

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, 2020**

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-19311
(Commission File Number)

33-0112644
(IRS Employer Identification No.)

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

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

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

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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, 2020, Biogen Inc. issued a press release announcing its results of operations and financial condition for the second quarter ended June 30, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Biogen's press release dated July 22, 2020
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/F. Ty Edmondson

F. Ty Edmondson

Chief Corporate and Compliance Counsel and Assistant Secretary

Date: **July 22, 2020**



BIOGEN REPORTS Q2 2020 REVENUES OF \$3.7 BILLION

GAAP diluted EPS increased 22%; Non-GAAP diluted EPS increased 12%

Biogen completed submission of BLA for aducanumab in Alzheimer's disease in the U.S.

New SPINRAZA data showed unprecedented survival in pre-symptomatic SMA

Biogen presented positive phase 2 data in cutaneous lupus erythematosus

Phase 1/2 tofersen data in SOD1 ALS published in The New England Journal of Medicine

Cambridge, Mass., July 22, 2020 -- Biogen Inc. (Nasdaq: BIIB) today reported second quarter 2020 financial results.

“In the second quarter, Biogen continued to deliver strong financial results. We are pleased to have completed the BLA submission for aducanumab and look forward to the prospect of launching the first therapy to reduce clinical decline in Alzheimer’s disease,” said Michel Vounatsos, Biogen’s Chief Executive Officer. “Our progress with aducanumab exemplifies our broader strategy of building a multi-franchise portfolio based on our deep expertise in neuroscience, and we have multiple near-term value creation opportunities in other areas such as ALS, ophthalmology, lupus, stroke, and biosimilars.”

Financial Results

- Second quarter total revenues were \$3,682 million, a 2% increase versus the second quarter of 2019.
 - Multiple sclerosis (MS) revenues, including \$208 million in royalties on the sales of OCREVUS[®], decreased 2% versus the prior year to \$2,335 million.
 - SPINRAZA[®] revenues increased 1% versus the prior year to \$495 million.
 - Biosimilars revenues decreased 7% versus the prior year to \$172 million.
 - Other revenues increased 155% versus the prior year to \$408 million primarily due to approximately \$330 million in revenues related to the license of certain manufacturing-related intellectual property to one of our corporate partners.
 - Biogen estimates that its first quarter 2020 product revenues benefitted by approximately \$100 million attributed to accelerated sales due to the COVID-19 pandemic, primarily in Europe, of which Biogen believes approximately \$75 million was utilized in the second quarter of 2020.
- Second quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$1,542 million and \$9.59, respectively, compared to \$1,494 million and \$7.85, respectively, in the second quarter of 2019.
- Second quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$1,651 million and \$10.26, respectively, compared to \$1,742 million and \$9.15, respectively, in the second quarter of 2019.

(In millions, except per share amounts)	Q2 '20	Q2 '19	Q1 '20	Q2 '20 v. Q2 '19	Q2 '20 v. Q1 '20
Total revenues	\$ 3,682	\$ 3,617	\$ 3,534	2%	4%
GAAP net income [#]	\$ 1,542	\$ 1,494	\$ 1,399	3%	10%
GAAP diluted EPS	\$ 9.59	\$ 7.85	\$ 8.08	22%	19%
Non-GAAP net income [#]	\$ 1,651	\$ 1,742	\$ 1,582	(5%)	4%
Non-GAAP diluted EPS	\$ 10.26	\$ 9.15	\$ 9.14	12%	12%

[#] Net income attributable to Biogen Inc.

Note: Percent changes represented as favorable/(unfavorable)

A reconciliation of GAAP to Non-GAAP quarterly financial results can be found in Table 3 at the end of this news release.

