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): **July 22, 2021**

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 July 22, 2021, Biogen Inc. issued a press release announcing its results of operations and financial condition for the second quarter ended June 30, 2021. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

Exhibit No.	Description
99.1	Biogen's press release dated July 22, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

BIOGEN INC.

By: /s/ Wendell Taylor
Wendell Taylor
Assistant Secretary

Date: July 22, 2021

BIOGEN REPORTS SECOND QUARTER 2021 RESULTS

Second quarter revenue $2,775 million; GAAP diluted EPS $2.99;
Non-GAAP diluted EPS $5.68

Received accelerated approval for ADUHELM (aducanumab-avwa) in the U.S. for initiation of treatment in patients with mild cognitive impairment or mild dementia due to Alzheimer's disease

Received FDA Breakthrough Therapy designation for lecanemab (BAN2401)

Advancing a diversified neuroscience pipeline with positive readouts in Phase 3 study in depression and Phase 2a study in stroke

New collaborations across multiple modalities including potential oral therapy for all forms of multiple sclerosis

Cambridge, Mass., July 22, 2021 -- Biogen Inc. (Nasdaq: BIIB) today reported second quarter 2021 financial results.

"We were pleased with our operational performance in the second quarter," said Michel Vounatsos, Biogen's Chief Executive Officer. "Biogen has the market-leading portfolio of therapies for MS, has launched the first approved and market-leading therapy for SMA, and now has the first approved therapy to address a defining pathology of Alzheimer's disease. In addition, we recently reported positive data in depression and stroke, and we look forward to the expected Phase 3 data for tofersen, the first genetically-targeted potential therapy for ALS, for which we have begun offering individual compassionate use access."

Second Quarter 2021 Financial Results

- Second quarter total revenue of $2,775 million decreased 25% versus the prior year at actual currency and decreased 26% at constant currency*.
  - Multiple sclerosis (MS) revenue, including royalties on sales of OCREVUS®, of $1,786 million decreased 24% versus the prior year at both actual and constant currency.
  - SPINRAZA® revenue of $500 million increased 1% versus the prior year at actual currency and decreased 3% at constant currency.
  - ADUHELM™ revenue was $2 million.
  - Biosimilars revenue of $202 million increased 18% versus the prior year at actual currency and increased 9% at constant currency.
  - Other revenue of $99 million decreased 76% versus the prior year at both actual and constant currency, primarily due to approximately $330 million in revenue in the second quarter of 2020 related to the license of certain manufacturing-related intellectual property to one of our corporate partners.
- Second quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were $448 million and $2.99, respectively.

- Second quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were $852 million and $5.68, respectively.

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

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

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

(In millions)	Q2 '21	Q2 '20	Q2 '21 v. Q2 '20
GAAP cost of sales	$ 460	$ 411	(12%)
Non-GAAP cost of sales	$ 460	$ 411	(12%)
GAAP R&D	$ 585	$ 648	10%
Non-GAAP R&D	$ 585	$ 648	10%
GAAP SG&A	$ 637	$ 555	(15%)
Non-GAAP SG&A	$ 635	$ 555	(14%)

Note: Percent changes represented as favorable/(unfavorable)

  - Beginning in the second quarter of 2021 material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP R&D and SG&A expenses. Non-GAAP financial results for the second quarter of 2020 have been updated to reflect the $208 million payment related to the collaboration with Sangamo Therapeutics, Inc. along with the associated transaction costs and income tax effect.
  - Second quarter 2021 GAAP and Non-GAAP R&D expense includes a $30 million upfront payment related to a commercialization and license agreement with Bio-Thera Solutions, Ltd. (Bio-Thera) in addition to $20 million in upfront payments related to collaboration agreements with Capsigen Inc. (Capsigen) and Ginkgo Bioworks (Ginkgo).
- Second quarter 2021 GAAP amortization and impairment of acquired intangible assets was $604 million, including an impairment charge of approximately $350 million related to BIIB111 (timrepigene emparvovec) in choroideremia and a $192 million impairment charge related to BIIB112 (cotoretigene toliparvovec) in X-linked retinitis pigmentosa, both of which were based on recent data readouts. These amounts are excluded from Non-GAAP financial results.
- Second quarter 2021 GAAP and Non-GAAP collaboration profit sharing reduced our net operating expenses by $15 million, which includes a reimbursement of $85 million from Eisai Co., Ltd. (Eisai) related to the commercialization of ADUHELM in the U.S.
- Second quarter 2021 GAAP other income was $96 million, primarily driven by unrealized gains on our strategic equity investments of $154 million. Second quarter 2021 Non-GAAP other expense was $58 million, primarily driven by interest expense.
- Second quarter 2021 effective GAAP and Non-GAAP tax rates were (70%) and 16%, respectively. The second quarter 2021 effective GAAP tax rate was impacted by a deferred tax benefit associated with the accelerated approval of ADUHELM by the U.S. Food and Drug Administration (FDA). We recorded a deferred tax asset of approximately $500 million related to Neurimmune SubOne AG's

