimilar referencing LUCENTIS®, approved in the U.S., E.U., and U.K.*

*Positive CHMP opinion received for VUMERITY in E.U.*

**Cambridge, Mass., October 20, 2021** -- Biogen Inc. (Nasdaq: BIIB) today reported third quarter 2021 financial results.

“The potential uptake of ADUHELM in the U.S. is delayed, but we continue to believe in its long-term potential. At the same time, Biogen has continued to execute well across its leading MS, SMA and biosimilars businesses, and we are particularly encouraged by the ongoing launch of VUMERITY,” said Michel Vounatsos, Biogen's Chief Executive Officer. “2021 continues to be a transformative year for Biogen with the launch of ADUHELM and the initiation of the rolling submission for lecanemab in Alzheimer’s disease. In addition, along with Sage Therapeutics we are pursuing a filing for zuranolone in depression.”

### **Third Quarter 2021 Financial Results**

- Third quarter total revenue of \$2,779 million decreased 18% versus the prior year at both actual currency and constant currency\*.
  - Multiple sclerosis (MS) revenue, including royalties on sales of OCREVUS®, of \$1,820 million decreased 19% versus the prior year at actual currency and 20% at constant currency.
  - SPINRAZA® revenue of \$444 million decreased 10% versus the prior year at actual currency and 11% at constant currency.
  - ADUHELM™ revenue was \$0.3 million.
  - Biosimilars revenue of \$203 million decreased 2% versus the prior year at actual currency and 4% at constant currency.
- Third quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$329 million and \$2.22, respectively.
- Third quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$710 million and \$4.77, 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.

- Third quarter 2021 cost of sales, R&D, and SG&A were:

(In millions)	Q3 '21	Q3 '20	Q3 '21 v. Q3 '20
GAAP cost of sales	\$ 512	\$ 449	(14%)
Non-GAAP cost of sales	\$ 512	\$ 449	(14%)
GAAP R&D	\$ 702	\$ 1,141	38%
Non-GAAP R&D	\$ 702	\$ 1,141	38%
GAAP SG&A	\$ 654	\$ 573	(14%)
Non-GAAP SG&A	\$ 651	\$ 573	(14%)

Note: Percent changes represented as favorable/(unfavorable)

- Beginning in the second quarter of 2021 material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP R&D and SG&A expenses. Non-GAAP financial results for the third quarter of 2020 have been updated to reflect the \$601 million payment related to the collaboration with Denali Therapeutics Inc. along with the associated transaction costs and income tax effect.
- Third quarter 2021 GAAP and Non-GAAP R&D expense includes a \$125 million upfront payment related to our collaboration with InnoCare Pharma Limited. In addition, during the third quarter we suspended further development of BIIB111 (timrepigene emparvovec) in choroideremia and BIIB112 (cotoretigene toliparvovec) in X-linked retinitis pigmentosa and recorded \$39 million of estimated clinical trial close-out costs and manufacturing commitments.
- Third quarter 2021 GAAP and Non-GAAP SG&A expense increased versus the prior year primarily due to investments in support of the launch of ADUHELM. Beginning in the second quarter, upon FDA approval, the reimbursement from Eisai for its share of U.S. ADUHELM SG&A expenses is reflected in collaboration profit sharing rather than SG&A.
- Third quarter 2021 GAAP amortization and impairment of acquired intangible assets was \$111 million, including an impairment charge of \$15 million related to BIIB111 and a \$28 million impairment charge related to BIIB112. These amounts are excluded from Non-GAAP financial results. Non-GAAP amortization was \$7 million.
- Third quarter 2021 GAAP and Non-GAAP collaboration profit sharing was a net expense of \$21 million, which includes a reimbursement of \$51 million from Eisai Co., Ltd. (Eisai) related to the commercialization of ADUHELM in the U.S.
- Third quarter 2021 GAAP other expense was \$503 million, primarily driven by unrealized losses on our strategic equity investments of \$424 million. Third quarter 2021 Non-GAAP other expense was \$79 million, primarily driven by interest expense.