Revenue Highlights

(In millions)	Q2 '20	Q2 '19	Q1 '20	Q2 '20 v. Q2 '19	Q2 '20 v. Q1 '20
Multiple Sclerosis:					
Total Fumarate	\$ 1,190	\$ 1,150	\$ 1,101	3%	8%
TECFIDERA®	\$ 1,182	\$ 1,150	\$ 1,098	3%	8%
VUMERITY®	\$ 9	\$ —	\$ 2	NMF	NMF
Total Interferon	\$ 481	\$ 554	\$ 466	(13%)	3%
AVONEX®	\$ 389	\$ 438	\$ 366	(11%)	6%
PLEGRIDY®	\$ 93	\$ 117	\$ 100	(21%)	(7%)
TYSABRI®	\$ 432	\$ 475	\$ 522	(9%)	(17%)
FAMPYRA™	\$ 23	\$ 24	\$ 28	(5%)	(19%)
Spinal Muscular Atrophy:					
SPINRAZA	\$ 495	\$ 488	\$ 565	1%	(12%)
Biosimilars:					
BENEPALI™	\$ 106	\$ 120	\$ 133	(12%)	(20%)
IMRALDI™	\$ 45	\$ 47	\$ 62	(5%)	(27%)
FLIXABI™	\$ 21	\$ 17	\$ 24	23%	(13%)
Other Product Revenues:					
FUMADERM™	\$ 3	\$ 4	\$ 3	(26%)	(16%)
Total Product Revenues:	\$ 2,796	\$ 2,880	\$ 2,905	(3%)	(4%)
OCREVUS Royalties	\$ 208	\$ 183	\$ 162	14%	28%
RITUXAN®/GAZYVA® Revenues	\$ 270	\$ 394	\$ 358	(31%)	(25%)
Other Revenues	\$ 408	\$ 160	\$ 109	155%	273%
Total Revenues	\$ 3,682	\$ 3,617	\$ 3,534	2%	4%
MS Product Revenues + OCREVUS Royalties	\$ 2,335	\$ 2,387	\$ 2,280	(2%)	2%

Note: Numbers may not foot due to rounding; percent changes represented as favorable/(unfavorable)

- In the second quarter of 2020 channel inventory levels in the U.S. increased by approximately \$10 million for TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, and TYSABRI combined. This compares to a decrease in inventory levels of approximately \$30 million in the second quarter of 2019 and a decrease of approximately \$115 million in the first quarter of 2020.

Expense Highlights

(In millions)	Q2 '20	Q2 '19	Q1 '20	Q2 '20 v. Q2 '19	Q2 '20 v. Q1 '20
GAAP cost of sales	\$ 411	\$ 476	\$ 454	14%	10%
Non-GAAP cost of sales	\$ 411	\$ 476	\$ 454	14%	10%
GAAP R&D	\$ 648	\$ 485	\$ 476	(34%)	(36%)
Non-GAAP R&D	\$ 564	\$ 477	\$ 476	(18%)	(19%)
GAAP SG&A	\$ 555	\$ 588	\$ 570	6%	3%
Non-GAAP SG&A	\$ 555	\$ 553	\$ 569	—%	3%

Note: Percent changes represented as favorable/(unfavorable)

- GAAP R&D expense in the second quarter of 2020 included \$208 million related to Biogen's agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop gene regulation therapies for Alzheimer's disease, Parkinson's disease, neuromuscular disease, and other neurological diseases. Non-GAAP R&D expense in the second quarter of 2020 included \$125 million related to the Sangamo agreement.
- GAAP SG&A expense in the second quarter of 2019 included acquisition-related charges incurred in connection with our acquisition of Nightstar Therapeutics plc, totaling \$33 million.

Other Financial Highlights

- For the second quarter of 2020 GAAP and Non-GAAP net expense related to collaboration profit sharing was \$22 million.
- For the second quarter of 2020 GAAP other income was \$63 million, which included \$103 million in unrealized gains on investments, principally driven by an increase in the fair value of Biogen's equity investments in Ionis Pharmaceuticals, Inc. and Sangamo. Non-GAAP other expense for the second quarter of 2020 was \$30 million, driven by net interest expense, foreign exchange rate losses, and losses on security sales.
- In the second quarter of 2020 net income attributable to noncontrolling interest included a \$75 million payment to Neurimmune SubOne AG related to completing the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the approval of aducanumab.
- For the second quarter of 2020 the Company's effective GAAP tax rate was approximately 22%, an increase from approximately 14% in the second quarter of 2019. This is due to a non-recurring prior year income tax benefit on a change in the Company's tax profile and a current year income tax expense related to a net valuation allowance against certain deferred tax assets, due to the decision of the U.S. District Court of the Northern District of West Virginia that the asserted claims of U.S. patent No. 8,399,514, which cover the treatment of MS with TECFIDERA, are invalid. For the second quarter of 2020 the Company's effective Non-GAAP tax rate was approximately 19%, an increase from approximately 14% in the second quarter of 2019, primarily due to the non-recurring benefit of the prior year change in the Company's tax profile.
- In the second quarter of 2020 Biogen repurchased approximately 9.0 million shares of the Company's common stock for a total value of approximately \$2,809 million.
 - As of June 30, 2020, approximately \$1,250 million remained under the share repurchase program authorized in December 2019.

