

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 23, 2019

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-19311
(Commission File Number)

33-0112644
(IRS Employer Identification No.)

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 23, 2019, Biogen Inc. issued a press release announcing its results of operations and financial condition for the second quarter ended June 30, 2019. 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.

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Biogen's press release dated July 23, 2019.

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/James Basta

James Basta

Chief Corporation Counsel and Assistant Secretary

Date: July 23, 2019



BIOGEN Q2 2019 REVENUES INCREASED 8% TO \$3.6 BILLION

GAAP diluted EPS increased 88%; Non-GAAP diluted EPS increased 58%

Company raises full year 2019 financial guidance

New results from NURTURE study demonstrated compelling efficacy of SPINRAZA

Company completed acquisition of Nightstar Therapeutics

Cambridge, Mass., July 23, 2019 – Biogen Inc. (Nasdaq: BIIB) today reported second quarter 2019 financial results.

“Biogen delivered solid performance globally in the second quarter, and we believe we are on track for a strong year,” said Michel Vounatsos, Biogen’s Chief Executive Officer. “We added four new programs to our pipeline this quarter, as we continued to diversify and build depth within neuroscience and pursue therapeutic adjacencies. Specifically, the acquisition of Nightstar Therapeutics has provided us with two potentially first-in-class mid- to late-stage gene therapy programs in specialty ophthalmology, and we initiated two new studies in our priority areas of multiple sclerosis and amyotrophic lateral sclerosis. We continued to allocate capital, and we remain focused on investing in the areas we believe have the highest potential return for shareholders.”

Financial Results

- Second quarter total revenues were \$3.6 billion, an 8% increase versus the second quarter of 2018.
 - Multiple sclerosis (MS) revenues, including \$183 million in royalties on the sales of OCREVUS[®], increased 3% versus the prior year to \$2.4 billion.
 - Revenue growth was driven in part by the continued global launch of SPINRAZA[®], which contributed \$488 million in revenues in the second quarter of 2019 compared to \$423 million in the second quarter of 2018.
 - Revenue growth was also driven by biosimilars revenues, which increased to \$184 million compared to \$127 million in the second quarter of 2018, primarily driven by IMRALDI[™].
 - Second quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$1.5 billion and \$7.85, respectively, compared to \$867 million and \$4.18, respectively, in the second quarter of 2018.
 - In the second quarter of 2018 GAAP net income and diluted EPS were impacted by \$589 million and \$2.84, net of tax, respectively, related to the 10-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis), the acquisition of BIIB104 from Pfizer Inc. (Pfizer), the option payment to Neurimmune SubOne AG, and the option agreement with TMS Co., Ltd. (TMS).
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- Second quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$1.7 billion and \$9.15, respectively, compared to \$1.2 billion and \$5.80, respectively, in the second quarter of 2018.
 - In the second quarter of 2018 Non-GAAP net income and diluted EPS were impacted by \$314 million and \$1.52, net of tax, respectively, related to the 10-year exclusive agreement with Ionis and the option agreement with TMS.

(In millions, except per share amounts)	Q2 '19	Q2 '18	Q1 '19	Q2 '19 v. Q2 '18	Q2 '19 v. Q1 '19
Total revenues	\$ 3,617	\$ 3,357	\$ 3,490	8%	4%
GAAP net income#	\$ 1,494	\$ 867	\$ 1,409	72%	6%
GAAP diluted EPS	\$ 7.85	\$ 4.18	\$ 7.15	88%	10%
Non-GAAP net income#	\$ 1,742	\$ 1,202	\$ 1,374	45%	27%
Non-GAAP diluted EPS	\$ 9.15	\$ 5.80	\$ 6.98	58%	31%