- Third quarter 2021 effective GAAP and Non-GAAP tax rates were (8.9%) and 14.5%, respectively. The third quarter 2021 effective GAAP tax rate was impacted by non-cash tax favorability from both the unrealized losses on our strategic equity investments and the previously described impairment charges related to BIIB111 and BIIB112.

### **Financial Position**

- As of September 30, 2021, Biogen had \$7,271 million in total debt. Cash, cash equivalents, and marketable securities totaled \$3,923 million. This resulted in net debt of \$3,348 million.
- In the third quarter of 2021 Biogen repurchased approximately 2.2 million shares of the Company's common stock for a total value of \$750 million. As of September 30, 2021, there was \$2,800 million remaining under the share repurchase program authorized in October 2020.
- For the third quarter of 2021 the Company's weighted average diluted shares were 149 million.
- Third quarter 2021 cash from operations was \$805 million. Capital expenditures were \$42 million, and free cash flow, defined as cash flow from operations less capital expenditures, was \$763 million.

### **Full Year 2021 Financial Guidance**

For the full year 2021, Biogen is updating its guidance ranges as follows:

	<b>Prior Guidance</b>	<b>Updated Guidance</b>
Total revenue	\$10.65 to \$10.85 billion	<b>\$10.8 to \$10.9 billion</b>
Non-GAAP diluted EPS	\$17.50 to \$19.00	<b>\$18.85 to \$19.35</b>
Capital expenditures	\$375 to \$425 million	<b>\$250 to \$300 million</b>

This financial guidance assumes minimal ADUHELM revenue in 2021, ramping thereafter. This guidance also continues to assume erosion of TECFIDERA® and RITUXAN® in the U.S. Biogen expects the decreased revenue from these high margin products to reduce its gross margin percentage compared to 2020.

Non-GAAP R&D expense is expected to be between \$2.45 billion and \$2.55 billion. Non-GAAP SG&A expense is expected to be between \$2.6 billion and \$2.7 billion.

We expect that we will utilize a portion of the remaining share repurchase authorization of \$2,800 million through the end of 2021.

This guidance assumes that foreign exchange rates as of September 30, 2021, will remain in effect for the remainder of 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 October 2021 Biogen and Sage Therapeutics, Inc. (Sage) announced their plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for zuranolone, an investigational two-week, once-daily therapeutic in the second half of 2022, with rolling submission expected to start in early 2022. The planned initial submission package will seek approval of zuranolone for the treatment of major depressive disorder (MDD), and an additional filing for postpartum depression (PPD) is anticipated in the first half of 2023. The decision to submit the application follows recent discussions with the FDA, including a pre-NDA meeting held this fall.
- In October 2021 Biogen announced topline results from its pivotal Phase 3 VALOR study of tofersen (BIIB067), an investigational antisense drug being evaluated for people with superoxide dismutase 1 (SOD1) amyotrophic lateral sclerosis (ALS). While tofersen did not meet the primary endpoint of change from baseline to week 28 in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), trends favoring tofersen were seen across multiple secondary and exploratory measures of biologic activity and clinical function. The totality of evidence from VALOR and its ongoing open-label extension showed that participants who started tofersen earlier experienced better outcomes, further suggesting a positive clinical effect. Biogen is actively engaging with regulators, the medical community, patient advocacy groups and other key stakeholders around the world to determine potential next steps. Given the high unmet medical need, Biogen will expand its ongoing early access program (EAP) to the broader SOD1-ALS population.
- In October 2021 Sage and Biogen announced new data from the LANDSCAPE and NEST clinical development program evaluating the efficacy and safety of zuranolone for the treatment of major depressive disorder and postpartum depression. Sage presented this data at the 34th European College of Neuropsychopharmacology Congress.
- In the third quarter of 2021 Eisai initiated a rolling submission to the FDA of a Biologics License Application (BLA) for lecanemab for the treatment of early AD. The BLA is being submitted under the accelerated approval pathway and is primarily based on clinical, biomarker and safety data from the Phase 2b clinical trial (Study 201) in people with early AD and confirmed amyloid pathology.
- In the third quarter of 2021 Biogen issued the first progress report of its signature *Healthy Climate, Healthy Lives*<sup>™</sup> initiative, a groundbreaking \$250 million, 20-year commitment to address the deeply interrelated issues of climate, health, and equity. This progress report details efforts to go fossil fuel free, including engagement with its employees and suppliers, and ongoing collaborations with renowned institutions to improve health – especially for vulnerable populations most impacted by climate-related events.
- In the third quarter of 2021 Biogen held a virtual Investor R&D Day, providing a comprehensive overview of the company's diversified pipeline in neuroscience and plans to advance innovative therapies for patients through the work of its world-class researchers and the strength of its global network of collaborators.
- In the third quarter of 2021 BYOOVIZ<sup>™</sup> (ranibizumab-nuna), a biosimilar referencing LUCENTIS (ranibizumab), was approved in the U.S., the E.U., and the U.K.