(Neurimmune) tax basis in ADUHELM, with an equal and offsetting amount assigned to noncontrolling interest, resulting in zero net impact to net income attributable to Biogen Inc.

- Second quarter 2021 GAAP and Non-GAAP income attributable to noncontrolling interest were $577 million and $84 million, respectively, which includes a milestone payment of $100 million to Neurimmune related to the launch of ADUHELM in the U.S. GAAP income attributable to noncontrolling interest also includes the offset to a deferred tax benefit related to Neurimmune's tax basis in ADUHELM of approximately $500 million.

Financial Position

- As of June 30, 2021, Biogen had $7,269 million in total debt. Cash, cash equivalents, and marketable securities totaled $3,966 million. This resulted in net debt of $3,303 million.
- In the second quarter of 2021 Biogen repurchased approximately 1.6 million shares of the Company's common stock for a total value of $450 million. As of June 30, 2021, there was $3,550 million remaining under the share repurchase program authorized in October 2020.
- For the second quarter of 2021 the Company's weighted average diluted shares were 150 million.
- Second quarter 2021 cash from operations was $1,227 million. Capital expenditures were $72 million, and free cash flow, defined as cash flow from operations less capital expenditures, was $1,155 million.

Full Year 2021 Financial Guidance

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

	Prior Guidance	Updated Guidance
Total revenue	$10.45 to $10.75 billion	$10.65 to $10.85 billion
Non-GAAP diluted EPS	$17.50 to $19.00	$17.50 to $19.00
Capital expenditures	$375 to $425 million	$375 to $425 million

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

Non-GAAP R&D expense is expected to be between $2.45 billion and $2.55 billion, an increase from prior guidance primarily due to an expected $125 million upfront payment in the third quarter of 2021 associated with our recently announced collaboration with InnoCare Pharma Limited (InnoCare). This payment was not included in our prior guidance. Non-GAAP SG&A expense is expected to be between $2.6 billion and $2.7 billion, consistent with our previous guidance. This guidance continues to reflect our expectation that both Non-GAAP R&D and Non-GAAP SG&A expenses will be higher in the second half of the year than they were in the first half due to collaborations, program readouts, and investments in ADUHELM.

We expect that we will utilize a portion of the remaining share repurchase authorization of $3,550 million throughout 2021.

This guidance assumes that foreign exchange rates as of June 30, 2021, will remain in effect for the remainder of the year, net of hedging activities.

With the exception of the proposed InnoCare collaboration, as described above, this financial guidance does not include any impact from potential acquisitions or large business development transactions, as both are hard to predict, or any impact of potential tax or healthcare reform.

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

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

Aducanumab Updates

- In July 2021 Biogen submitted a Marketing Authorization Application (MAA) for aducanumab to the United Arab Emirates Ministry of Health and Prevention under its Fast Track Process. This follows the submission of MAAs in South Korea and Mexico in June 2021 and Israel in July 2021.
- In July 2021 the last patient was enrolled in the aducanumab re-dosing study, EMBARK (n = 1,695). EMBARK was initiated in March 2020 and is designed to evaluate aducanumab in eligible Alzheimer's disease patients who were actively enrolled in aducanumab studies (PRIME, EVOLVE, EMERGE, and ENGAGE) in March 2019.
- In July 2021 Biogen and Eisai announced the FDA approved an updated label for ADUHELM injection 100 mg/mL solution to emphasize the disease stages studied in the clinical trials.
- In the second quarter of 2021 Biogen announced that the FDA granted accelerated approval for ADUHELM as the first and only Alzheimer's disease treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain.