- As of June 30, 2020, Biogen had cash, cash equivalents, and marketable securities totaling \$5,250 million and \$7,424 million in notes payable.
- In the second quarter of 2020 the Company generated approximately \$1,948 million in net cash flows from operations.
- For the second quarter of 2020 the Company's weighted average diluted shares were 161 million.

2020 Financial Guidance

Biogen provided an update to its full year 2020 financial guidance. This financial guidance consists of the following components:

- Revenue is expected to be approximately \$13.8 billion to \$14.2 billion, compared to the prior guidance range of \$14.0 billion to \$14.3 billion.
- GAAP and Non-GAAP R&D expense is expected to be approximately 16% to 17% of total revenues, compared to the prior guidance range of approximately 15% to 16% of total revenues.
- GAAP and Non-GAAP SG&A expense is expected to be approximately 17.5% to 18.5% of total revenues, compared to the prior guidance range of approximately 19.5% to 20.5% of total revenues.
- GAAP tax rate is expected to be approximately 18.5% to 19.5%, compared to the prior guidance range of approximately 18% to 19%.
- Non-GAAP tax rate is expected to be approximately 18% to 19%, unchanged versus the prior guidance range.
- GAAP diluted EPS is expected to be between \$32.00 and \$34.00, an increase from the prior guidance range of \$29.50 to \$31.50.
- Non-GAAP diluted EPS is expected to be between \$34.00 and \$36.00, an increase from the prior guidance range of \$31.50 to \$33.50.

This financial guidance does not include any operational impact from the potential entry of generic versions of TECFIDERA in the U.S. in 2020. This financial guidance does not include any impact from potential acquisitions or large business development transactions, as both are hard to predict. This financial guidance assumes additional SG&A expense in the second half of 2020 related to aducanumab, a stable share count, and no change to foreign exchange rates for the remainder of the year.

Biogen may incur charges, realize gains or losses, or experience other events or circumstances in 2020 that could cause actual results to vary from this financial guidance. A reconciliation of GAAP to Non-GAAP financial guidance can be found in Table 3 at the end of this news release.

Recent Events

- In July 2020 Biogen completed the submission of a BLA to the FDA for aducanumab as a treatment for Alzheimer's disease. The completed submission followed ongoing collaboration with the FDA and includes clinical data from the Phase 3 EMERGE and ENGAGE studies as well as the Phase 1b PRIME study. As part of the completed submission, Biogen has requested Priority Review. If approved, aducanumab would become the first therapy to reduce the clinical decline of Alzheimer's disease and would also be the first therapy to demonstrate that removing amyloid beta resulted in better clinical outcomes. Aducanumab is being developed in collaboration with Eisai Co., Ltd.
- In July 2020 Biogen announced it plans to initiate a global Phase 4 clinical study, RESPOND, to evaluate the efficacy and safety of SPINRAZA in patients with spinal muscular atrophy (SMA) who have a suboptimal response to gene therapy Zolgensma® (onasemnogene abeparvovec). People with SMA do not produce enough survival motor neuron (SMN) protein, which is critical for the

maintenance of motor neurons that support walking and basic functions of life, including breathing and swallowing. The RESPOND study will seek to understand if the proven efficacy of SPINRAZA and its continuous production of SMN protein may also benefit patients treated with gene therapy. Biogen plans to submit the study protocol to the regulatory authorities in the coming months and aims for the first eligible patients to be enrolled in the RESPOND study in Q1 2021.