- In the third quarter of 2021 the European Medicines Agency’s Committee for Medicinal Products for Human Use adopted a positive opinion for VUMERITY® (diroximel fumarate) for the treatment of adults with relapsing-remitting multiple sclerosis.
- In the third quarter of 2021 Biogen announced topline results from its Phase 2 CONVEY study of vixotrigine (BIIB074), a non-opioid investigational oral pain drug being evaluated for the treatment of small fiber neuropathy. The CONVEY study 200 mg twice daily arm met its primary endpoint of change from baseline to week 12 of the double-blind period in mean average daily pain score. While the 350 mg twice daily arm did not meet the primary endpoint, it met statistical significance in the Patient Global Impression of Change at week 12, an important self-reported measure of a patient’s overall improvement since with the start of the study.
- In the third quarter of 2021 Biogen announced plans to initiate a global Phase 3b clinical study, ASCEND, to evaluate the clinical outcomes and assess the safety of a higher dose of nusinersen in children, teens and adults with later-onset spinal muscular atrophy following treatment with Evrysdi® (risdiplam).
- In the third quarter of 2021 Biogen announced results from Phase 3b NOVA study evaluating efficacy of every six-week (Q6W) dosing with natalizumab as compared to the approved every four-week (Q4W) dosing in relapsing-remitting multiple sclerosis.
- In the third quarter of 2021 Eisai and Biogen presented multiple analyses at the 2021 Alzheimer’s Association International Conference (AAIC), including:
  - A preliminary assessment of the clinical effects of lecanemab following 18 months of treatment in the open-label extension of the Phase 2 proof of concept study
  - The design of the real-world observational Phase 4 study of aducanumab in Alzheimer’s disease called ICARE AD-US
  - Item-level analysis of clinical measures in the Phase 3 EMERGE study of aducanumab
  - An assessment of the correlation between reductions in amyloid beta and other biomarkers of Alzheimer’s disease and clinical decline after treatment with aducanumab
  - Subgroup analyses of the effect of aducanumab on amyloid PET from the EMERGE and ENGAGE studies
  - Considerations for the real-world management of ARIA from the Phase 3 EMERGE and ENGAGE studies of aducanumab
  - Positive clinical data for the Phase 1b clinical study of BIIB080 demonstrating robust time and dose-dependent lowering of tau protein in cerebrospinal fluid over the three-month treatment period and sustained reductions during the six-month post-treatment period

#### **Conference Call and Webcast**

The Company’s earnings conference call for the third quarter will be broadcast via the internet at 8:00 a.m. ET on October 20, 2021, and will be accessible through the Investors section of Biogen’s website, [www.biogen.com](http://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**

