

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

FORM 8-K/A
(Amendment No. 1)

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

Date of Report (Date of earliest event reported): July 20, 2022

BIAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-19311
(Commission File Number)

33-0112644
(IRS Employer Identification No.)

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

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

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

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

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

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

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

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

Earlier today, July 20, 2022, Biogen Inc. (the "Company") issued a press release announcing its results of operations and financial condition for the second quarter ended June 30, 2022, and furnished a copy of the press release as Exhibit 99.1 to a Current Report on Form 8-K filed by the Company (the "Original Report").

This Current Report on Form 8-K/A amends the Original Report on Form 8-K solely to correct a typographical error in the dates appearing in the header of the second table on page 11 of the press release furnished with the Original Report.

A copy of the revised press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K/A report to item 2.02, and is incorporated herein by reference. The revised press release 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/A.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Biogen's press release dated July 20, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Biogen Reports Second Quarter 2022 Results

- Second quarter revenue \$2,589 million; GAAP diluted EPS \$7.24; Non-GAAP diluted EPS \$5.25
- FDA granted Priority Review for lecanemab in early Alzheimer's disease under the accelerated approval pathway with a decision expected by January 6, 2023; Phase 3 data expected in the Fall of 2022
- Second Positive Phase 3 study further supports potential of zuranolone in postpartum depression (PPD); Joint U.S. regulatory filing for both major depressive disorder and PPD expected in the second half of 2022
- Biogen launches BYOOVIZ, the first biosimilar referencing LUCENTIS, in the U.S.
- Company raises full year 2022 financial guidance

Cambridge, Mass. — July 20, 2022 — Biogen Inc. (Nasdaq: BIIB) today reported second quarter 2022 financial results.

“We continued to execute on our near-term operational priorities in the second quarter and are pleased to be raising our financial guidance for the year. At the same time, we continue to face revenue declines due in part to generic and biosimilar competition for TECFIDERA and RITUXAN,” said Michel Vounatsos, Biogen's Chief Executive Officer. “We made important progress towards bringing new potential treatments to patients suffering from Alzheimer's disease and depression, which we believe are critical steps on our path to drive value creation for both patients and shareholders over time.”

Second Quarter 2022 Operating Results

- Second quarter total revenue of \$2,589 million decreased 7% versus the prior year at actual currency and 5% at constant currency*. Multiple sclerosis (MS) revenue, including royalties on sales of OCREVUS®, of \$1,719 million decreased 4% versus the prior year at actual currency and 3% at constant currency. SPINRAZA® revenue of \$431 million decreased 14% versus the prior year at actual currency and 11% at constant currency. Biosimilars revenue of \$194 million decreased 4% versus the prior year at actual currency and increased 3% at constant currency. RITUXAN®/GAZYVA® profits attributable to Biogen were \$144 million, a decrease of 21% versus the prior year.
- Second quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$1,058 million and \$7.24, respectively. Second quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$767 million and \$5.25, respectively. A reconciliation of GAAP to Non-GAAP financial measures can be found in Table 4 at the end of this news release.
- Second quarter GAAP and Non-GAAP cost of sales was \$484 million, as compared to \$460 million in the second quarter of 2021. Second quarter 2022 GAAP and Non-GAAP cost of sales includes approximately \$26 million of idle capacity charges. Eisai Co., Ltd.'s (Eisai) share of these charges (approximately \$10 million) is reflected in collaboration profit sharing.
- Second quarter GAAP and Non-GAAP R&D expense was \$529 million, as compared to \$585 million in the second quarter of 2021. Second quarter 2021 GAAP and Non-GAAP R&D expense includes \$50 million in upfront payments to Bio-Thera Solutions, Ltd., Capsigen Inc., and Ginkgo Bioworks. Second quarter 2022 GAAP and Non-GAAP R&D expense includes \$18 million in upfront payments related to collaborations with MedRhythms and Alectos Therapeutics.
- Second quarter GAAP and Non-GAAP SG&A expense was \$573 million and \$570 million, respectively, as compared to \$637 million and \$635 million, respectively, in the second quarter of 2021. Second

quarter 2022 GAAP and Non-GAAP SG&A expense includes approximately \$29 million related to ADUHELM® commercialization. Eisai's reimbursement of U.S. ADUHELM SG&A expense of approximately \$17 million is reflected in collaboration profit sharing.

