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 25, 2022**

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-19311**	**33-0112644**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(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 October 25, 2022, Biogen Inc. issued a press release announcing its results of operations and financial condition for the third quarter ended September 30, 2022. 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.

Exhibit No.	Description
99.1	Biogen's press release dated October 25, 2022
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/ Wendell Taylor
Wendell Taylor
Assistant Secretary

Date: October 25, 2022

Biogen

Biogen Reports Third Quarter 2022 Results

- Third quarter revenue $2,508 million; GAAP diluted EPS $7.84; Non-GAAP diluted EPS $4.77
- Phase 3 study of lecanemab in early Alzheimer's disease met the primary endpoint and all key secondary endpoints with highly statistically significant results
- New data support the potential for zuranolone as a novel treatment for major depressive disorder and postpartum depression
- New Drug Application for tofersen accepted and granted priority review by the FDA; PDUFA date of April 25, 2023
- Company raises full year 2022 financial guidance

Cambridge, Mass. — October 25, 2022 — Biogen Inc. (Nasdaq: BIIB) today reported third quarter 2022 financial results.

"In the third quarter, Biogen made important progress toward building a foundation for growth while executing against our core business objectives," said Michel Vounatsos, Biogen's Chief Executive Officer. "We are excited about the topline results of the Clarity AD trial for lecanemab and believe this potential new therapy could provide a meaningful benefit for Alzheimer's patients. We also continue to make progress toward delivering new impactful therapies for patients suffering from depression and SOD1 ALS, with important upcoming regulatory milestones."

Third Quarter 2022 Operating Results

- Third quarter total revenue of $2,508 million decreased 10% versus the prior year at actual currency and 8% at constant currency*. Multiple sclerosis revenue, including royalties on sales of OCREVUS®, of $1,621 million decreased 11% versus the prior year at actual currency and 9% at constant currency. SPINRAZA® revenue of $431 million decreased 3% versus the prior year at actual currency and increased 2% at constant currency. Biosimilars revenue of $188 million decreased 7% versus the prior year at actual currency and 4% at constant currency. RITUXAN®/GAZYVA® profits attributable to Biogen were $136 million, a decrease of 10% versus the prior year.

- Third quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were $1,135 million and $7.84, respectively. Third quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were $691 million and $4.77, respectively. A reconciliation of GAAP to Non-GAAP financial measures can be found in Table 4 at the end of this news release.

- Third quarter GAAP and Non-GAAP cost of sales was $470 million, as compared to $512 million in the third quarter of 2021. Third quarter 2022 GAAP and Non-GAAP cost of sales includes approximately $12 million of idle capacity charges. Eisai Co., Ltd.'s (Eisai) share of these charges (approximately $5 million) is reflected in collaboration profit sharing.

- Third quarter GAAP and Non-GAAP R&D expense was $549 million, as compared to $702 million in the third quarter of 2021. Third quarter 2021 GAAP and Non-GAAP R&D expense included a $125 million upfront payment to InnoCare Pharma Limited and $39 million of estimated clinical trial close-out costs and manufacturing commitments due to suspended development of BIIB111 in choroideremia and BIIB112 in X-linked retinitis pigmentosa.

- Third quarter GAAP and Non-GAAP SG&A expense was $563 million and $562 million, respectively, as compared to $654 million and $651 million, respectively, in the third quarter of 2021. The decrease in SG&A expense was driven primarily by cost savings initiatives.

- Third quarter GAAP and Non-GAAP collaboration profit sharing was a net expense of $45 million, primarily driven by net profit sharing expense related to Biogen's collaboration with Samsung Bioepis.

- Third quarter GAAP gain of $504 million resulted from Biogen's sale of its building at 125 Broadway as part of an initiative to optimize its office footprint in Cambridge, MA to align with reduced space requirements under hybrid work models.