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 '19	Q2 '18	Q1 '19	Q2 '19 v. Q2 '18	Q2 '19 v. Q1 '19
Multiple Sclerosis:					
TECFIDERA®	\$ 1,150	\$ 1,087	\$ 999	6%	15%
Total Interferon	\$ 554	\$ 626	\$ 501	(11%)	11%
AVONEX®	\$ 438	\$ 502	\$ 397	(13%)	10%
PLEGRIDY®	\$ 117	\$ 124	\$ 104	(6%)	12%
TYSABRI®	\$ 475	\$ 467	\$ 460	2%	3%
FAMPYRA™	\$ 24	\$ 23	\$ 23	5%	5%
Spinal Muscular Atrophy:					
SPINRAZA	\$ 488	\$ 423	\$ 518	15%	(6%)
Biosimilars:					
BENEPALI™	\$ 120	\$ 116	\$ 124	4%	(3%)
IMRALDI	\$ 47	\$ 0	\$ 36	NMF	32%
FLIXABI™	\$ 17	\$ 11	\$ 15	50%	14%
Other Product Revenues:					
FUMADERM™	\$ 4	\$ 6	\$ 4	(33%)	(10%)
Total Product Revenues:	\$ 2,880	\$ 2,758	\$ 2,680	4%	7%
OCREVUS Royalties	\$ 183	\$ 113	\$ 112	62%	64%
RITUXAN®/GAZYVA® Revenues	\$ 394	\$ 377	\$ 406	4%	(3%)
Other Revenues	\$ 160	\$ 109	\$ 292	47%	(45%)
Total Revenues	\$ 3,617	\$ 3,357	\$ 3,490	8%	4%
MS Product Revenues + OCREVUS Royalties	\$ 2,387	\$ 2,316	\$ 2,095	3%	14%

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

- In the second quarter of 2019 channel inventory levels in the U.S. decreased by approximately \$25 million for TECFIDERA, AVONEX, PLEGRIDY, and TYSABRI combined. This compares to a decrease in inventory levels of approximately \$175 million in the first quarter of 2019 and a decrease of approximately \$50 million in the second quarter of 2018.
- In the second quarter of 2019 SPINRAZA revenues comprised \$231 million in sales in the U.S. and \$258 million in sales outside the U.S. The number of commercial patients receiving SPINRAZA grew approximately 4% in the U.S. and approximately 17% outside the U.S. versus the first quarter of 2019. Versus the first quarter of 2019, SPINRAZA revenues outside the U.S. decreased 13%, due primarily to a positive pricing adjustment in France in the first quarter of 2019, the timing of shipments across several international markets, and a continued transition from loading to maintenance doses in more mature markets.

Expense Highlights

(In millions)	Q2 '19	Q2 '18	Q1 '19	Q2 '19 v. Q2 '18	Q2 '19 v. Q1 '19
GAAP cost of sales	\$ 476	\$ 421	\$ 602	(13%)	21%
Non-GAAP cost of sales	\$ 476	\$ 421	\$ 602	(13%)	21%
GAAP R&D	\$ 485	\$ 981	\$ 564	51%	14%
Non-GAAP R&D	\$ 477	\$ 819	\$ 564	42%	15%
GAAP SG&A	\$ 588	\$ 516	\$ 568	(14%)	(4%)
Non-GAAP SG&A	\$ 553	\$ 512	\$ 563	(8%)	2%

Note: Percent changes represented as favorable/(unfavorable)

- R&D expense in the first quarter of 2019 included \$39 million related to Biogen's agreement with Skyhawk Therapeutics, Inc.
- R&D expense in the first quarter of 2019 included approximately \$45 million in net closeout costs for the Phase 3 studies of aducanumab in Alzheimer's disease.
- R&D expense in the second quarter of 2018 included \$324 million related to the upfront payment to Ionis under the 10-year exclusive agreement. In addition, GAAP R&D expense in the second quarter of 2018 included a \$162 million charge related to the premium paid on Biogen's equity investment in Ionis.
- The increase in GAAP SG&A expense in the second quarter of 2019, as compared to the second quarter of 2018, was primarily due to acquisition related charges incurred in connection with our recent acquisition of Nightstar Therapeutics plc (NST), totaling approximately \$33 million, including \$18 million of stock-based compensation expense associated with the accelerated vesting of stock options previously granted to NST employees.