- In July 2020 the Alzheimer's Clinical Trials Consortium, Eisai Co., Ltd. and Biogen announced that a new Phase 3 clinical study (AHEAD 3-45) of BAN2401, an anti-amyloid beta (A β) antibody, has been initiated for individuals with preclinical Alzheimer's disease who have intermediate or elevated levels of amyloid in their brains. Currently, BAN2401 is being studied in a pivotal Phase 3 clinical study in symptomatic early Alzheimer's disease (Clarity AD), following the outcome of a Phase 2 clinical study (Study 201). AHEAD 3-45 will be conducted in the U.S., Japan, Canada, Australia, Singapore, and Europe.
- In July 2020 Biogen announced that positive results from a Phase 1/2 study of tofersen (BIIB067) for the potential treatment of superoxide dismutase 1 (*SOD1*) amyotrophic lateral sclerosis (ALS) were published in *The New England Journal of Medicine*. Final Phase 1/2 study results demonstrated proof-of-concept and proof-of-biology of tofersen, which is currently being investigated in the ongoing Phase 3 VALOR study. *SOD1* ALS is the second most common genetic form of ALS, accounting for approximately 2% of all ALS cases. Tofersen is Biogen's lead clinical program in its ALS portfolio, which also includes BIIB078 (IONIS-C9_{Rx}) for *C9orf72* ALS and BIIB100 (XPO1 inhibitor) for all forms of ALS.
- In July 2020 Biogen dosed the first patient in a Phase 1 study of BIIB101, an antisense oligonucleotide targeting alpha synuclein, in multiple system atrophy.
- In July 2020 Biogen entered into an exclusive licensing agreement with Massachusetts Eye and Ear, a member hospital of Mass General Brigham, to develop a potential treatment for inherited retinal degeneration due to mutations in the *PRPF31* gene, which are among the most common causes for autosomal dominant retinitis pigmentosa. Biogen will conduct pre-clinical studies needed to support progression to clinical trials of *PRPF31* gene therapy. As part of this agreement, Biogen will receive an exclusive license to develop the potential treatment worldwide and will be responsible for all FDA required investigational new drug enabling studies, clinical development, and commercialization.
- In June 2020 Samsung Bioepis Co., Ltd. (Samsung Bioepis) initiated a Phase 3 study for SB15, a biosimilar referencing EYLEA[®]. EYLEA is widely used to treat ophthalmologic conditions such as neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema (DME), and diabetic retinopathy in patients with DME. Biogen has the exclusive rights to commercialize SB15 in major markets worldwide, including the U.S., Canada, Europe, Japan, and Australia.
- In June 2020 Biogen submitted a Supplemental Biologics License Application (sBLA) for a subcutaneous (SC) formulation of TYSABRI (natalizumab) to the FDA. This follows a regulatory submission for SC TYSABRI to the European Medicines Agency in March 2020. The filings are supported by data from the DELIVER and REFINE studies, which demonstrated that natalizumab 300 mg SC every 4 weeks (Q4W) was comparable to standard 300 mg intravenous Q4W dosing with respect to clinical and MRI efficacy, pharmacokinetics / pharmacodynamics, immunogenicity, and safety.
- In June 2020 Biogen announced new results from NURTURE, the longest study of pre-symptomatic patients with SMA. In infants genetically diagnosed with SMA, new data demonstrated that early and sustained treatment with SPINRAZA for up to 4.8 years enabled unprecedented survival. Patients

continued to maintain and make progressive gains in motor function compared to the natural course of the disease. These results were presented at the virtual Cure SMA Research & Clinical Care Meeting.