- Second quarter GAAP and Non-GAAP amortization and impairment of acquired intangible assets was \$68 million and \$7 million, respectively.
- Second quarter GAAP and Non-GAAP collaboration profit sharing was a net expense of \$29 million, which includes \$58 million of net profit sharing expense related to Biogen's collaboration with Samsung Bioepis, partially offset by reimbursement of \$29 million from Eisai related to the commercialization of ADUHELM in the U.S.
- Second quarter GAAP restructuring expense was \$71 million, primarily associated with the substantial elimination of the Company's global commercial infrastructure supporting ADUHELM.
- Second quarter GAAP other income was \$429 million, primarily driven by an approximately \$1.5 billion gain on the sale of our equity stake in the Samsung Bioepis Joint Venture, partially offset by net unrealized losses on strategic equity investments of \$77 million, net interest expense of \$53 million, and \$900 million, plus estimated fees and expenses, related to an agreement in principle to resolve previously disclosed qui tam litigation relating to conduct prior to 2015. This agreement in principle does not include any admission of liability and is subject to the negotiation of final settlement agreements and documents. Second quarter Non-GAAP other expense was \$79 million, primarily driven by interest expense.
- Second quarter GAAP and Non-GAAP effective tax rates were 17% and 15%, respectively. The second quarter 2022 GAAP effective tax rate was unfavorably impacted by the gain on the sale of our equity stake in the Samsung Bioepis Joint Venture and the estimated tax impact of the agreement in principle to resolve the litigation described above, partially offset by the deferred tax impacts of an international restructuring.
- Second quarter GAAP and Non-GAAP income attributable to noncontrolling interest was approximately \$1 million.

* 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

- Second quarter 2022 cash flow from operations was \$737 million. Capital expenditures were \$37 million, and free cash flow, defined as cash flow from operations less capital expenditures, was \$700 million.
- As of June 30, 2022, Biogen had cash, cash equivalents, and marketable securities totaling \$5,901 million and \$7,277 million in total debt, resulting in net debt of \$1,376 million. Subsequent to June 30, 2022, the Company repaid its Senior Notes due September 2022, with an aggregate principal amount of \$1 billion.
- In the second quarter of 2022 Biogen repurchased approximately 2.4 million shares of the Company's common stock for a total value of \$500 million. As of June 30, 2022, there was \$2,300 million remaining under the share repurchase program authorized in October 2020.
- For the second quarter of 2022 the Company's weighted average diluted shares were 146 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	\$9.7 to \$10.0 billion	\$9.9 to \$10.1 billion
Non-GAAP diluted EPS	\$14.25 to \$16.00	\$15.25 to \$16.75

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 in the U.S. due to generic entry. Further, this guidance reflects a range of scenarios for the impact of TECFIDERA generics in the E.U., which is difficult to predict.

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 July 15, 2022, will remain in effect for the remainder of the year, net of hedging activities. Subsequent to issuing its most recent 2022 financial guidance, the Company has experienced a headwind of approximately \$55 million to full year 2022 revenue and approximately \$0.20 to full year 2022 Non-GAAP diluted EPS due to currency fluctuations, net of hedging activities, from April 29, 2022 through July 15, 2022.

Biogen expects to utilize a portion of the remaining share repurchase authorization of \$2,300 million through the end of 2022. 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.

Key Recent Events

- In July 2022 Eisai and Biogen announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) and granted priority review for lecanemab for people with mild cognitive impairment due to Alzheimer's disease (AD) and mild AD with confirmed presence of amyloid pathology in the brain under the accelerated approval pathway. The BLA submission for

lecanemab is based on clinical, biomarker, and safety data from the proof-of-concept Phase 2b (Study 201 Core) in 856 people with early AD with confirmed presence of amyloid pathology, biomarker and safety data from the Study 201 OLE (180 subjects), and blinded safety data from the confirmatory Clarity AD Phase 3 study. The FDA is expected to make a decision on approval by January 6, 2023.