Board of Director Updates

- In the second quarter of 2021 Biogen announced that Robert W. Pangia, who served as a Biogen director since 1997, retired from the Company's Board of Directors, effective at the 2021 annual meeting of stockholders. Maria C. Freire, Ph.D. and William D. Jones were elected as new members of the Board of Directors at the 2021 annual meeting of stockholders.

Other Recent Events

- In July 2021 the last participant received their final dose in the Phase 3 VALOR study of tofersen (SOD1 ASO) in adults with amyotrophic lateral sclerosis (ALS) with a confirmed *SOD1* mutation. Biogen has begun offering individual compassionate use access to tofersen for a subset of the *SOD1*-ALS population with the most rapidly progressive disease.
- In July 2021 Biogen and InnoCare announced that they have entered into a license and collaboration agreement for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor (BTKi) for the potential treatment of MS. Orelabrutinib is a covalent BTKi with high selectivity and the ability to cross the blood-brain barrier, and is currently being studied in a multi-country, placebo-controlled Phase 2 trial in relapsing-remitting MS. InnoCare will receive a $125 million upfront payment and is eligible to receive up to $812.5 million in potential development milestones and potential commercial

payments should the collaboration achieve certain development and commercial milestones and sales thresholds. InnoCare is also eligible to receive tiered royalties in the low to high teens on potential future net sales of any product resulting from the collaboration. Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

- In the second quarter of 2021 Samsung Bioepis Co., Ltd. and Biogen announced that the European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion for BYOOVIZ™, a biosimilar candidate referencing Lucentis® (ranibizumab), also known as SB11.
- In the second quarter of 2021 Eisai and Biogen announced that the FDA granted Breakthrough Therapy designation for lecanemab (BAN2401), an investigational anti-amyloid beta antibody for the potential treatment of Alzheimer's disease. Breakthrough Therapy designation is an FDA program intended to expedite the development and review of medicines for serious or life-threatening conditions. The benefits of a Breakthrough Therapy designation include more intensive guidance on an efficient development program as well as eligibility for rolling review and potentially priority review.
- In the second quarter of 2021 Biogen announced that the first patient had been dosed in the global clinical study, TOPAZ-1, evaluating the clinical efficacy and assessing the safety of BIIB059, a first in-class, humanized IgG1 monoclonal antibody targeting blood dendritic cell antigen 2, as compared to placebo, in participants with active systemic lupus erythematosus (SLE). TOPAZ-1 is expected to be conducted at approximately 135 sites worldwide and aims to enroll 540 adults with active SLE.
- In the second quarter of 2021 Sage Therapeutics, Inc. and Biogen announced that the WATERFALL Study in patients with major depression disorder met its primary endpoint with zuranolone (SAGE-217/BIIB125) 50 mg showing statistically significant improvement in depressive symptoms compared with placebo at Day 15 as assessed by the 17-item Hamilton Rating Scale for Depression.
- In the second quarter of 2021 Biogen announced new research supporting the continued development of an investigational higher dose of SPINRAZA and additional data reinforcing the strength of SPINRAZA's clinical profile in improving the lives of individuals with spinal muscular atrophy (SMA) over the long term. These data were presented at the virtual Cure SMA Research & Clinical Care Meeting.
- In the second quarter of 2021 Biogen and Bio-Thera announced results from the Phase 3 study of BAT1806, a proposed biosimilar referencing ACTEMRA®/RoACTEMRA® (tocilizumab). The study met its primary endpoints, demonstrating equivalence to the reference medicine in patients with moderate to severe rheumatoid arthritis inadequately controlled by methotrexate therapy. In April 2021 Biogen and Bio-Thera announced that they entered into a commercialization and license agreement to develop, manufacture, and commercialize BAT1806.
- In the second quarter of 2021 Biogen and Ginkgo announced a gene therapy collaboration. Together, the companies aim to redefine the industry standard for manufacturing recombinant adeno-associated virus (AAV)-based vectors. Recombinant AAV-based vectors are widely used to develop innovative gene therapies and have the potential to treat certain neurological and neuromuscular diseases as well as other conditions across multiple therapeutic areas.
- In the second quarter of 2021 Biogen and Envisagenics announced a new collaboration to advance ribonucleic acid (RNA) splicing research within central nervous system (CNS) diseases. As part of the collaboration, Biogen will leverage Envisagenics' proprietary artificial intelligence-driven RNA splicing platform, SpliceCore®, to define and understand the regulation of different RNA isoforms in CNS cell types.
- In the second quarter of 2021 Biogen and TMS Co., Ltd. (TMS) announced that Biogen exercised its option to acquire TMS-007 (BIIB131), an investigational drug for acute ischemic stroke, from TMS.