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir 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, and is providing the first and only approved treatment to address a defining pathology of Alzheimer’s disease. Biogen is also commercializing biosimilars and focusing on advancing the industry’s most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, \$250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company’s operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at [www.biogen.com](http://www.biogen.com). To learn more, please visit [www.biogen.com](http://www.biogen.com) and follow Biogen 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; 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; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, 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; 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; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; 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:**

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TABLE 1

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product, net	2,205.7	2,690.3	6,653.4	8,390.6
Revenue from anti-CD20 therapeutic programs	415.4	560.1	1,244.4	1,558.8
Other	157.8	125.7	350.1	642.6
Total revenue	<u>2,778.9</u>	<u>3,376.1</u>	<u>8,247.9</u>	<u>10,592.0</u>
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	511.8	449.1	1,449.6	1,314.6
Research and development	702.4	1,140.9	1,801.7	2,264.8
Selling, general and administrative	654.1	573.1	1,886.4	1,698.3
Amortization and impairment of acquired intangible assets	111.0	82.6	813.2	215.6
Collaboration profit sharing	21.2	73.0	74.5	166.5
(Gain) loss on fair value remeasurement of contingent consideration	(15.6)	(29.0)	(49.1)	(23.5)
Acquired in-process research and development	—	—	18.0	75.0
Total cost and expense	<u>1,984.9</u>	<u>2,289.7</u>	<u>5,994.3</u>	<u>5,711.3</u>
Income from operations	794.0	1,086.4	2,253.6	4,880.7
Other income (expense), net	(502.9)	(128.6)	(913.4)	(186.1)
Income before income tax expense and equity in loss of investee, net of tax	291.1	957.8	1,340.2	4,694.6
Income tax (benefit) expense	(25.9)	240.8	(390.7)	979.0
Equity in (income) loss of investee, net of tax	(1.1)	13.1	(17.2)	12.7
Net income	318.1	703.9	1,748.1	3,702.9
Net income (loss) attributable to noncontrolling interests, net of tax	(11.1)	2.4	560.2	60.2
Net income attributable to Biogen Inc.	<u>\$ 329.2</u>	<u>\$ 701.5</u>	<u>\$ 1,187.9</u>	<u>\$ 3,642.7</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 2.22	\$ 4.47	\$ 7.93	\$ 22.29
Diluted earnings per share attributable to Biogen Inc.	\$ 2.22	\$ 4.46	\$ 7.90	\$ 22.25
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	148.0	156.9	149.9	163.4
Diluted earnings per share attributable to Biogen Inc.	148.6	157.2	150.3	163.7

TABLE 2

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

	<u>As of September 30, 2021</u>	<u>As of December 31, 2020</u>
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 2,955.1	\$ 2,610.1
Accounts receivable, net	1,723.0	1,913.8
Inventory	1,347.9	1,068.6
Other current assets	1,136.3	1,294.6
Total current assets	7,162.3	6,887.1
Marketable securities	968.3	772.1
Property, plant and equipment, net	3,410.7	3,411.5
Operating lease assets	389.1	433.3
Intangible assets, net	2,286.8	3,084.3
Goodwill	5,760.5	5,762.1
Deferred tax asset	1,810.4	1,369.5
Investments and other assets	2,018.6	2,899.0
<b>TOTAL ASSETS</b>	<b>\$ 23,806.7</b>	<b>\$ 24,618.9</b>
<b>LIABILITIES AND EQUITY</b>		
Current portion of notes payable	\$ 998.8	\$ —
Other current liabilities	3,212.8	3,742.2
Total current liabilities	4,211.6	3,742.2
Notes payable	6,272.3	7,426.2
Deferred tax liability	774.7	1,032.8
Long-term operating lease liabilities	348.2	402.0
Other long-term liabilities	1,318.2	1,329.6
Equity	10,881.7	10,686.1
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 23,806.7</b>	<b>\$ 24,618.9</b>