- In June 2020 Biogen shared positive data from the 16-week cutaneous lupus erythematosus (CLE) portion of the Phase 2 LILAC study. The study evaluated the efficacy and safety of BIIB059, a fully humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) expressed on plasmacytoid dendritic cells (pDCs). The data were presented at the European E-Congress of Rheumatology (EULAR).
- In May 2020 Biogen entered into a process development and manufacturing agreement with Vir Biotechnology, Inc. (Vir). Under this agreement, Biogen will perform process development activities and specified manufacturing and process transfer services to enable commercial supply of Vir's SARS-CoV-2 monoclonal antibodies.
- In May 2020 Samsung Bioepis announced that the primary endpoints were met in the randomized, double-masked, Phase 3 trial comparing the efficacy, safety, and immunogenicity of SB11 to the reference product (LUCENTIS®). Biogen has the exclusive rights to commercialize SB11 in major markets worldwide, including the U.S., Canada, Europe, Japan, and Australia.
- In May 2020, through the 2020 American Academy of Neurology (AAN) Science Highlights virtual platform, Biogen announced new data from its MS treatment portfolio. Additional clinical data support VUMERITY as an important oral treatment option in relapsing MS and reinforce the efficacy of TECFIDERA. In addition, an analysis of TYSABRI contributed to data demonstrating the reduced risk of progressive multifocal leukoencephalopathy (PML) through extended interval dosing (EID; approximately every six weeks) as compared to the currently approved dosing of every four weeks.
- In May 2020, through the 2020 AAN Science Highlights virtual platform, Biogen announced additional data from the SPINRAZA clinical development program that further demonstrated the sustained efficacy and longer-term safety of SPINRAZA in a broad range of patients with SMA. The SHINE open-label extension study (NCT02594124) has enrolled 292 patients (infants through teenagers) from 5 previous SPINRAZA clinical studies, including ENDEAR. New findings from the SHINE study show that treatment with SPINRAZA resulted in motor function improvement or disease stabilization in toddlers, children, and young adults who were treated continuously, some for up to six and a half years.
- In April 2020 Biogen released its 2019 Corporate Responsibility Report that demonstrated continuous progress across several environmental, social, and governance (ESG) metrics. The report outlines the Company's long-term commitment to corporate responsibility by taking a multi-stakeholder approach to business decisions, creating an inclusive culture, reducing its environmental footprint, and increasing reporting transparency on ESG issues.

Leadership Update

- In July 2020 Biogen announced that Michael R. McDonnell has been appointed Executive Vice President (EVP) and Chief Financial Officer (CFO) effective August 15, 2020, replacing Jeffrey D. Capello, who will step down as EVP and CFO. Mr. Capello will remain at the Company through September 15, 2020, and will assist with the transition.

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, 2020, 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, immunology, neurocognitive disorders, acute neurology, and 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 our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, including the enrollment of our 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 products and investigational therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; 2020 financial guidance; and the direct and indirect impact of COVID-19 on our business and operations, including sales, expenses, supply chain, manufacturing, research and development costs, clinical trials, and employees. 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; failure to protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; 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; 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; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; risks relating to technology failures or breaches; 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 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; risks related to commercialization of biosimilars; fluctuations in our operating results; fluctuations in our effective tax rate; risks related to investment in properties; the market, interest, and credit risks associated with our portfolio of marketable securities; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; environmental risks; 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; change in control provisions in certain of our collaboration agreements; and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC).

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 Media Contact:	Biogen Investor Contact:
David Caouette	Joe Mara
Biogen Inc.	Biogen Inc.
Tel: (781) 464-3260	Tel: (781) 464-2442

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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,	
	2020	2019	2020	2019
Revenues:				
Product, net	\$ 2,795.7	\$ 2,880.3	\$ 5,700.3	\$ 5,560.3
Revenues from anti-CD20 therapeutic programs	478.3	576.4	998.7	1,093.8
Other	407.6	160.0	516.9	452.4
Total revenues	<u>3,681.6</u>	<u>3,616.7</u>	<u>7,215.9</u>	<u>9,926.6</u>
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	411.1	476.3	865.5	1,078.3
Research and development	647.6	484.8	1,123.9	1,048.5
Selling, general and administrative	555.1	587.6	1,125.2	1,155.3
Amortization and impairment of acquired intangible assets	61.5	70.1	133.0	138.3
Collaboration profit (loss) sharing	21.8	63.5	93.5	121.6
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	(2.3)	—	113.2
(Gain) loss on fair value remeasurement of contingent consideration	10.0	(20.0)	5.5	(8.5)
Restructuring charges	—	0.8	—	1.2
Acquired in-process research and development	—	—	75.0	—
Total cost and expenses	<u>1,707.1</u>	<u>1,660.8</u>	<u>3,421.6</u>	<u>5,481.1</u>
Income from operations	<u>1,974.5</u>	<u>1,955.9</u>	<u>3,794.3</u>	<u>4,445.5</u>
Other income (expense), net	<u>63.0</u>	<u>(197.4)</u>	<u>(57.5)</u>	<u>159.9</u>
Income before income tax expense and equity in loss of investee, net of tax	<u>2,037.5</u>	<u>1,758.5</u>	<u>3,736.8</u>	<u>4,485.1</u>
Income tax expense	446.1	248.1	738.2	670.6
Equity in loss of investee, net of tax	<u>(15.1)</u>	<u>16.3</u>	<u>(0.4)</u>	<u>45.0</u>
Net income	<u>1,606.5</u>	<u>1,494.1</u>	<u>2,999.0</u>	<u>3,529.1</u>
Net income (loss) attributable to noncontrolling interests, net of tax	64.4	—	57.8	—
Net income attributable to Biogen Inc.	<u>\$ 1,542.1</u>	<u>\$ 1,494.1</u>	<u>\$ 2,941.2</u>	<u>\$ 3,483.9</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	<u>\$ 9.60</u>	<u>\$ 7.85</u>	<u>\$ 17.65</u>	<u>\$ 15.01</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 9.59</u>	<u>\$ 7.85</u>	<u>\$ 17.61</u>	<u>\$ 14.99</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	<u>160.6</u>	<u>190.3</u>	<u>166.7</u>	<u>193.4</u>
Diluted earnings per share attributable to Biogen Inc.	<u>160.9</u>	<u>190.4</u>	<u>167.0</u>	<u>193.7</u>