Biogen's decision to acquire TMS-007 was based on positive data from a Phase 2a study, which met its primary safety objective with no incidence of symptomatic intracranial hemorrhage and demonstrated positive impacts on both blood vessel reopening in the brain as well as patient functional recovery at 90 days. Biogen incurred a one-time $18 million expense as part of the acquisition of TMS-007.

- In the second quarter of 2021 Biogen and Capsigen announced that they entered into a strategic research collaboration to engineer novel AAV capsids that have the potential to deliver transformative gene therapies that address the underlying genetic causes of various CNS and neuromuscular disorders. Capsigen received a $15 million upfront payment and is eligible to receive up to $42 million in potential research milestones and up to an additional $1.25 billion in potential development and commercial payments should the collaboration programs achieve certain developmental milestones and sales thresholds. Capsigen is also eligible to receive royalties on future net sales of products that incorporate capsids resulting from the collaboration.
- In the second quarter of 2021 Biogen announced that it received a Complete Response Letter (CRL) from the FDA for its supplemental Biologic License Application for a new subcutaneous route of administration of TYSABRI® to treat relapsing MS. The CRL indicates that the FDA is unable to approve the Company's filing as submitted. Biogen is evaluating the CRL and will determine next steps in the U.S.

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 22, 2021, and will be accessible through the Investors section of Biogen's website, www.biogen.com. Supplemental information in the form of a slide presentation is also accessible at the same location on the internet and will be subsequently available on the website for at least one month.

About Biogen

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

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

Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; 2021 financial guidance; plans relating to share repurchases; and the

anticipated completion and timing of the proposed collaboration with InnoCare. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “potential,” “possible,” “prospect,” “will,” “would,” and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; risks relating to technology failures or breaches; risks relating to management and key personnel changes, including attracting and retaining key personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; fluctuations in our effective tax rate; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; environmental risks; risks that the proposed collaboration with InnoCare will not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed collaboration with InnoCare will not be satisfied; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

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

Biogen Investor Contact: Biogen Media Contact:
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TABLE 1

BIOGEN 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,	
	2021	2020	2021	2020
Revenue:				
Product, net	$ 2,236.0	$ 2,795.7	$ 4,447.7	$ 5,700.3
Revenue from anti-CD20 therapeutic programs	440.0	478.3	829.0	998.7
Other	99.0	407.6	192.3	516.9
Total revenue	2,775.0	3,681.6	5,469.0	7,215.9
Cost and expense:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	459.7	411.1	937.8	865.5
Research and development	585.1	647.6	1,099.3	1,123.9
Selling, general and administrative	637.3	555.1	1,232.3	1,125.2
Amortization and impairment of acquired intangible assets	604.1	61.5	702.2	133.0
Collaboration profit sharing	(15.2)	21.8	53.3	93.5
(Gain) loss on fair value remeasurement of contingent consideration	0.3	10.0	(33.5)	5.5
Acquired in-process research and development	18.0	—	18.0	75.0
Total cost and expense	2,289.3	1,707.1	4,009.4	3,421.6
Income from operations	485.7	1,974.5	1,459.6	3,794.3
Other income (expense), net	96.4	63.0	(410.5)	(57.5)
Income before income tax expense and equity in loss of investee, net of tax	582.1	2,037.5	1,049.1	3,736.8
Income tax (benefit) expense	(409.1)	446.1	(364.9)	738.2
Equity in (income) loss of investee, net of tax	(34.3)	(15.1)	(16.1)	(0.4)
Net income	1,025.5	1,606.5	1,430.1	2,999.0
Net income (loss) attributable to noncontrolling interests, net of tax	577.0	64.4	571.4	57.8
Net income attributable to Biogen Inc.	$ 448.5	$ 1,542.1	$ 858.7	$ 2,941.2
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 3.00	$ 9.60	$ 5.70	$ 17.65
Diluted earnings per share attributable to Biogen Inc.	$ 2.99	$ 9.59	$ 5.68	$ 17.61
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	149.7	160.6	150.8	166.7
Diluted earnings per share attributable to Biogen Inc.	150.1	160.9	151.2	167.0