- In July 2022 Biogen announced that the TALLY Phase 2 study of BIIB104 in cognitive impairment associated with schizophrenia did not meet its primary or secondary efficacy endpoints. Most adverse events in the BIIB104 treatment arms were mild to moderate in severity. Given the consistent lack of efficacy observed across the primary and secondary measures of cognition and functioning, while demonstrating expected drug-exposure levels during the entire 12-week evaluation period, Biogen has decided to discontinue the BIIB104 program in cognitive impairment associated with schizophrenia.
- In July 2022 Roche announced that the FDA accepted the company's BLA and granted priority review for LUNSUMIO® (mosunetuzumab) for people with relapsed or refractory follicular lymphoma. This follows the European Commission approval of LUNSUMIO for people with relapsed or refractory follicular lymphoma in the second quarter of 2022. LUNSUMIO is the first CD20xCD3 T-cell engaging bispecific antibody available to treat the most common slow-growing form of non-Hodgkin lymphoma, follicular lymphoma. Biogen will share in the operating profits and losses of mosunetuzumab in United States in the low to mid 30% range and is eligible to receive low single-digit royalties on sales outside the United States.
- In the second quarter of 2022 Eisai published results in *Neurology and Therapy* regarding the potential long-term health outcomes of lecanemab using simulation modeling based on the results of the Phase 2b Study. This analysis suggested that compared to standard of care (SoC) alone, individuals treated with lecanemab in addition to SoC may potentially experience slower disease progression to mild, moderate and severe AD from baseline by 2.51, 3.13 and 2.34 years on average, respectively. The preliminary results of this model-based simulation could possibly translate into additional quality-adjusted life years and reduction in the formal and informal care costs.
- In the second quarter of 2022 Biogen and Sage Therapeutics, Inc. announced that the Phase 3 SKYLARK Study of zuranolone, an investigational oral drug being evaluated in women with postpartum depression, met its primary and all key secondary endpoints. Subsequently, Sage and Biogen have decided to submit a single New Drug Application (NDA) seeking approval of zuranolone for the treatment of both major depressive disorder (MDD) and PPD. Sage and Biogen expect to complete the submission of this single NDA in the second half of 2022, and to seek priority review of the filing.
- In the second quarter of 2022 Biogen announced that the European Patent Office has granted a patent that expires in February 2028 related to TECFIDERA. The patent, EP 2 653 873, is directed to treating MS using dimethyl fumarate dosed at 480mg per day, which is the European Medicines Agency recommended maintenance dose for TECFIDERA. Patent EP 2 653 873 was granted from a divisional patent application of European Patent No. 2 137 537 and includes amended claims, which the European Patent Office Examining Division determined were allowable under the relevant provisions of the European Patent Convention.
- In the second quarter of 2022 Biogen announced new 12-month data for tofersen, an investigational antisense drug for people with superoxide dismutase 1 (SOD1) amyotrophic lateral sclerosis (ALS). The data show that earlier initiation of tofersen (compared to delayed initiation six months later in the open-label extension study) slowed declines in clinical function, respiratory function, muscle strength, and quality of life. Biogen continues to engage with FDA and other regulators with these data and will provide updates when appropriate.
- In the second quarter of 2022 Biogen presented new data from clinical studies aimed at assessing remaining unmet needs for people living with spinal muscular atrophy (SMA) and evaluating the potential impact of SPINRAZA in different patient populations at the SMA Research & Clinical Care Meeting hosted by Cure SMA. Biogen's continued R&D investments, including the ongoing DEVOTE, RESPOND and ASCEND studies, aim to assess options and inform therapy decisions for the SMA community.