TABLE 2

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

	As of June 30, 2020	As of December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	\$ 4,327.6	\$ 4,475.9
Accounts receivable, net	2,133.6	1,880.5
Inventory	952.7	804.2
Other current assets	1,079.9	1,221.2
Total current assets	8,493.8	8,381.8
Marketable securities	922.8	1,408.1
Property, plant and equipment, net	3,330.7	3,247.3
Operating lease assets	436.2	427.0
Intangible assets, net	3,383.8	3,527.4
Goodwill	5,751.0	5,757.8
Investments and other assets	3,193.5	4,484.9
TOTAL ASSETS	\$ 25,511.8	\$ 27,234.3
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ —	\$ 1,495.8
Other current liabilities	3,447.1	3,368.0
Total current liabilities	3,447.1	4,863.8
Notes payable	7,423.8	4,459.0
Long-term operating lease liabilities	414.8	412.7
Other long-term liabilities	2,936.9	4,159.7
Equity	11,289.2	13,339.1
TOTAL LIABILITIES AND EQUITY	\$ 25,511.8	\$ 27,234.3

TABLE 3

BIOPEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION:
NET INCOME ATTRIBUTABLE TO BIOPEN INC. AND DILUTED EARNINGS PER SHARE
(unaudited, in millions, except per share amounts)

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

	For the Three Months Ended		
	June 30, 2020	June 30, 2019	March 31, 2020
GAAP earnings per share - Diluted	\$ 9.59	\$ 7.85	\$ 8.08
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.67	1.30	1.06
Non-GAAP earnings per share - Diluted	<u>\$ 10.26</u>	<u>\$ 9.15</u>	<u>\$ 9.14</u>

	For the Six Months Ended June 30,	
	June 30, 2020	June 30, 2019
GAAP earnings per share - Diluted	\$ 17.61	\$ 14.99
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	1.75	1.10
Non-GAAP earnings per share - Diluted	<u>\$ 19.36</u>	<u>\$ 16.09</u>

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

	For the Three Months Ended		
	June 30, 2020	June 30, 2019	March 31, 2020
GAAP net income attributable to Biogen Inc.	\$ 1,542.1	\$ 1,494.1	\$ 1,399.1
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets A	61.5	70.1	71.5
Acquired in-process research and development	—	—	75.0
(Gain) loss on fair value remeasurement of contingent consideration	10.0	(20.0)	(4.6)
Loss on assets and liabilities held for sale B	—	(2.3)	—
Stock option expense C	—	26.2	—
Acquisition-related transaction and integration costs	0.6	19.4	1.2
Subtotal: Acquisition and divestiture related costs	72.1	93.4	143.1
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation D	—	0.7	—
Restructuring charges D	—	0.8	—
Subtotal: Restructuring, business transformation and other cost saving initiatives	—	1.5	—
(Gain) loss on equity security investments	(102.9)	174.2	60.9
Premium paid on the purchase of Sangamo common stock E	83.2		
Premium paid on early debt redemption	9.4		
Valuation allowance associated with deferred tax assets F	56.0		
Income tax effect related to reconciling items	(7.4)	(43.1)	(38.4)
Amortization included in equity in loss of investee, net of tax G	(1.5)	21.7	17.3
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 1,651.0</u>	<u>\$ 1,741.8</u>	<u>\$ 1,582.0</u>