TABLE 3

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

For the Three Months Ended September 30,

	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 179.2	\$ 319.4	\$ 498.6	\$ 669.8	\$ 283.3	\$ 953.1
VUMERITY®	120.7	0.2	120.9	14.4	—	14.4
Total Fumarate	299.9	319.6	619.5	684.2	283.3	967.5
AVONEX®	213.2	88.1	301.3	279.9	100.6	380.5
PLEGRIDY®	39.2	47.0	86.2	47.4	46.2	93.6
Total Interferon	252.4	135.1	387.5	327.3	146.8	474.1
TYSABRI	281.1	241.7	522.8	304.2	212.3	516.5
FAMPYRA®	—	26.2	26.2	—	26.8	26.8
Spinal Muscular Atrophy:						
SPINRAZA	139.8	304.3	444.1	182.5	311.9	494.4
Alzheimer's disease:						
ADUHELM*	0.3	—	0.3	—	—	—
Biosimilars:						
BENEPALI™	—	120.8	120.8	—	124.2	124.2
IMRALDI™	—	57.4	57.4	—	56.2	56.2
FLIXABI™	—	24.6	24.6	—	27.5	27.5
Other:						
FUMADERM™	—	2.5	2.5	—	3.1	3.1
Total product revenue, net	\$ 973.5	\$ 1,232.2	\$ 2,205.7	\$ 1,498.2	\$ 1,192.1	\$ 2,690.3

\* In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the United States (U.S.) during the second quarter of 2021.

TABLE 3 (continued)

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

	For the Nine Months Ended September 30,					
	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 520.1	\$ 945.3	\$ 1,465.4	\$ 2,358.0	\$ 875.2	\$ 3,233.2
VUMERITY	285.0	0.5	285.5	25.4	—	25.4
Total Fumarate	805.1	945.8	1,750.9	2,383.4	875.2	3,258.6
AVONEX	636.4	286.9	923.3	823.5	312.0	1,135.5
PLEGRIDY	115.2	149.9	265.1	142.0	144.0	286.0
Total Interferon	751.6	436.8	1,188.4	965.5	456.0	1,421.5
TYSABRI	854.2	696.2	1,550.4	826.0	644.9	1,470.9
FAMPYRA	—	78.8	78.8	—	78.1	78.1
Spinal Muscular Atrophy:						
SPINRAZA	437.8	1,026.6	1,464.4	628.2	925.8	1,554.0
Alzheimer's disease:						
ADUHELM*	2.0	—	2.0	—	—	—
Biosimilars:						
BENEPALI	—	363.9	363.9	—	363.9	363.9
IMRALDI	—	170.9	170.9	—	162.6	162.6
FLIXABI	—	75.4	75.4	—	71.8	71.8
Other:						
FUMADERM	—	8.3	8.3	—	9.2	9.2
Total product revenue, net	\$ 2,850.7	\$ 3,802.7	\$ 6,653.4	\$ 4,803.1	\$ 3,587.5	\$ 8,390.6

\* In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the United States (U.S.) during the second quarter of 2021.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue	\$ 2,205.7	\$ 2,690.3	\$ 6,653.4	\$ 8,390.6
OCREVUS royalties	264.3	272.4	730.5	643.0
RITUXAN/GAZYVA® revenue	151.1	287.7	513.9	915.8
Other revenue	157.8	125.7	350.1	642.6
Total revenue	\$ 2,778.9	\$ 3,376.1	\$ 8,247.9	\$ 10,592.0

TABLE 4

**BIOGEN INC. AND SUBSIDIARIES**  
**GAAP TO NON-GAAP RECONCILIATION**  
**OPERATING EXPENSE & OTHER INCOME (EXPENSE), NET**  
*(unaudited, in millions, except per share amounts)*