- In the second quarter of 2022 Biogen and Bio-Thera Solutions, Ltd. presented positive Phase 3 data for BIIB800 (BAT1806), a biosimilar candidate referencing ACTEMRA®/ROACTEMRA® (tocilizumab), an anti-interleukin-6 receptor monoclonal antibody, at the Annual European Congress of Rheumatology. Data from the Phase 3 comparative clinical trial demonstrated that the investigational biosimilar candidate BIIB800 has equivalent efficacy and comparable safety and immunogenicity profile to the reference tocilizumab product.
- In the second quarter of 2022 Biogen and Samsung Bioepis Co., Ltd. launched BYOOVIZ™ (ranibizumab-nuna), a biosimilar referencing LUCENTIS®, in the United States. BYOOVIZ is the first biosimilar launch in the U.S. under the Biogen and Samsung Bioepis' collaboration.
- In the second quarter of 2022 Biogen and Denali Therapeutics Inc. announced that dosing commenced in the global Phase 2b LUMA study to evaluate the efficacy and safety of BIIB122 (DNL151), as compared to placebo in approximately 640 participants with early-stage Parkinson's disease. BIIB122 is an inhibitor of LRRK2, a novel target with the potential to impact the underlying biology and slow the progression of Parkinson's disease.
- In the second quarter of 2022 Biogen and Alectos Therapeutics entered into a license and collaboration agreement to develop and commercialize a novel preclinical selective GBA2 inhibitor, AL01811, which has first-in-class potential as an oral disease modifying treatment for patients with Parkinson's disease.
- In the second quarter of 2022 Biogen and MedRhythms entered into a license agreement to develop and commercialize MR-004, an investigational prescription digital therapeutic for the potential treatment of gait deficits in MS.

Conference Call and Webcast

The Company's earnings conference call for the second quarter will be broadcast via the internet at 8:00 a.m. ET on July 20, 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 posts 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; risks that uncertainty as to whether the anticipated benefits of the transaction with Samsung Biologics can be achieved; uncertainty as to whether the anticipated benefits of the cost-reduction and productivity measures can be achieved; 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; 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.

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TABLE 1

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product, net	\$ 2,054.9	\$ 2,236.0	\$ 4,121.2	\$ 4,447.7
Revenue from anti-CD20 therapeutic programs	436.3	440.0	835.7	829.0
Other	97.9	99.0	164.0	192.3
Total revenue	<u>2,589.1</u>	<u>2,775.0</u>	<u>5,120.9</u>	<u>5,469.0</u>
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	484.0	459.7	1,237.9	937.8
Research and development	528.6	585.1	1,080.3	1,099.3
Selling, general and administrative	572.6	637.3	1,207.5	1,232.3
Amortization and impairment of acquired intangible assets	67.5	604.1	134.4	702.2
Collaboration profit (loss) sharing	29.4	(15.2)	(87.9)	53.3
(Gain) loss on fair value remeasurement of contingent consideration	(4.5)	0.3	(11.6)	(33.5)
Acquired in-process research and development	—	18.0	—	18.0
Restructuring charges	70.6	—	108.7	—
Other (income) expense, net	(428.6)	(96.4)	(165.3)	410.5
Total cost and expense	<u>1,319.6</u>	<u>2,192.9</u>	<u>3,504.0</u>	<u>4,419.9</u>
Income before income tax expense and equity in loss of investee, net of tax	1,269.5	582.1	1,616.9	1,049.1
Income tax (benefit) expense	216.7	(409.1)	342.3	(364.9)
Equity in (income) loss of investee, net of tax	(5.9)	(34.3)	(2.6)	(16.1)
Net income	1,058.7	1,025.5	1,277.2	1,430.1
Net income (loss) attributable to noncontrolling interests, net of tax	0.7	577.0	(84.6)	571.4
Net income attributable to Biogen Inc.	<u>\$ 1,058.0</u>	<u>\$ 448.5</u>	<u>\$ 1,361.8</u>	<u>\$ 858.7</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 7.25	\$ 3.00	\$ 9.30	\$ 5.70
Diluted earnings per share attributable to Biogen Inc.	\$ 7.24	\$ 2.99	\$ 9.27	\$ 5.68
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	145.9	149.7	146.5	150.8
Diluted earnings per share attributable to Biogen Inc.	146.2	150.1	146.8	151.2