TABLE 2

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

	As of June 30, 2021	As of December 31, 2020
ASSETS		
Cash, cash equivalents and marketable securities	$ 3,050.8	$ 2,610.1
Accounts receivable, net	1,688.0	1,913.8
Inventory	1,254.8	1,068.6
Other current assets	1,190.1	1,294.6
Total current assets	7,183.7	6,887.1
Marketable securities	915.1	772.1
Property, plant and equipment, net	3,442.2	3,411.5
Operating lease assets	402.5	433.3
Intangible assets, net	2,385.0	3,084.3
Goodwill	5,763.9	5,762.1
Deferred tax asset	1,849.9	1,369.5
Investments and other assets	2,528.1	2,899.0
TOTAL ASSETS	$ 24,470.4	$ 24,618.9
LIABILITIES AND EQUITY		
Current liabilities	$ 3,347.2	$ 3,742.2
Notes payable	7,269.2	7,426.2
Deferred tax liability	918.9	1,032.8
Long-term operating lease liabilities	363.9	402.0
Other long-term liabilities	1,356.4	1,329.6
Equity	11,214.8	10,686.1
TOTAL LIABILITIES AND EQUITY	$ 24,470.4	$ 24,618.9

TABLE 3

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

	For the Three Months Ended June 30,					
	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 178.4	$ 309.2	$ 487.6	$ 913.0	$ 268.6	$ 1,181.6
VUMERITY®	90.7	0.2	90.9	8.7	—	8.7
Total Fumarate	269.1	309.4	578.5	921.7	268.6	1,190.3
AVONEX®	214.0	96.9	310.9	294.8	93.7	388.5
PLEGRIDY®	43.4	46.1	89.5	50.8	42.1	92.9
Total Interferon	257.4	143.0	400.4	345.6	135.8	481.4
TYSABRI	299.8	224.4	524.2	244.1	187.9	432.0
FAMPYRA®	—	26.1	26.1	—	23.0	23.0
Spinal Muscular Atrophy:						
SPINRAZA	149.3	350.4	499.7	210.3	284.3	494.6
Alzheimer's disease:						
ADUHELM*	1.6	—	1.6	—	—	—
Biosimilars:						
BENEPALI™	—	121.5	121.5	—	106.2	106.2
IMRALDI™	—	55.6	55.6	—	44.8	44.8
FLIXABI™	—	25.3	25.3	—	20.6	20.6
Other:						
FUMADERM™	—	3.1	3.1	—	2.8	2.8
Total product revenue, net	$ 977.2	$ 1,258.8	$ 2,236.0	$ 1,721.7	$ 1,074.0	$ 2,795.7

*In June 2021 the U.S. Food and Drug Administration (FDA) granted accelerated approval of ADUHELM, which became commercially available in the 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,					
	2021			2020		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	$ 340.8	$ 626.0	$ 966.8	$ 1,688.1	$ 591.9	$ 2,280.0
VUMERITY	164.3	0.3	164.6	11.1	—	11.1
Total Fumarate	505.1	626.3	1,131.4	1,699.2	591.9	2,291.1
AVONEX	423.2	198.8	622.0	543.5	211.4	754.9
PLEGRIDY	76.0	102.9	178.9	94.7	97.8	192.5
Total Interferon	499.2	301.7	800.9	638.2	309.2	947.4
TYSABRI	573.1	454.4	1,027.5	521.8	432.6	954.4
FAMPYRA	—	52.7	52.7	—	51.3	51.3
Spinal Muscular Atrophy:						
SPINRAZA	298.0	722.2	1,020.2	445.7	613.9	1,059.6
Alzheimer's disease:						
ADUHELM*	1.6	—	1.6	—	—	—
Biosimilars:						
BENEPALI	—	243.2	243.2	—	239.7	239.7
IMRALDI	—	113.5	113.5	—	106.4	106.4
FLIXABI	—	50.8	50.8	—	44.3	44.3
Other:						
FUMADERM	—	5.9	5.9	—	6.1	6.1
Total product revenue, net	$ 1,877.0	$ 2,570.7	$ 4,447.7	$ 3,304.9	$ 2,395.4	$ 5,700.3

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Product revenue	$ 2,236.0	$ 2,795.7	$ 4,447.7	$ 5,700.3
OCREVUS royalties	257.0	208.2	466.3	370.5
RITUXAN/GAZYVA® revenue	183.0	270.1	362.7	628.2
Other revenue	99.0	407.6	192.3	516.9
Total revenue	$ 2,775.0	$ 3,681.6	$ 5,469.0	$ 7,215.9