- Third quarter GAAP other income was $56 million, primarily driven by net unrealized gains on strategic equity investments of $110 million, partially offset by net interest expense of $36 million. Third quarter Non-GAAP other expense was $55 million, primarily driven by interest expense.

- Third quarter GAAP and Non-GAAP effective tax rates were 17% and 16%, respectively.

* 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.

Financial Position

- Third quarter 2022 cash flow from operations was $661 million. Capital expenditures were $59 million, and free cash flow, defined as cash flow from operations less capital expenditures, was $602 million.

- As of September 30, 2022, Biogen had cash, cash equivalents, and marketable securities totaling $5,771 million and $6,279 million in total debt, resulting in net debt of $508 million.

- In the third quarter of 2022 Biogen repurchased approximately 1.2 million shares of the Company's common stock for a total value of $250 million. As of September 30, 2022, there was $2,050 million remaining under the share repurchase program authorized in October 2020.

- For the third quarter of 2022 the Company's weighted average diluted shares were 145 million.

Full Year 2022 Financial Guidance

For the full year 2022, Biogen is updating its revenue and Non-GAAP diluted EPS guidance ranges as follows:

	Prior Guidance	Updated Guidance
Total revenue	$9.9 to $10.1 billion	$10.0 to $10.15 billion
Non-GAAP diluted EPS	$15.25 to $16.75	$16.50 to $17.15

The increase in full year 2022 revenue and Non-GAAP diluted EPS guidance is driven primarily by better-than-expected topline performance and continued cost management.

This guidance assumes continued declines in RITUXAN revenue due to biosimilar competition, as well as continued erosion of TECFIDERA® revenue due to generic entry.

Non-GAAP R&D expense is expected to be between $2.2 billion and $2.3 billion, unchanged from prior guidance.

Non-GAAP SG&A expense is expected to be between $2.3 billion and $2.4 billion, unchanged from prior guidance.

The Non-GAAP tax rate for 2022 is expected to be between 15.5% and 16.5%, unchanged from prior guidance.

This guidance assumes that foreign exchange rates as of September 30, 2022, 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 or pending and future litigation, as all 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 2022 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.

Alzheimer's Disease Updates

- In the third quarter of 2022 Biogen and Eisai announced positive topline results from Eisai's large global Phase 3 confirmatory Clarity AD clinical trial of lecanemab (BAN2401), an investigational anti-amyloid beta protofibril antibody for the treatment of mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease (collectively known as early Alzheimer's disease) with confirmed presence of amyloid pathology in the brain. Lecanemab met the primary endpoint (CDR-SB: Clinical Dementia Rating Scale-Sum of Boxes) and all key secondary endpoints with highly statistically significant results. Eisai will discuss these data with regulatory authorities in the U.S., Japan, and Europe with the aim to file for traditional approval in the US and for marketing authorization applications in Japan and Europe by March 31, 2023. Additionally, Eisai will present the Clarity AD study results on November 29, 2022, at the Clinical Trials on Alzheimer's Congress and intends to publish the findings in a peer-reviewed medical journal.

- In the third quarter of 2022 Eisai presented new findings at the Alzheimer's Association International Conference on a subcutaneous formulation of lecanemab and the modeling simulation of the impact of ApoE4 genotype on the incidence of amyloid-related imaging abnormalities – edema/effusion, or ARIA-E, in subjects treated with lecanemab.

Recent Events

- In October 2022 Biogen and Sage Therapeutics presented analyses from the Phase 3 SKYLARK Study of zuranolone, an investigational, oral, once-daily, 14-day treatment in clinical development for adult patients with major depressive disorder (MDD) and postpartum depression (PPD) at the European College of Neuropsychopharmacology Congress (ECNP). The SKYLARK Study, evaluating zuranolone in PPD, achieved the primary and all key secondary endpoints, with study participants demonstrating rapid and significant improvements in depressive symptoms as early as Day 3 that were sustained through Day 45. Additional secondary endpoint data presented at ECNP showed that a higher proportion of participants in the zuranolone 50 mg arm achieved a HAMD-17 response (≥ 50% decrease from baseline HAMD-17 total score) as compared with the placebo arm at Days 3, 8, 15, 21, and 28 ($p<0.05$ at all time points). Data also showed that a higher proportion of participants in the zuranolone arm achieved HAMD-17 remission (HAMD-17 total score ≤ 7) than in the placebo arm from Day 3 through Day 45 (Day 45 $p<0.05$).