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.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021*	2020**	2021*	2020**
<b>Selling, General and Administrative Expense:</b>				
Total selling, general and administrative, GAAP	\$ 654.1	\$ 573.1	\$ 1,886.4	\$ 1,698.3
Less: other	3.0	—	5.2	(0.1)
Total selling, general and administrative, Non-GAAP	\$ 651.1	\$ 573.1	\$ 1,881.2	\$ 1,698.4
<b>Amortization and Impairment of Acquired Intangible Assets:</b>				
Total amortization and impairment of acquired intangible assets, GAAP	\$ 111.0	\$ 82.6	\$ 813.2	\$ 215.6
Less: impairment charges <sup>A</sup>	44.3	19.3	629.3	19.3
Less: amortization of acquired intangible assets	59.4	63.3	176.6	196.3
Total amortization and impairment of acquired intangible assets, Non-GAAP	\$ 7.3	\$ —	\$ 7.3	\$ —
<b>(Gain) Loss on Fair Value Remeasurement of Contingent Consideration:</b>				
Total (gain) loss on fair value remeasurement of contingent consideration, GAAP	\$ (15.6)	\$ (29.0)	\$ (49.1)	\$ (23.5)
Less: (gain) loss on fair value remeasurement of contingent consideration	(15.6)	(29.0)	(49.1)	(23.5)
Total (gain) loss on fair value remeasurement of contingent consideration, Non-GAAP	\$ —	\$ —	\$ —	\$ —
<b>Other Income (Expense), net:</b>				
Total other income (expense), net, GAAP	\$ (502.9)	\$ (128.6)	\$ (913.4)	\$ (186.1)
Less: gain (loss) on equity security investments	(424.2)	(82.2)	(705.9)	(40.2)
Plus: premium paid on debt exchange or early debt redemption	—	—	9.5	9.4
Total other income (expense), net, Non-GAAP	\$ (78.7)	\$ (46.4)	\$ (198.0)	\$ (136.5)
<b>Income Tax (Benefit) Expense:</b>				
Total income tax (benefit) expense, GAAP	\$ (25.9)	\$ 240.8	\$ (390.7)	\$ 979.0
Less: Neurimmune step-up tax basis <sup>B</sup>	—	—	(492.0)	—
Less: valuation allowance associated with deferred tax assets	—	33.3	—	89.3
Less: income tax effect related to Non-GAAP reconciling items	(142.7)	(1.0)	(335.3)	(29.7)
Total income tax expense, Non-GAAP	\$ 116.8	\$ 208.5	\$ 436.6	\$ 919.4
<b>Effective Tax Rate:</b>				
Total effective tax rate, GAAP	(8.9) %	25.1 %	(29.2) %	20.9
Less: Neurimmune step-up tax basis <sup>B</sup>	—	—	(36.7)	—
Less: valuation allowance associated with deferred tax assets	—	3.5	—	1.9
Less: impact of GAAP to Non-GAAP adjustments	(23.4)	2.5	(7.9)	0.7
Total effective tax rate, Non-GAAP	14.5 %	19.1 %	15.4 %	18.3

TABLE 4 (continued)

**BIOGEN INC. AND SUBSIDIARIES**  
**GAAP TO NON-GAAP RECONCILIATION**  
**INCOME TAX, NET INCOME ATTRIBUTABLE TO BIOGEN INC. & DILUTED EPS**  
*(unaudited, in millions, except per share amounts)*