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 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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Selling, General and Administrative Expense:				
Total selling, general and administrative, GAAP	$ 637.3	$ 555.1	$ 1,232.3	$ 1,125.2
Less: other	2.0	—	2.2	—
Total selling, general and administrative, Non-GAAP	$ 635.3	$ 555.1	$ 1,230.1	$ 1,125.2
Amortization and Impairment of Acquired Intangible Assets:				
Total amortization and impairment of acquired intangible assets, GAAP	$ 604.1	$ 61.5	$ 702.2	$ 133.0
Less: impairment charges [A]	541.6	—	585.9	—
Less: amortization of acquired intangible assets	62.5	61.5	116.3	133.0
Total amortization and impairment of acquired intangible assets, Non-GAAP	$ —	$ —	$ —	$ —
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration:				
Total (gain) loss on fair value remeasurement of contingent consideration, GAAP	$ 0.3	$ 10.0	$ (33.5)	$ 5.5
Less: (gain) loss on fair value remeasurement of contingent consideration	0.3	10.0	(33.5)	5.5
Total (gain) loss on fair value remeasurement of contingent consideration, Non-GAAP	$ —	$ —	$ —	$ —
Other Income (Expense), net:				
Total other income (expense), net, GAAP	$ 96.4	$ 63.0	$ (410.5)	$ (57.5)
Less: gain (loss) on equity security investments	154.3	102.9	(281.8)	42.0
Plus: premium paid on debt exchange or early debt redemption	—	9.4	9.5	9.4
Total other income (expense), net, Non-GAAP	$ (57.9)	$ (30.5)	$ (119.2)	$ (90.1)
Income Tax (Benefit) Expense:				
Total income tax (benefit) expense, GAAP	$ (409.1)	$ 446.1	$ (364.9)	$ 738.2
Less: Neurimmune step-up tax basis [B]	(492.0)	—	(492.0)	—
Less: valuation allowance associated with deferred tax assets	—	56.0	—	56.0
Less: income tax effect related to Non-GAAP reconciling items	(83.4)	9.7	(192.7)	(28.7)
Total income tax expense, Non-GAAP	$ 166.3	$ 380.4	$ 319.8	$ 710.9
Effective Tax Rate:				
Total effective tax rate, GAAP	(70.3) %	21.9 %	(34.8) %	19.8
Less: Neurimmune step-up tax basis [B]	(84.5)		(46.9)	
Less: valuation allowance associated with deferred tax assets	—	2.7	—	1.5
Less: impact of GAAP to Non-GAAP adjustments	(1.6)	0.3	(3.7)	0.2
Total effective tax rate, Non-GAAP	15.8 %	18.9 %	15.8 %	18.1

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 June 30,		For the Six Months Ended June 30,	
	2021	2020*	2021	2020*
Equity in (Income) Loss of Investee, Net of Tax:				
Total equity in (income) loss of investee, GAAP	$ (34.3)	$ (15.1)	$ (16.1)	$ (0.3)
Less: amortization of equity in (income) loss of investee	16.0	2.0	23.2	22.9
Total equity in (income) loss of investee, Non-GAAP	$ (50.3)	$ (17.1)	$ (39.3)	$ (23.2)
Net Income (Loss) Attributable to Noncontrolling Interests, Net of Tax:				
Total net income (loss) attributable to noncontrolling interests, GAAP	$ 577.0	$ 64.4	$ 571.4	$ 57.8
Less: Neurimmune step-up tax basis [B]	492.0	—	492.0	—
Less: net distribution to noncontrolling interests and other	0.9	(3.5)	(4.4)	(7.1)
Total net income (loss) attributable to noncontrolling interests, Non-GAAP	$ 84.1	$ 67.9	$ 83.8	$ 64.9
Net Income Attributable to Biogen Inc.:				
Total net income attributable to Biogen Inc., GAAP	$ 448.5	$ 1,542.1	$ 858.7	$ 2,941.2
Plus: impairment charges [A]	541.6	—	585.9	—
Plus: amortization of acquired intangible assets	62.5	61.5	116.3	133.0
Plus: acquired in-process research and development	18.0	—	18.0	75.0
Plus: (gain) loss on fair value remeasurement of contingent consideration	0.3	10.0	(33.5)	5.5
Plus: (gain) loss on equity security investments	(154.3)	(102.9)	281.8	(42.0)
Plus: net distribution to noncontrolling interests & amortization of equity in loss of investee [B]	16.9	(1.5)	18.8	15.8
Plus: premium paid on debt exchange or early debt redemption	—	9.4	9.5	9.4
Plus: other	2.1	—	2.2	—
Plus: valuation allowance associated with deferred tax assets	—	56.0	—	56.0
Plus: income tax effect related to Non-GAAP reconciling items	(83.4)	9.7	(192.7)	(28.8)
Total net income attributable to Biogen Inc., Non-GAAP	$ 852.2	$ 1,584.3	$ 1,665.0	$ 3,165.1
Diluted Earnings Per Share				
Total diluted earnings per share, GAAP	$ 2.99	$ 9.59	$ 5.68	$ 17.61
Plus: adjustments to GAAP net income attributable to Biogen Inc. (as detailed above)	2.69	0.26	5.34	1.34
Total diluted earnings per share, Non-GAAP	$ 5.68	$ 9.85	$ 11.02	$ 18.95