TABLE 3 (Continued)

BIOGEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION:
NET INCOME ATTRIBUTABLE TO BIOGEN INC. AND DILUTED EARNINGS PER SHARE
(unaudited, in millions, except per share amounts)

	For the Six Months Ended June 30,	
	June 30, 2020	June 30, 2019
GAAP net income attributable to Biogen Inc.	\$ 2,941.2	\$ 2,902.9
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets ^A	133.0	138.3
Acquired in-process research and development	75.0	—
(Gain) loss on fair value remeasurement of contingent consideration	5.4	(8.5)
Loss on assets and liabilities held for sale ^B	—	113.2
Stock option expense ^C	—	26.2
Acquisition-related transaction and integration costs	1.6	23.7
Subtotal: Acquisition and divestiture related costs	215.0	292.9
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation ^D	—	1.7
Restructuring charges ^D	—	1.2
Subtotal: Restructuring, business transformation and other cost saving initiatives	—	2.9
(Gain) loss on equity security investments	(41.9)	(201.9)
Premium paid on the purchase of Sangamo common stock ^E	83.2	
Premium paid on early debt redemption	9.4	
Valuation allowance associated with deferred tax assets ^F	56.0	
Income tax effect related to reconciling items	(45.8)	83.0
Amortization included in equity in loss of investee, net of tax ^G	15.8	36.4
Non-GAAP net income attributable to Biogen Inc.	\$ 3,232.9	\$ 3,116.2

2020 Full Year Guidance: GAAP to Non-GAAP Reconciliation

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

	2020 Full Year Guidance		
	\$	Shares	Diluted EPS
GAAP net income attributable to Biogen Inc.	\$ 5,375.0	162.9	\$ 33.00
Adjustments:			
Amortization of acquired intangible assets	260.0		
Loss (gain) on fair value remeasurement of contingent consideration	8.0		
Acquired in-process research and development	35.0		
Amortization included in equity in loss of investee, net of tax ^G	36.0		
Other	(10.0)		
Valuation allowance associated with deferred tax assets ^F	56.0		
Income tax effect related to reconciling items	(59.0)		
Non-GAAP net income attributable to Biogen Inc.	\$ 5,701.0	162.9	\$ 35.00

Notes to GAAP to Non-GAAP Reconciliation

A Amortization and impairment of acquired intangible assets for the three and six months ended June 30, 2020, compared to the same periods in 2019, decreased primarily due to a lower rate of amortization for acquired intangible assets.

B In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation (FUJIFILM) to sell all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark. The transaction closed in August 2019.

For the six months ended June 30, 2019, we recorded a loss of approximately \$174.5 million in our condensed consolidated statements of income. This estimated loss included a pre-tax loss of \$113.2 million, which reflected a \$2.3 million decrease to our original estimate as of March 31, 2019, reflecting our estimated fair value of the assets and liabilities held for sale as of June 30, 2019, adjusted for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately \$10.0 million and included our initial estimate of the fair value of an adverse commitment of approximately \$120.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. In addition, we recorded a tax expense of \$61.3 million related to the planned transaction during the six months ended June 30, 2019.

In August 2019 this transaction closed and we received approximately \$881.9 million in cash, which may be adjusted based on contractual terms. We determined that the operations disposed of in this transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

In addition, we may earn certain contingent payments based on future manufacturing activities at the Hillerød facility. For the disposition of a business, our policy is to recognize contingent consideration when the consideration is realizable. Consistent with our assessment as of the transaction date, we currently believe the probability of earning these payments is remote and therefore we did not include these contingent payments in our calculation of the fair value of the operations.

C Stock option expense reflects the accelerated vesting of stock options previously granted to Nightstar Therapeutics plc (NST) employees as a result of our acquisition of NST in the second quarter of 2019.

D 2017 corporate strategy implementation and restructuring charges are related to our efforts to create a leaner and simpler operating model.

E In February 2020 we entered into a collaboration and license agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. In connection with the closing of this transaction in April 2020 we purchased \$225.0 million of Sangamo common stock, or approximately 24 million shares at \$9.21 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately \$83.0 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Sangamo common stock.