Other Financial Highlights

- For the second quarter of 2019 GAAP other expense was \$197 million, which included \$174 million in net losses on investments, principally driven by a decrease in the fair value of Biogen's equity investment in Ionis as well as a realized loss on the sale of a portion of Biogen's investment in Ionis common stock versus the prior quarter. Biogen realized a \$40 million cash gain when compared to the original cost basis on the shares the Company sold during the second quarter of 2019. Non-GAAP other expense for the second quarter of 2019 was \$19 million.
 - For the second quarter of 2019 the Company's effective GAAP and non-GAAP tax rates were approximately 14%. During the second quarter of 2019 Biogen's tax rates benefitted from a change to the Company's tax profile. This benefit is not expected to recur post 2019.
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- In the second quarter of 2019 Biogen repurchased approximately 10.4 million shares of the Company's common stock for a total value of approximately \$2.4 billion.
 - Biogen completed the remaining authorization under the share repurchase program authorized in August 2018.
 - As of June 30, 2019, there was approximately \$4.1 billion remaining under the share repurchase program authorized in March 2019.
- As of June 30, 2019, Biogen had cash, cash equivalents, and marketable securities totaling approximately \$4.3 billion, and approximately \$5.9 billion in notes payable.
- In the second quarter of 2019 the Company generated \$2.0 billion in net cash flows from operations.
- For the second quarter of 2019 the Company's weighted average diluted shares were 190 million.

2019 Financial Guidance

Biogen is raising its full year 2019 financial guidance. This financial guidance consists of the following components:

- Revenue is expected to be approximately \$14.0 billion to \$14.2 billion, an increase from the prior guidance range of approximately \$13.6 billion to \$13.8 billion.
- GAAP and Non-GAAP R&D expense is expected to be approximately 15.5% to 16.5% of total revenue, compared to the prior guidance range of approximately 16% to 17%.
- GAAP SG&A expense is expected to be approximately 16% to 17% of total revenue, unchanged versus the prior guidance range.
- Non-GAAP SG&A expense is expected to be approximately 15.5% to 16.5% of total revenue, compared to the prior guidance range of approximately 16% to 17%.
- GAAP tax rate is expected to be approximately 17% to 18%, compared to the prior guidance range of approximately 18.5% to 19.5%.
- Non-GAAP tax rate is expected to be approximately 15.5% to 16.5%, compared to the prior guidance range of approximately 18% to 19%.
- GAAP diluted EPS is expected to be between \$29.60 and \$30.40, an increase from the prior guidance range of \$26.65 and \$27.65.
- Non-GAAP diluted EPS is expected to be between \$31.50 and \$32.30, an increase from the prior guidance range of \$28.00 to \$29.00.

This financial guidance does not include any impact from potential acquisitions or large business development transactions, as both are hard to predict.

Biogen may incur charges, realize gains, or experience other events or circumstances in 2019 that could cause actual results to vary from this financial guidance.