*Beginning in the second quarter of 2021 material upfront payments and premiums paid on the acquisition of common stock associated with significant collaboration and licensing arrangements along with the related transaction costs incurred are no longer excluded from Non-GAAP R&D and SG&A expenses. Non-GAAP financial results for 2020 have been updated to include the $208 million payment related to the collaboration with Sangamo Therapeutics, Inc. along with the associated transaction costs and income tax effect for the three and six months ended June 30, 2020.

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, 2021		For the Six Months Ended Ju 30, 2021
Total Revenue			
Revenue growth, as reported	(24.6)	%	(24.2)
Less: impact of foreign currency translation and hedging (gains) losses	1.4		1.2
Revenue growth at constant currency	(26.0)	%	(25.4)
Total MS Revenue (including OCREVUS royalties)			
Revenue growth, as reported	(23.5)	%	(28.0)
Less: impact of foreign currency translation and hedging (gains) losses	0.6		(3.0)
Revenue growth at constant currency	(24.1)	%	(25.0)
Total SPINRAZA Revenue			
Revenue growth, as reported	1.0	%	(3.7)
Less: impact of foreign currency translation and hedging (gains) losses	3.8		3.8
Revenue growth at constant currency	(2.8)	%	(7.5)
Total Biosimilars Revenue			
Revenue growth, as reported	17.9	%	4.4
Less: impact of foreign currency translation and hedging (gains) losses	8.7		7.7
Revenue growth at constant currency	9.2	%	(3.3)
Total Other Revenue			
Revenue growth, as reported	(75.7)	%	(62.8)
Less: impact of foreign currency translation and hedging (gains) losses	0.1		0.1
Revenue growth at constant currency	(75.8)	%	(62.9)

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,	
	2021	2020	2021	2020
Cash Flow:				
Net cash provided by (used in) operating activities	$ 1,227.3	$ 1,948.5	$ 1,996.3	$ 3,415.8
Net cash provided by (used in) investing activities	(152.7)	(832.7)	(217.4)	(389.8)
Net cash provided by (used in) financing activities	(564.5)	(1,313.4)	(1,349.5)	(3,558.7)
Net increase (decrease) in cash and cash equivalents	$ 510.1	$ (197.6)	$ 429.4	$ (532.7)
Net cash provided by (used in) operating activities	$ 1,227.3	$ 1,948.5	$ 1,996.3	$ 3,415.8
Less: Purchases of property, plant and equipment	71.9	105.0	164.5	254.7
Free cash flow	$ 1,155.4	$ 1,843.5	$ 1,831.8	$ 3,161.1

Notes to GAAP to Non-GAAP Reconciliation

[A] For the three and six months ended June 30, 2021, amortization and impairment of acquired intangible assets totaled $604.1 million and $702.2 million, respectively, compared to $61.5 million and $133.0 million, respectively, in the prior year comparative periods.

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). For the three and six months ended June 30, 2020, we had no impairment charges.

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 in-process research and development (IPR&D) 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 asset from $220.0 million to $28.4 million.

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

Use of Non-GAAP Financial Measures

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

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

1. Acquisitions and divestitures

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

2. Restructuring, business transformation and other cost saving initiatives

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

3. (Gain) loss on equity security investments

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

4. Other items

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