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
<b>Equity in (Income) Loss of Investee, Net of Tax:</b>				
Total equity in (income) loss of investee, GAAP	\$ (1.1)	\$ 13.1	\$ (17.2)	\$ 12.7
Less: amortization of equity in (income) loss of investee	7.8	10.3	31.0	33.2
Total equity in (income) loss of investee, Non-GAAP	<u>\$ (8.9)</u>	<u>\$ 2.8</u>	<u>\$ (48.2)</u>	<u>\$ (20.5)</u>
<b>Net Income (Loss) Attributable to Noncontrolling Interests, Net of Tax:</b>				
Total net income (loss) attributable to noncontrolling interests, GAAP	\$ (11.1)	\$ 2.4	\$ 560.2	\$ 60.2
Less: Neurimmune step-up tax basis <sup>B</sup>	—	—	492.0	—
Less: net distribution to noncontrolling interests and other	—	7.4	(4.4)	0.3
Total net income (loss) attributable to noncontrolling interests, Non-GAAP	<u>\$ (11.1)</u>	<u>\$ (5.0)</u>	<u>\$ 72.6</u>	<u>\$ 59.9</u>
<b>Net Income Attributable to Biogen Inc.:</b>				
Total net income attributable to Biogen Inc., GAAP	\$ 329.2	\$ 701.5	\$ 1,187.9	\$ 3,642.7
Plus: impairment charges <sup>A</sup>	44.3	19.3	629.3	19.3
Plus: amortization of acquired intangible assets	59.4	63.3	176.6	196.3
Plus: acquired in-process research and development	—	—	18.0	75.0
Plus: (gain) loss on fair value remeasurement of contingent consideration	(15.6)	(29.0)	(49.1)	(23.5)
Plus: (gain) loss on equity security investments	424.2	82.2	705.9	40.2
Plus: net distribution to noncontrolling interests & amortization of equity in loss of investee	7.8	17.7	26.6	33.5
Plus: premium paid on debt exchange or early debt redemption	—	—	9.5	9.4
Plus: other	3.0	—	5.2	(0.1)
Plus: valuation allowance associated with deferred tax assets	—	33.3	—	89.3
Plus: income tax effect related to Non-GAAP reconciling items	(142.7)	(1.0)	(335.3)	(29.7)
Total net income attributable to Biogen Inc., Non-GAAP	<u>\$ 709.6</u>	<u>\$ 887.3</u>	<u>\$ 2,374.6</u>	<u>\$ 4,052.4</u>
<b>Diluted Earnings Per Share</b>				
Total diluted earnings per share, GAAP	\$ 2.22	\$ 4.46	\$ 7.90	\$ 22.25
Plus: adjustments to GAAP net income attributable to Biogen Inc. (as detailed above)	2.55	1.18	7.89	2.50
Total diluted earnings per share, Non-GAAP	<u>\$ 4.77</u>	<u>\$ 5.64</u>	<u>\$ 15.79</u>	<u>\$ 24.75</u>

\*Beginning in the third quarter of 2021 amortization expense recorded related to intangible assets that arose from collaboration and licensing arrangements are no longer excluded from our Non-GAAP results on a prospective basis. Non-GAAP financial results for 2020 have not been updated to reflect this change.

\*\*Beginning in the second quarter of 2021 material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP R&D and SG&A expenses. Non-GAAP financial results for 2020 have been updated to include the \$601 million payment related to the collaboration with Denali Therapeutics, Inc. recorded in the third quarter of 2020 and the \$208 million payment related to the collaboration with Sangamo Therapeutics, Inc. recorded in the second quarter of 2020 along with the associated transaction costs and income tax effect.



**TABLE 4 (continued)**

**BIOGEN INC. AND SUBSIDIARIES  
GAAP TO NON-GAAP RECONCILIATION  
REVENUE GROWTH AT CONSTANT CURRENCY  
(unaudited)**

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.