Recent Events

- In June and July 2019 Biogen presented new results from the NURTURE study, adding data to the longest study of spinal muscular atrophy (SMA) in pre-symptomatic infants (n=25). The data reported, after up to 45.1 months of analysis, continued to demonstrate efficacy and safety in patients treated pre-symptomatically with SPINRAZA in comparison to the natural history of SMA. These new data also showed that patients treated with SPINRAZA had continuous improvement, with the overwhelming majority of patients achieving motor milestones in a normal timeframe. These data were presented at the Cure SMA Annual SMA Conference in Anaheim, Calif. (June 28-July 1, 2019) and the 5th Congress of the European Academy of Neurology in Oslo, Norway (June 29-July 2, 2019).
 - In June 2019 Roche announced positive topline results for NOBILITY, a Phase 2 study investigating the safety and efficacy of GAZYVA for adults with proliferative lupus nephritis. The study met its primary endpoint, showing GAZYVA, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo plus standard of care alone in achieving complete renal response at one year. In addition, GAZYVA met key secondary endpoints showing improved overall renal responses (complete and partial renal response) and serologic markers of disease activity as compared to placebo. In the U.S., GAZYVA is part of a collaboration between Biogen and Genentech, Inc., a wholly-owned member of the Roche Group.
 - In June 2019 Biogen presented new data at the European Congress of Rheumatology (EULAR) 2019 in Madrid, Spain (June 12-15, 2019). The data included real-world evidence from the Company's biosimilar anti-TNF portfolio, which includes BENEPALI (etanercept), FLIXABI (infliximab), and IMRALDI (adalimumab), confirming the safety and efficacy of these biosimilars and the high adherence of patients to treatment.
 - In June 2019, at the EULAR conference, Biogen's collaboration partner UCB presented interim results from the Phase 2b study of dapirolizumab pegol (DZP) in patients with active systemic lupus erythematosus (SLE) despite standard-of-care treatment. The primary endpoint of the study was to demonstrate a dose response at 24 weeks on the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) (p=0.06). The study demonstrated consistent and potentially meaningful improvements for the majority of clinical endpoints in patients treated with DZP compared with placebo. In addition, biomarker data demonstrated evidence of proof of biology. DZP was well tolerated and demonstrated an acceptable safety profile.
 - In June 2019 Biogen completed its acquisition of NST, a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. As a result of the acquisition, Biogen added two mid- to late-stage clinical assets, as well as preclinical programs, in ophthalmology. The total transaction value was approximately \$800 million, after taking into account transaction expenses and cash acquired at closing.
 - In May 2019 Biogen presented new interim data from the ongoing open-label, pivotal EVOLVE-MS-1 study of BIIB098 (diroximel fumarate) in relapsing MS (RMS) at the annual meeting of the Consortium of Multiple Sclerosis Centers in Seattle, Wash. (May 28-June 1, 2019). These data indicated that diroximel fumarate was generally well tolerated and significantly reduced disease activity in newly diagnosed RMS patients and those previously treated with interferons or glatiramer acetate. Treatment discontinuations due to gastrointestinal events occurred at a low rate over one year. Diroximel fumarate is a novel oral fumarate candidate in development with Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc.
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- In May 2019 Biogen's collaboration partner Eisai, Co., Ltd. dosed the first patient in the global Phase 3 study (Clarity AD) of BAN2401 in early Alzheimer's disease.
- In May 2019 The National Institute for Health and Care Excellence (NICE) in the United Kingdom recommended funding for SPINRAZA on the National Health Service. The positive recommendation is for the treatment of infants, children, and adults with 5q SMA, including pre-symptomatic and symptomatic SMA Types 1, 2, and 3.
- In May 2019 Biogen presented new data for its MS portfolio at the 71st annual meeting of the American Academy of Neurology (AAN) in Philadelphia, Pa. (May 4-11, 2019). The presentations included data on the safety and efficacy of diroximel fumarate from the EVOLVE-MS-1 study, updated safety analyses evaluating extended interval dosing of approximately every six weeks for natalizumab compared to the approved every four-week dosing, and data demonstrating that treatment with TECFIDERA significantly slowed the rate of whole brain volume loss compared to placebo.
- In May 2019 Biogen presented new data at the 71st annual meeting of the AAN affirming the safety and durability of SPINRAZA, including data from the SHINE extension study, with patients followed for up to four years, and the NURTURE study of pre-symptomatic infants.
- In May 2019, at the 71st annual meeting of the AAN and The European Network for the Cure of ALS meeting in Tours, France (May 15-17, 2019), Biogen presented interim results of the Phase 1/2 study of BIIB067 (tofersen), an antisense oligonucleotide being studied for the potential treatment of amyotrophic lateral sclerosis (ALS) in adults with a confirmed superoxide dismutase 1 (SOD1) mutation. The data demonstrated a statistically significant reduction in SOD1 protein levels and a numerical trend towards slowing of clinical decline in SOD1-ALS patients treated with tofersen compared to placebo.
- In April 2019 Biogen published data from CS2/CS12, an open-label study of the safety and tolerability of SPINRAZA in individuals with later-onset SMA, in the peer-reviewed journal *Neurology*, the medical journal of the AAN. The data showed that individuals with later-onset SMA, treated with SPINRAZA, regained motor function that had been previously lost and that treatment stabilized their disease activity leading to improvements in activities of daily living.