- In October 2022 Biogen announced that the first patient was dosed in the global clinical study, AMETHYST, a Phase 2/3 study evaluating the efficacy and safety of litifilimab (also known as BIIB059), a first in-class, humanized IgG1 monoclonal antibody targeting blood dendritic cell antigen 2, as compared to placebo, in participants with cutaneous lupus erythematosus.

- On October 6, 2022, the Advocate General of the Court of Justice of the European Union (CJEU) issued a nonbinding advisory opinion in Biogen's favor relating to regulatory data protection for TECFIDERA. This opinion recommends that the CJEU set aside the earlier judgement of the European General Court annulling the European Medicine Agency's decision not to validate an application to market a generic version of TECFIDERA. If the Advocate General's recommendation is adopted in the final CJEU decision, Biogen expects TECFIDERA to be entitled to the statutory period of market protection through at least February 2024.

- In October 2022 Biogen and Denali Therapeutics Inc. announced that dosing has commenced in the global Phase 3 LIGHTHOUSE study to evaluate the efficacy and safety profile of BIIB122 (DNL151), as compared to placebo in approximately 400 participants with Parkinson's disease and a confirmed pathogenic mutation in the leucine-rich repeat kinase 2, or LRRK2, gene.

- In the third quarter of 2022 Biogen announced that the European Medicines Agency has accepted the Marketing Authorization Application for BIIB800, a biosimilar candidate referencing RoACTEMRA®, an anti-interleukin-6 receptor monoclonal antibody.

- In the third quarter of 2022 Biogen announced that *The New England Journal of Medicine* published detailed results from the Phase 3 VALOR study and the combined analysis of VALOR and its open label extension study evaluating tofersen for the treatment of superoxide dismutase 1 amyotrophic lateral sclerosis, or SOD1 ALS. 12-month data showed that earlier initiation of tofersen slowed decline across critical measures of function and strength.

- In the third quarter of 2022 Biogen announced that the U.S. Food and Drug Administration (FDA) accepted a New Drug Application for tofersen and granted Priority Review. As part of the ongoing review, Biogen submitted responses to information requests by the FDA, which the FDA considered a Major Amendment to the application that will require additional time for review. As a result, the review period has been extended by three months and the Prescription Drug User Fee Act goal date has been updated from January 25, 2023 to April 25, 2023.

- In the third quarter of 2022 Biogen announced that *The New England Journal of Medicine* published two manuscripts detailing positive results from the company's two-part Phase 2 LILAC study, which evaluated litifilimab, an investigational drug, in systemic lupus erythematosus and cutaneous lupus erythematosus.

- In the third quarter of 2022 Biogen and Sage Therapeutics announced new analyses from across the development program for zuranolone. An interim analysis from the ongoing open-label, longitudinal SHORELINE Study in MDD (30 mg cohort n=725, 50 mg cohort n=199) found the median time to the first repeat treatment course for those participants who responded to the initial 14-day treatment course (30 mg, n=489; 50 mg, n=146) was 135 days for the 30 mg cohort and 249 days for the 50 mg cohort. These data further support zuranolone as a potential episodic treatment for people with MDD.

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 25, 2022 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

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 a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry's most diversified pipelines 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.

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.

Biogen 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; 2022 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; the potential impact of the conflict in Ukraine; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; 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 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 technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements 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.