F Income tax expense for the three and six months ended June 30, 2020, included \$56.0 million in income tax expense related to a net valuation allowance against certain deferred tax assets, due to the decision of the U.S. District Court of the Northern District of West Virginia that the asserted claims of U.S. patent No. 8,399,514, which cover the treatment of MS with TECFIDERA, are invalid.

G Amortization included in equity in loss of investee, net of tax represents the amortization of the differences between the fair value of our investment in Samsung Bioepis Co., Ltd. and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life.

Use of Non-GAAP Financial Measures

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered “Non-GAAP” financial measures under applicable SEC rules. We believe that the disclosure of these Non-GAAP financial measures provides additional insight into the ongoing economics of our business and reflects how we manage our business internally, set operational goals and form the basis of our management incentive programs. These Non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be viewed in isolation or as a substitute for reported, or GAAP, net income attributable to Biogen Inc. and diluted earnings per share.

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. Acquisition and divestiture related costs

We exclude transaction, integration and certain other costs related to the acquisition and divestiture of businesses. We exclude certain purchase accounting related items associated with the acquisition of assets and amounts in relation to the 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.

TABLE 4

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

	For the Three Months Ended								
	June 30, 2020			June 30, 2019			March 31, 2020		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
Fumarate*	\$ 921.7	\$ 268.6	\$ 1,190.3	\$ 869.8	\$ 280.4	\$ 1,150.2	\$ 777.5	\$ 323.3	\$ 1,100.8
Interferon**	345.6	135.8	481.4	379.7	174.7	554.4	292.6	173.4	466.0
TYSABRI	244.1	187.9	432.0	264.3	211.0	475.3	277.7	244.7	522.4
FAMPYRA	—	23.0	23.0	—	24.1	24.1	—	28.3	28.3
Spinal Muscular Atrophy:									
SPINRAZA	210.3	284.3	494.6	230.6	257.6	488.2	235.4	329.6	565.0
Biosimilars:									
BENEPALI	—	106.2	106.2	—	120.3	120.3	—	133.5	133.5
IMRALDI	—	44.8	44.8	—	47.3	47.3	—	61.6	61.6
FLIXABI	—	20.6	20.6	—	16.8	16.8	—	23.7	23.7
Other Product Revenues:									
FUMADERM	—	2.8	2.8	—	3.7	3.7	—	3.3	3.3
Total product revenues	<u>\$ 1,721.7</u>	<u>\$ 1,074.0</u>	<u>\$ 2,795.7</u>	<u>\$ 1,744.4</u>	<u>\$ 1,135.9</u>	<u>\$ 2,880.3</u>	<u>\$ 1,583.2</u>	<u>\$ 1,321.4</u>	<u>\$ 2,904.6</u>

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.

**Interferon includes AVONEX and PLEGRIDY.

	For the Six Months Ended June 30,					
	June 30, 2020			June 30, 2019		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	\$ 1,699.2	\$ 591.9	\$ 2,291.1	\$ 1,587.5	\$ 561.5	\$ 2,149.0
Interferon**	638.2	309.2	947.4	707.0	348.3	1,055.3
TYSABRI	521.8	432.6	954.4	509.3	426.4	935.7
FAMPYRA	—	51.3	51.3	—	47.0	47.0
Spinal Muscular Atrophy:						
SPINRAZA	445.7	613.9	1,059.6	453.9	552.8	1,006.7
Biosimilars:						
BENEPALI	—	239.7	239.7	—	244.3	244.3
IMRALDI	—	106.4	106.4	—	83.0	83.0
FLIXABI	—	44.3	44.3	—	31.5	31.5
Other Product Revenues:						
FUMADERM	—	6.1	6.1	—	7.8	7.8
Total product revenues	<u>\$ 3,304.9</u>	<u>\$ 2,395.4</u>	<u>\$ 5,700.3</u>	<u>\$ 3,257.7</u>	<u>\$ 2,302.6</u>	<u>\$ 5,560.3</u>

*Fumarate includes TECFIDERA and VUMERITY. VUMERITY became commercially available in the U.S. in November 2019.

**Interferon includes AVONEX and PLEGRIDY.