TABLE 2

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

	As of June 30, 2022	As of December 31, 2021
ASSETS		
Cash, cash equivalents and marketable securities	\$ 4,797.9	\$ 3,802.5
Accounts receivable, net	1,567.6	1,549.4
Inventory	1,294.2	1,351.5
Other current assets	2,081.2	1,153.1
Total current assets	9,740.9	7,856.5
Marketable securities	1,102.9	892.0
Property, plant and equipment, net	3,355.1	3,416.4
Operating lease assets	321.1	375.4
Intangible assets, net	2,075.3	2,221.3
Goodwill	5,749.6	5,761.1
Deferred tax asset	1,235.7	1,415.1
Investments and other assets	1,500.8	1,939.5
TOTAL ASSETS	\$ 25,081.4	\$ 23,877.3
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ 999.8	\$ 999.1
Other current liabilities	4,018.2	3,299.1
Total current liabilities	5,018.0	4,298.2
Notes payable	6,277.4	6,274.0
Deferred tax liability	480.6	694.5
Long-term operating lease liabilities	274.2	330.4
Other long-term liabilities	1,167.8	1,320.5
Equity	11,863.4	10,959.7
TOTAL LIABILITIES AND EQUITY	\$ 25,081.4	\$ 23,877.3

TABLE 3

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

For the Three Months Ended June 30,

	2022			2021		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 120.7	\$ 277.2	\$ 397.9	\$ 178.4	\$ 309.2	\$ 487.6
VUMERITY®*	129.9	6.9	136.8	90.7	0.2	90.9
Total Fumarate	250.6	284.1	534.7	269.1	309.4	578.5
AVONEX®	171.0	87.7	258.7	214.0	96.9	310.9
PLEGRIDY®	40.2	51.3	91.5	43.4	46.1	89.5
Total Interferon	211.2	139.0	350.2	257.4	143.0	400.4
TYSABRI	291.9	224.3	516.2	299.8	224.4	524.2
FAMPYRA®	—	25.5	25.5	—	26.1	26.1
Spinal Muscular Atrophy:						
SPINRAZA	139.8	291.3	431.1	149.3	350.4	499.7
Biosimilars:						
BENEPALI™	—	115.8	115.8	—	121.5	121.5
IMRALDI™	—	57.6	57.6	—	55.6	55.6
FLIXABI™	—	20.5	20.5	—	25.3	25.3
BYOOVIZ™ **	0.5	—	0.5	—	—	—
Other:						
FUMADERM™	—	2.7	2.7	—	3.1	3.1
ADUHELM***	0.1	—	0.1	1.6	—	1.6
Total product revenue, net	\$ 894.1	\$ 1,160.8	\$ 2,054.9	\$ 977.2	\$ 1,258.8	\$ 2,236.0

* VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.

** BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022.

*** 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 Six Months Ended June 30,					
	2022			2021		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 237.8	\$ 570.0	\$ 807.8	\$ 340.8	\$ 626.0	\$ 966.8
VUMERITY®*	255.1	9.7	264.8	164.3	0.3	164.6
Total Fumarate	492.9	579.7	1,072.6	505.1	626.3	1,131.4
AVONEX®	319.0	169.3	488.3	423.2	198.8	622.0
PLEGRIDY®	74.5	97.0	171.5	76.0	102.9	178.9
Total Interferon	393.5	266.3	659.8	499.2	301.7	800.9
TYSABRI	576.4	460.6	1,037.0	573.1	454.4	1,027.5
FAMPYRA®	—	51.7	51.7	—	52.7	52.7
Spinal Muscular Atrophy:						
SPINRAZA	303.1	600.5	903.6	298.0	722.2	1,020.2
Biosimilars:						
BENEPALI™	—	230.5	230.5	—	243.2	243.2
IMRALDI™	—	114.7	114.7	—	113.5	113.5
FLIXABI™	—	43.0	43.0	—	50.8	50.8
BYOOVIZ™ **	0.5	—	0.5	—	—	—
Other:						
FUMADERM™	—	4.9	4.9	—	5.9	5.9
ADUHELM***	2.9	—	2.9	1.6	—	1.6
Total product revenue, net	\$ 1,769.3	\$ 2,351.9	\$ 4,121.2	\$ 1,877.0	\$ 2,570.7	\$ 4,447.7

* VUMERITY became commercially available in the E.U. during the fourth quarter of 2021.