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TABLE 1

BIOGEN 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,	
	2022	2021	2022	2021
Revenue:				
Product, net	$ 1,962.1	$ 2,205.7	$ 6,083.3	$ 6,653.4
Revenue from anti-CD20 therapeutic programs	416.9	415.4	1,252.6	1,244.4
Other	129.5	157.8	293.5	350.1
Total revenue	2,508.5	2,778.9	7,629.4	8,247.9
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	469.5	511.8	1,707.4	1,449.6
Research and development	549.2	702.4	1,629.5	1,801.7
Selling, general and administrative	563.3	654.1	1,770.8	1,886.4
Amortization and impairment of acquired intangible assets	56.5	111.0	190.9	813.2
Collaboration profit (loss) sharing	45.3	21.2	(42.6)	74.5
(Gain) loss on fair value remeasurement of contingent consideration	(2.1)	(15.6)	(13.7)	(49.1)
Acquired in-process research and development	—	—	—	18.0
Restructuring charges	15.4	—	124.1	—
Gain on sale of building	(503.7)	—	(503.7)	—
Other (income) expense, net	(56.0)	502.9	(221.3)	913.4
Total cost and expense	1,137.4	2,487.8	4,641.4	6,907.7
Income before income tax expense and equity in loss of investee, net of tax	1,371.1	291.1	2,988.0	1,340.2
Income tax (benefit) expense	236.2	(25.9)	578.5	(390.7)
Equity in (income) loss of investee, net of tax	—	(1.1)	(2.6)	(17.2)
Net income	1,134.9	318.1	2,412.1	1,748.1
Net income (loss) attributable to noncontrolling interests, net of tax	0.2	(11.1)	(84.4)	560.2
Net income attributable to Biogen Inc.	$ 1,134.7	$ 329.2	$ 2,496.5	$ 1,187.9
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 7.86	$ 2.22	$ 17.12	$ 7.93
Diluted earnings per share attributable to Biogen Inc.	$ 7.84	$ 2.22	$ 17.07	$ 7.90
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	144.4	148.0	145.8	149.9
Diluted earnings per share attributable to Biogen Inc.	144.8	148.6	146.2	150.3

TABLE 2

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

	As of September 30, 2022	As of December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	$ 4,911.1	$ 3,802.5
Accounts receivable, net	1,568.8	1,549.4
Inventory	1,375.0	1,351.5
Other current assets	1,910.9	1,153.1
Total current assets	9,765.8	7,856.5
Marketable securities	860.3	892.0
Property, plant and equipment, net	3,266.4	3,416.4
Operating lease assets	424.5	375.4
Intangible assets, net	2,008.9	2,221.3
Goodwill	5,741.2	5,761.1
Deferred tax asset	1,174.5	1,415.1
Investments and other assets	1,612.6	1,939.5
TOTAL ASSETS	$ 24,854.2	$ 23,877.3
LIABILITIES AND EQUITY		
Current portion of notes payable	$ —	$ 999.1
Other current liabilities	3,926.4	3,299.1
Total current liabilities	3,926.4	4,298.2
Notes payable	6,279.2	6,274.0
Deferred tax liability	328.9	694.5
Long-term operating lease liabilities	354.8	330.4
Other long-term liabilities	1,198.1	1,320.5
Equity	12,766.8	10,959.7
TOTAL LIABILITIES AND EQUITY	$ 24,854.2	$ 23,877.3