	<b>For the Three Months Ended September 30, 2021</b>		<b>For the Nine Months Ended September 30, 2021</b>	
<b>Total Revenue</b>				
Revenue growth, as reported	(17.7)	%	(22.1)	
Less: impact of foreign currency translation and hedging (gains) losses	0.5		1.0	
Revenue growth at constant currency	(18.2)	%	(23.1)	
<b>Total MS Revenue (including OCREVUS royalties)</b>				
Revenue growth, as reported	(19.4)	%	(22.9)	
Less: impact of foreign currency translation and hedging (gains) losses	0.5		0.4	
Revenue growth at constant currency	(19.9)	%	(23.3)	
<b>Total SPINRAZA Revenue</b>				
Revenue growth, as reported	(10.2)	%	(5.8)	
Less: impact of foreign currency translation and hedging (gains) losses	0.4		2.7	
Revenue growth at constant currency	(10.6)	%	(8.5)	
<b>Total Biosimilars Revenue</b>				
Revenue growth, as reported	(2.4)	%	2.0	
Less: impact of foreign currency translation and hedging (gains) losses	1.1		5.4	
Revenue growth at constant currency	(3.5)	%	(3.4)	
<b>Total Other Revenue</b>				
Revenue growth, as reported	25.6	%	(45.5)	
Less: impact of foreign currency translation and hedging (gains) losses	—		0.1	
Revenue growth at constant currency	25.6	%	(45.6)	

**TABLE 4 (continued)**

**BIOGEN INC. AND SUBSIDIARIES**  
**GAAP TO NON-GAAP RECONCILIATION**  
**FREE CASH FLOW**  
*(unaudited, in millions)*

We define free cash flow as net cash provided by (used in) operating activities in the period less capital expenditures made in the period. The following table reconciles net cash provided by (used in) operating activities, a GAAP measure, to free cash flow, a Non-GAAP measure.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Cash Flow:</b>				
Net cash provided by (used in) operating activities	\$ 805.3	\$ 1,181.1	\$ 2,801.6	\$ 4,596.9
Net cash provided by (used in) investing activities	(233.6)	(52.4)	(451.0)	(442.2)
Net cash provided by (used in) financing activities	(746.5)	(1,312.9)	(2,096.0)	(4,871.6)
Net increase (decrease) in cash and cash equivalents	\$ (174.8)	\$ (184.2)	\$ 254.6	\$ (716.9)
Net cash provided by (used in) operating activities	\$ 805.3	\$ 1,181.1	\$ 2,801.6	\$ 4,596.9
Less: Purchases of property, plant and equipment	42.0	84.1	206.5	338.8
Free cash flow	\$ 763.3	\$ 1,097.0	\$ 2,595.1	\$ 4,258.1

## Notes to GAAP to Non-GAAP Reconciliation

<sup>^</sup> For the three and nine months ended September 30, 2021, amortization and impairment of acquired intangible assets totaled \$111.0 million and \$813.2 million, respectively, compared to \$82.6 million and \$215.6 million, respectively, in the prior year comparative periods.

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 and our Phase 2/3 XIRIUS study of BIIB112 did not meet their primary endpoints. In the third quarter of 2021 we suspended further development on these programs based on the decision by management as part of its strategic review process. For the three and nine months ended September 30, 2021, we recorded impairment charges of \$15.0 million and \$365.0 million, respectively, related to BIIB111, and impairment charges of \$28.4 million and \$220.0 million, respectively, related to BIIB112. As a result, the remaining book values associated with these programs were reduced to zero.

For the three and nine months ended September 30, 2020, amortization and impairment of acquired intangible assets reflects the impact of a \$19.3 million impairment charge related to one of our IPR&D intangible assets.

<sup>^</sup> For the nine months ended September 30, 2021, compared to the same period in 2020, we recorded a current year deferred tax benefit associated with the accelerated approval of ADUHELM by the U.S. Food and Drug Administration in the U.S. We recorded approximately \$500.0 million in a deferred tax asset related to Neurimmune SubOne AG's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM and approval of the Swiss cantonal tax authorities, with an equal and offsetting amount assigned to noncontrolling interest, resulting in zero net impact to net income attributable to Biogen Inc.

## 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 and divestitures

We exclude transaction, integration and certain other costs related to the acquisition and divestiture of businesses, the acquisitions of assets and items associated with the initial consolidation or deconsolidation of variable interest entities. These adjustments include, but are not limited to, 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.