** BYOOVIZ launched in the U.S. in June 2022 and will be commercially available in July 2022.

*** In June 2021 the FDA granted accelerated approval of ADUHELM, which became commercially available in the U.S. during the second quarter of 2021.

(In millions)	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue	\$ 2,054.9	\$ 2,236.0	\$ 4,121.2	\$ 4,447.7
OCREVUS royalties	291.9	257.0	544.1	466.3
RITUXAN/GAZYVA® revenue	144.4	183.0	291.6	362.7
Other revenue	97.9	99.0	164.0	192.3
Total revenue	\$ 2,589.1	\$ 2,775.0	\$ 5,120.9	\$ 5,469.0

TABLE 4

BIODEN 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.

(In millions, except per share amounts)	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022 ⁽¹⁾	2021 ^(1,2)	2022 ⁽¹⁾	2021 ⁽¹⁾
Selling, General and Administrative Expense:				
Total selling, general and administrative, GAAP	\$ 572.6	\$ 637.3	\$ 1,207.5	\$ 1,181.1
Less: other	2.2	2.0	2.0	2.0
Total selling, general and administrative, Non-GAAP	<u>\$ 570.4</u>	<u>\$ 635.3</u>	<u>\$ 1,205.5</u>	<u>\$ 1,179.1</u>
Amortization and Impairment of Acquired Intangible Assets:				
Total amortization and impairment of acquired intangible assets, GAAP	\$ 67.5	\$ 604.1	\$ 134.4	\$ 604.1
Less: impairment charges ^A	—	541.6	—	—
Less: amortization of acquired intangible assets	60.2	62.5	119.5	119.5
Total amortization and impairment of acquired intangible assets, Non-GAAP	<u>\$ 7.3</u>	<u>\$ —</u>	<u>\$ 14.9</u>	<u>\$ —</u>
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration:				
Total (gain) loss on fair value remeasurement of contingent consideration, GAAP	\$ (4.5)	\$ 0.3	\$ (11.6)	\$ (11.6)
Less: (gain) loss on fair value remeasurement of contingent consideration	(4.5)	0.3	(11.6)	(11.6)
Total (gain) loss on fair value remeasurement of contingent consideration, Non-GAAP	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Other (Income) Expense, net:				
Total other (income) expense, net, GAAP	\$ (428.6)	\$ (96.4)	\$ (165.3)	\$ (165.3)
Less: (gain) loss on equity security investments	77.2	(154.3)	267.9	267.9
Less: (gain) on sale of equity interest in Samsung Bioepis ^B	(1,505.3)	—	(1,505.3)	—
Less: litigation settlement agreed to in principle ^C	900.0	—	900.0	—
Less: other	20.0	—	20.0	—
Total other (income) expense, net, Non-GAAP	<u>\$ 79.5</u>	<u>\$ 57.9</u>	<u>\$ 152.1</u>	<u>\$ 152.1</u>
Income Tax (Benefit) Expense:				
Total income tax (benefit) expense, GAAP	\$ 216.7	\$ (409.1)	\$ 342.3	\$ (409.1)
Less: Neurimmune step-up tax basis ^D	—	(492.0)	83.9	(492.0)
Less: international reorganization & income tax effect related to Non-GAAP reconciling items	81.5	(79.6)	25.6	(79.6)
Total income tax expense, Non-GAAP	<u>\$ 135.2</u>	<u>\$ 162.5</u>	<u>\$ 232.8</u>	<u>\$ 162.5</u>
Effective Tax Rate:				
Total effective tax rate, GAAP	17.1 %	(70.3)%	21.2 %	(70.3)%
Less: Neurimmune step-up tax basis ^D	—	(84.5)	5.2	(84.5)
Less: impact of GAAP to Non-GAAP adjustments	1.9	(1.5)	0.7	(1.5)
Total effective tax rate, Non-GAAP	<u>15.2 %</u>	<u>15.7 %</u>	<u>15.3 %</u>	<u>15.7 %</u>