TABLE 3

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

	For the Three Months Ended September 30,					
	2022			2021		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 92.5	$ 246.5	$ 339.0	$ 179.2	$ 319.4	$ 498.6
VUMERITY®*	127.9	9.9	137.8	120.7	0.2	120.9
Total Fumarate	220.4	256.4	476.8	299.9	319.6	619.5
AVONEX®	174.8	80.3	255.1	213.2	88.1	301.3
PLEGRIDY®	39.7	41.2	80.9	39.2	47.0	86.2
Total Interferon	214.5	121.5	336.0	252.4	135.1	387.5
TYSABRI	273.0	232.5	505.5	281.1	241.7	522.8
FAMPYRA®	—	22.0	22.0	—	26.2	26.2
Spinal Muscular Atrophy:						
SPINRAZA	140.2	290.9	431.1	139.8	304.3	444.1
Biosimilars:						
BENEPALI™	—	110.2	110.2	—	120.8	120.8
IMRALDI™	—	57.7	57.7	—	57.4	57.4
FLIXABI™	—	19.0	19.0	—	24.6	24.6
BYOOVIZ™ **	0.7	—	0.7	—	—	—
Other:						
FUMADERM™	—	1.5	1.5	—	2.5	2.5
ADUHELM	1.6	—	1.6	0.3	—	0.3
Total product revenue, net	$ 850.4	$ 1,111.7	$ 1,962.1	$ 973.5	$ 1,232.2	$ 2,205.7

* VUMERITY became commercially available in the European Union (E.U.) during the fourth quarter of 2021.
** BYOOVIZ launched in the United States (U.S.) in June 2022 and became commercially available during the third quarter of 2022.

TABLE 3 (continued)

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

	For the Nine Months Ended September 30,					
	2022			2021		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 330.3	$ 816.5	$ 1,146.8	$ 520.1	$ 945.3	$ 1,465.4
VUMERITY®*	383.0	19.6	402.6	285.0	0.5	285.5
Total Fumarate	713.3	836.1	1,549.4	805.1	945.8	1,750.9
AVONEX®	493.8	249.6	743.4	636.4	286.9	923.3
PLEGRIDY®	114.2	138.2	252.4	115.2	149.9	265.1
Total Interferon	608.0	387.8	995.8	751.6	436.8	1,188.4
TYSABRI	849.4	693.1	1,542.5	854.2	696.2	1,550.4
FAMPYRA®	—	73.7	73.7	—	78.8	78.8
Spinal Muscular Atrophy:						
SPINRAZA	443.3	891.4	1,334.7	437.8	1,026.6	1,464.4
Biosimilars:						
BENEPALI™	—	340.7	340.7	—	363.9	363.9
IMRALDI™	—	172.4	172.4	—	170.9	170.9
FLIXABI™	—	62.0	62.0	—	75.4	75.4
BYOOVIZ™ **	1.2	—	1.2	—	—	—
Other:						
FUMADERM™	—	6.4	6.4	—	8.3	8.3
ADUHELM	4.5	—	4.5	2.0	—	2.0
Total product revenue, net	$ 2,619.7	$ 3,463.6	$ 6,083.3	$ 2,850.7	$ 3,802.7	$ 6,653.4

* VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.
** BYOOVIZ launched in the U.S. in June 2022 and became commercially available during the third quarter of 2022.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2022	2021	2022	2021
Product revenue	$ 1,962.1	$ 2,205.7	$ 6,083.3	$ 6,653.4
OCREVUS royalties	281.1	264.2	825.2	730.5
RITUXAN/GAZYVA® revenue	135.8	151.2	427.4	513.9
Other revenue	129.5	157.8	293.5	350.1
Total revenue	$ 2,508.5	$ 2,778.9	$ 7,629.4	$ 8,247.9