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)

(In millions, except per share amounts)	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	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	\$ (5.9)	\$ (34.3)	\$ (2.6)	\$ (16.1)
Less: amortization of equity in (income) loss of investee	7.1	16.0	14.4	23.2
Total equity in (income) loss of investee, Non-GAAP	<u>\$ (13.0)</u>	<u>\$ (50.3)</u>	<u>\$ (17.0)</u>	<u>\$ (39.3)</u>
Net Income (Loss) Attributable to Noncontrolling Interests, Net of Tax:				
Total net income (loss) attributable to noncontrolling interests, GAAP	\$ 0.7	\$ 577.0	\$ (84.6)	\$ 571.4
Less: Neurimmune step-up tax basis ^D	—	492.0	(83.9)	492.0
Less: other	—	0.9	(1.5)	(4.4)
Total net income (loss) attributable to noncontrolling interests, Non-GAAP	<u>\$ 0.7</u>	<u>\$ 84.1</u>	<u>\$ 0.8</u>	<u>\$ 83.8</u>
Net Income Attributable to Biogen Inc.:				
Total net income attributable to Biogen Inc., GAAP	\$ 1,058.0	\$ 448.5	\$ 1,361.8	\$ 858.7
Plus: impairment charges ^A	—	541.6	—	585.9
Plus: amortization of acquired intangible assets	60.2	62.5	119.5	116.3
Plus: restructuring charges	70.6	—	108.7	—
Plus: (gain) loss on fair value remeasurement of contingent consideration	(4.5)	0.3	(11.6)	(33.5)
Plus: (gain) loss on equity security investments	77.2	(154.3)	267.9	281.8
Plus: noncontrolling interests, amortization of equity in (income) loss of investee & other	7.1	16.9	12.9	18.8
Plus: premium paid on debt exchange or early debt redemption	—	—	—	—
Plus: gain on sale of equity interest in Samsung Bioepis ^B	(1,505.3)	—	(1,505.3)	—
Plus: litigation settlement agreed to in principle ^C	900.0	—	900.0	—
Plus: international reorganization & income tax effect related to Non-GAAP reconciling items	81.5	(79.6)	25.6	(188.7)
Plus: other	22.2	2.1	22.1	11.7
Total net income attributable to Biogen Inc., Non-GAAP	<u>\$ 767.0</u>	<u>\$ 838.0</u>	<u>\$ 1,301.6</u>	<u>\$ 1,651.0</u>
Diluted Earnings Per Share				
Total diluted earnings per share, GAAP	\$ 7.24	\$ 2.99	\$ 9.27	\$ 5.68
(Less) Plus: adjustments to GAAP net income attributable to Biogen Inc. (as detailed above)	(1.99)	2.59	(0.41)	5.24
Total diluted earnings per share, Non-GAAP	<u>\$ 5.25</u>	<u>\$ 5.58</u>	<u>\$ 8.86</u>	<u>\$ 10.92</u>

⁽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.

	For the Three Months Ended June 30, 2022 vs. Comparable Period in 2021	For the Six Months End June 30, 2022 vs. Compar Period in 2021
Total Revenue		
Revenue change, as reported	(6.7)%	(6.7)%
Less: impact of foreign currency translation and hedging gains / losses	(1.7)	(1.7)
Revenue change at constant currency	(5.0)%	(4.0)%
Total MS Revenue (including OCREVUS royalties)		
Revenue change, as reported	(3.8)%	(3.8)%
Less: impact of foreign currency translation and hedging gains / losses	(1.1)	(1.1)
Revenue change at constant currency	(2.7)%	(2.7)%
Total TECFIDERA Revenue		
Revenue change, as reported	(18.4)%	(18.4)%
Less: impact of foreign currency translation and hedging gains / losses	(1.9)	(1.9)
Revenue change at constant currency	(16.5)%	(16.5)%
Total VUMERITY Revenue		
Revenue change, as reported	50.6 %	60.6 %
Less: impact of foreign currency translation and hedging gains / losses	(0.9)	(0.9)
Revenue change at constant currency	51.5 %	61.5 %
Total TYSABRI Revenue		
Revenue change, as reported	(1.5)%	(1.5)%
Less: impact of foreign currency translation and hedging gains / losses	(1.2)	(1.2)
Revenue change at constant currency	(0.3)%	(0.3)%
Total INTERFERON Revenue		
Revenue change, as reported	(12.5)%	(17.5)%
Less: impact of foreign currency translation and hedging gains / losses	(1.2)	(1.2)
Revenue change at constant currency	(11.3)%	(16.3)%
Total SPINRAZA Revenue		
Revenue change, as reported	(13.8)%	(11.8)%
Less: impact of foreign currency translation and hedging gains / losses	(2.7)	(2.7)
Revenue change at constant currency	(11.1)%	(9.1)%
Total Biosimilars Revenue		
Revenue change, as reported	(4.0)%	(4.0)%
Less: impact of foreign currency translation and hedging gains / losses	(6.5)	(6.5)
Revenue change at constant currency	2.5 %	(2.5)%

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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Cash Flow:				
Net cash provided by (used in) operating activities	\$ 736.5	\$ 1,227.3	\$ 898.3	\$ 1,996.3
Net cash provided by (used in) investing activities	693.5	(152.7)	45.5	(217.4)
Net cash provided by (used in) financing activities	(471.5)	(564.5)	(488.0)	(1,349.5)
Net increase (decrease) in cash and cash equivalents	\$ 958.5	\$ 510.1	\$ 455.8	\$ 429.4
Net cash provided by (used in) operating activities	\$ 736.5	\$ 1,227.3	\$ 898.3	\$ 1,996.3
Less: Purchases of property, plant and equipment	36.9	71.9	94.8	164.5
Free cash flow	\$ 699.6	\$ 1,155.4	\$ 803.5	\$ 1,831.8

Notes to GAAP to Non-GAAP Reconciliation

^A Amortization and impairment of acquired intangible assets for the three and six months ended June 30, 2022, compared to the same periods in 2021, decreased primarily due to \$585.9 million of impairment charges recorded during 2021. For the three and six months ended June 30, 2022, we had no impairment charges.

For the three months ended June 30, 2021, amortization and impairment of acquired intangible assets reflects a \$350.0 million impairment charge related to BIIB111 (timrepigene emparvovec) for the potential treatment of choroideremia and a \$191.6 million impairment charge related to BIIB112 (cotoretigene toliparvovec) for the potential treatment of X-linked retinitis pigmentosa.

For the six months ended June 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).

During the second quarter of 2021 we announced that our Phase 3 STAR study of BIIB111 did not meet its primary or key secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of \$350.0 million during the second quarter of 2021, which resulted in a reduction of the IPR&D intangible asset from \$365.0 million to \$15.0 million.

During the second quarter of 2021 we announced that our Phase 2/3 XIRIUS study of BIIB112 did not meet its primary endpoint; however, positive trends were observed across several clinically relevant prespecified secondary endpoints. We reassessed the fair value of the program based on the results of this study and recognized an impairment charge of \$191.6 million during the second quarter of 2021, which resulted in a reduction of the IPR&D intangible asset from \$220.0 million to \$28.4 million.

^B In April 2022 we completed the sale of our 49.9% equity interest in Samsung Bioepis to 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 the transaction.

For the three and six months ended June 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 For the three months ended June 30, 2022, we recorded \$900.0 million related to an agreement in principle to resolve previously disclosed qui tam litigation relating to conduct prior to 2015. This agreement in principle does not include any admission of liability and is subject to the negotiation of final settlement agreements and documents.

^D For the three and six months ended June 30, 2022, compared to the same periods in 2021, the increases in our GAAP effective tax rate was primarily due to a deferred tax expense related to a valuation allowance, as discussed below, and the non-cash tax effects of changes in the value of our equity investments. The tax effects of this change in value of our equity investments were recorded discretely, since changes in value of equity investments cannot be forecasted.

During the second quarter of 2021 we recorded a net deferred tax asset in Switzerland of approximately \$490.0 million on Neurimmune SubOne AG's (Neurimmune) 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.

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 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.