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 cash 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 Sep 30,	
(In millions, except per share amounts)	**2022[1]**	**2021[1][2]**	**2022[1]**	**2021[1]**
Selling, General and Administrative Expense:				
Total selling, general and administrative, GAAP	$ 563.3	$ 654.1	$ 1,770.8	$ 1,
Less: other	1.5	3.0	3.5	
Total selling, general and administrative, Non-GAAP	$ 561.8	$ 651.1	$ 1,767.3	$ 1,
Amortization and Impairment of Acquired Intangible Assets:				
Total amortization and impairment of acquired intangible assets, GAAP	$ 56.5	$ 111.0	$ 190.9	$
Less: impairment charges [A]	—	44.3	—	
Less: amortization of acquired intangible assets	48.6	59.4	168.1	
Total amortization and impairment of acquired intangible assets, Non-GAAP	$ 7.9	$ 7.3	$ 22.8	$
Other (Income) Expense, net:				
Total other (income) expense, net, GAAP	$ (56.0)	$ 502.9	$ (221.3)	$
Less: (gain) loss on equity security investments	(109.8)	424.2	158.1	
Less: (gain) on sale of equity interest in Samsung Bioepis [B]	—	—	(1,505.3)	
Less: litigation settlement agreed to in principle [C]	—	—	900.0	
Less: premium paid on debt exchange or early debt redemption [D]	2.2	—	2.2	
Less: other	(3.0)	—	17.0	
Total other (income) expense, net, Non-GAAP	$ 54.6	$ 78.7	$ 206.7	$
Income Tax (Benefit) Expense:				
Total income tax (benefit) expense, GAAP	$ 236.2	$ (25.9)	$ 578.5	$ (
Less: Neurimmune step-up tax basis [E]	—	—	83.9	(
Less: international reorganization & income tax effect related to Non-GAAP reconciling items	107.6	(142.7)	133.1	(
Total income tax expense, Non-GAAP	$ 128.6	$ 116.8	$ 361.5	$
Effective Tax Rate:				
Total effective tax rate, GAAP	17.2 %	(8.9)%	19.4 %	
Less: Neurimmune step-up tax basis [E]	—	—	2.8	
Less: impact of GAAP to Non-GAAP adjustments	1.5	(23.4)	1.1	
Total effective tax rate, Non-GAAP	15.7 %	14.5 %	15.5 %	

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,	
(In millions, except per share amounts)	**2022[1]**	**2021[1][2]**	**2022[1]**	**2021[1][2]**
Equity in (Income) Loss of Investee, Net of Tax:				
Total equity in (income) loss of investee, GAAP	$ —	$ (1.1)	$ (2.6)	$ (17.2)
Less: amortization of equity in (income) loss of investee	—	7.8	14.4	31.0
Total equity in (income) loss of investee, Non-GAAP	$ —	$ (8.9)	$ (17.0)	$ (48.2)
Net Income (Loss) Attributable to Noncontrolling Interests, Net of Tax:				
Total net income (loss) attributable to noncontrolling interests, GAAP	$ 0.2	$ (11.1)	$ (84.4)	$ 560.2
Less: Neurimmune step-up tax basis [E]	—	—	(83.9)	492.0
Less: net distribution to noncontrolling interests	—	—	(1.5)	(4.4)
Total net income (loss) attributable to noncontrolling interests, Non-GAAP	$ 0.2	$ (11.1)	$ 1.0	$ 72.6
Net Income Attributable to Biogen Inc.:				
Total net income attributable to Biogen Inc., GAAP	$ 1,134.7	$ 329.2	$ 2,496.5	$ 1,187.9
Plus: impairment charges [A]	—	44.3	—	629.3
Plus: amortization of acquired intangible assets	48.6	59.4	168.1	176.6
Plus: restructuring charges	15.4	—	124.1	—
Plus: (gain) loss on fair value remeasurement of contingent consideration	(2.1)	(15.6)	(13.7)	(49.1)
Plus: (gain) loss on equity security investments	(109.8)	424.2	158.1	705.9
Plus: net distribution to noncontrolling interests & amortization of equity in (income) loss of investee	—	7.8	12.9	26.6
Plus: gain on sale of equity interest in Samsung Bioepis [B]	—	—	(1,505.3)	—
Plus: litigation settlement agreed to in principle [C]	—	—	900.0	—
Plus: (gain) on sale of building [F]	(503.7)	—	(503.7)	—
Plus: premium paid on debt exchange or early debt redemption [D]	2.2	—	2.2	9.5
Plus: international reorganization & income tax effect related to Non-GAAP reconciling items	107.6	(142.7)	133.1	(331.4)
Plus: other	(1.7)	3.0	20.4	5.2
Total net income attributable to Biogen Inc., Non-GAAP	$ 691.2	$ 709.6	$ 1,992.7	$ 2,360.5
Diluted Earnings Per Share				
Total diluted earnings per share, GAAP	$ 7.84	$ 2.22	$ 17.07	$ 7.90
(Less) Plus: adjustments to GAAP net income attributable to Biogen Inc. (as detailed above)	(3.07)	2.55	(3.44)	7.80
Total diluted earnings per share, Non-GAAP	$ 4.77	$ 4.77	$ 13.63	$ 15.70

[1] 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 research and development expense and selling, general and administrative expense. Beginning in the first quarter of 2022 material payments paid on the acquisition of in-process research and development assets are no longer excluded in the determination of Non-GAAP net income. Prior period Non-GAAP results have been updated to reflect these changes.

[2] Beginning in the third quarter of 2021 amortization expense recorded in intangible assets that arose from collaboration and licensing arrangements is no longer excluded from our Non-GAAP results on a prospective basis. Non-GAAP financial results prior to the third quarter of 2021 have not been updated to reflect this change.

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.

	Q3 2022 vs. Q3 2021	YTD 2022 vs. YTD 2021
Total Revenue		
Revenue change, as reported	(9.7)%	(7
Less: impact of foreign currency translation and hedging gains / losses	(2.0)	(1
Revenue change at constant currency	(7.7)%	(5
Total MS Revenue (including OCREVUS royalties)		
Revenue change, as reported	(10.9)%	(5
Less: impact of foreign currency translation and hedging gains / losses	(1.5)	(1
Revenue change at constant currency	(9.4)%	(4
Total TECFIDERA Revenue		
Revenue change, as reported	(32.0)%	(21
Less: impact of foreign currency translation and hedging gains / losses	(1.8)	(1
Revenue change at constant currency	(30.2)%	(20
Total VUMERITY Revenue		
Revenue change, as reported	14.0 %	41
Less: impact of foreign currency translation and hedging gains / losses	(1.2)	(0
Revenue change at constant currency	15.2 %	41
Total TYSABRI Revenue		
Revenue change, as reported	(3.3)%	(0
Less: impact of foreign currency translation and hedging gains / losses	(2.1)	(1
Revenue change at constant currency	(1.2)%	0
Total INTERFERON Revenue		
Revenue change, as reported	(13.3)%	(16
Less: impact of foreign currency translation and hedging gains / losses	(1.4)	(1
Revenue change at constant currency	(11.9)%	(15
Total SPINRAZA Revenue		
Revenue change, as reported	(2.9)%	(8
Less: impact of foreign currency translation and hedging gains / losses	(4.4)	(3
Revenue change at constant currency	1.5 %	(5
Total SPINRAZA Rest of World Revenue		
Revenue change, as reported	(4.4)%	(13
Less: impact of foreign currency translation and hedging gains / losses	(6.5)	(4
Revenue change at constant currency	2.1 %	(8
Total Biosimilars Revenue		
Revenue change, as reported	(7.5)%	(5
Less: impact of foreign currency translation and hedging gains / losses	(3.9)	(5
Revenue change at constant currency	(3.6)%	(0

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,	
	2022	**2021**	**2022**	**2021**
Cash Flow:				
Net cash provided by (used in) operating activities	$ 661.0	$ 805.3	$ 1,559.3	$ 2,801.6
Net cash provided by (used in) investing activities	1,672.2	(233.6)	1,717.7	(451.0)
Net cash provided by (used in) financing activities	(1,251.9)	(746.5)	(1,739.9)	(2,096.0)
Net increase (decrease) in cash and cash equivalents	$ 1,081.3	$ (174.8)	$ 1,537.1	$ 254.6
Net cash provided by (used in) operating activities	$ 661.0	$ 805.3	$ 1,559.3	$ 2,801.6
Less: Purchases of property, plant and equipment	59.1	42.0	153.9	206.5
Free cash flow	$ 601.9	$ 763.3	$ 1,405.4	$ 2,595.1

Notes to GAAP to Non-GAAP Reconciliation

[A] Amortization and impairment of acquired intangible assets for the three and nine months ended September 30, 2022, compared to the same periods in 2021, decreased primarily due to impairment charges recorded during 2021. For the three and nine months ended September 30, 2022, we had no impairment charges.

For the three and nine months ended September 30, 2021, amortization and impairment of acquired intangible assets reflects impairment charges of $15.0 million and $365.0 million, respectively, related to BIIB111 (timrepigene emparvovec) for the potential treatment of choroideremia and impairment charges of $28.4 million and $220.0 million, respectively, related to BIIB112 (cotoretigene toliparvovec) for the potential treatment of X-linked retinitis pigmentosa. 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 nine months ended September 30, 2021, amortization and impairment of acquired intangible assets also reflects a $44.3 million impairment charge related to vixotrigine (BIIB074) for the potential treatment of trigeminal neuralgia (TGN).

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

For the nine months ended September 30, 2022, we recognized a pre-tax gain of approximately $1.5 billion related to the transaction, which was recorded in other (income) expense, net in our condensed consolidated statements of income.

[C] During the second quarter of 2022 we recorded a pre-tax charge of $900.0 million related to a litigation settlement agreement to resolve a qui tam litigation relating to conduct prior to 2015.

[D] In July 2022 we redeemed our 3.625% Senior Notes due September 15, 2015, prior to their maturity and recognized a net pre-tax charge of approximately $2.2 million upon the extinguishment of these Senior Notes related to the payment of an early call premium. These charges were recognized as interest expense in other (income) expense, net in our condensed consolidated statements of income for the three and nine months ended September 30, 2022.

[E] For the three and nine months ended September 30, 2022, compared to the same periods in 2021, the increases in our effective tax rates include the tax impacts on the sale of one of our buildings and the favorable prior year tax effects of changes in the value of our equity investments, where we recorded unrealized losses, and the BIIB111 and BIIIB112 impairment charges. The tax effects of this change in value of our equity investments were recorded discretely as changes in value of equity investments cannot be forecasted.

For the nine months ended September 30, 2022, compared to the same period in 2021, the increase in our effective tax rate also reflects the net effects of the Neurimmune SubOne AG (Neurimmune) matters, as discussed below, and the litigation settlement agreement.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately $490.0 million on Neurimmune's tax basis in ADUHELM, the realization of which is dependent on future sales of ADUHELM. During the fourth quarter of 2021, due to reduced future expected revenue associated with ADUHELM, we recorded a valuation allowance of approximately $390.0 million.

During the first quarter of 2022, upon issuance of the final NCD related to ADUHELM, we recorded an additional valuation allowance of approximately $85.0 million to reduce the net value of this deferred tax asset to zero. These adjustments to our deferred tax assets and their valuation allowances are each recorded with an equal and offsetting amount assigned to net income (loss) attributable to noncontrolling interests, net of tax in our condensed consolidated statements of income, resulting in a zero net impact to net income attributable to Biogen Inc.

[F] In September 2022 we completed the sale of our building and land parcel located at 125 Broadway, Cambridge, MA (125 Broadway) for an aggregate sales price of approximately $603.0 million, which is inclusive of a $10.8 million tenant allowance. This sale resulted in a pre-tax gain on sale of approximately $503.7 million, net of transaction costs for the three and nine months ended September 30, 2022.

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 cash 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 and items associated with the initial consolidation or deconsolidation of variable interest entities. These adjustments include, but are not limited to, 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 related to 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.