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 23, 2019, 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, and today 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, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, 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, and data readouts and presentations; regulatory filings 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; 2019 financial guidance; and the anticipated timing of the proposed transaction with FUJIFILM Corporation. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “possible,” “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; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for 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; 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; risks relating to technology failures or breaches; 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; 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; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to management and key personnel changes, including attracting and retaining key personnel; 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; risks that our proposed transaction with FUJIFILM Corporation will not be completed in a timely manner or at all; the possibility that certain closing conditions to our proposed transaction with FUJIFILM Corporation will not be satisfied; uncertainty as to whether the anticipated benefits of our proposed transaction with FUJIFILM Corporation can be achieved; 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.

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.

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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,	
	2019	2018	2019	2018
Revenues:				
Product, net	\$ 2,880.3	\$ 2,757.5	\$ 5,560.3	\$ 5,281.0
Revenues from anti-CD20 therapeutic programs	576.4	490.4	1,093.8	933.6
Other	160.0	108.6	452.4	273.0
Total revenues	<u>3,616.7</u>	<u>3,356.5</u>	<u>7,106.5</u>	<u>6,487.6</u>
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	476.3	421.0	1,078.3	867.0
Research and development	484.8	981.0	1,048.5	1,477.7
Selling, general and administrative	587.6	516.2	1,155.3	1,017.5
Amortization and impairment of acquired intangible assets	70.1	107.4	138.3	211.3
Collaboration profit (loss) sharing	63.5	39.2	121.6	81.7
Loss on assets and liabilities held for sale	(2.3)	—	113.2	—
(Gain) loss on fair value remeasurement of contingent consideration	(20.0)	1.9	(8.5)	(3.7)
Restructuring charges	0.8	1.6	1.2	3.2
Acquired in-process research and development	—	75.0	—	85.0
Total cost and expenses	<u>1,660.8</u>	<u>2,143.3</u>	<u>3,647.9</u>	<u>3,739.7</u>
Income from operations	1,955.9	1,213.2	3,458.6	2,747.9
Other income (expense), net	(197.4)	(34.5)	159.9	(75.5)
Income before income tax expense and equity in loss of investee, net of tax	1,758.5	1,178.7	3,618.5	2,672.4
Income tax expense	248.1	263.7	670.6	586.2
Equity in loss of investee, net of tax	16.3	—	45.0	—
Net income	<u>1,494.1</u>	<u>915.0</u>	<u>2,902.9</u>	<u>2,086.2</u>
Net income (loss) attributable to noncontrolling interests, net of tax	—	48.4	—	46.7
Net income attributable to Biogen Inc.	<u>\$ 1,494.1</u>	<u>\$ 866.6</u>	<u>\$ 2,902.9</u>	<u>\$ 2,039.5</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	<u>\$ 7.85</u>	<u>\$ 4.18</u>	<u>\$ 15.01</u>	<u>\$ 9.75</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 7.85</u>	<u>\$ 4.18</u>	<u>\$ 14.99</u>	<u>\$ 9.73</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	<u>190.3</u>	<u>207.1</u>	<u>193.4</u>	<u>209.2</u>
Diluted earnings per share attributable to Biogen Inc.	<u>190.4</u>	<u>207.3</u>	<u>193.7</u>	<u>209.5</u>

TABLE 2

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

	As of June 30, 2019	As of December 31, 2018
ASSETS		
Cash, cash equivalents and marketable securities	\$ 2,952.2	\$ 3,538.0
Accounts receivable, net	1,959.6	1,958.5
Inventory	776.7	929.9
Assets held for sale	683.4	—
Other current assets	1,537.9	1,214.5
Total current assets	7,909.8	7,640.9
Marketable securities	1,309.3	1,375.9
Property, plant and equipment, net	3,077.5	3,601.2
Operating lease assets	434.4	—
Intangible assets, net	3,681.3	3,120.0
Goodwill	5,749.2	5,706.4
Investments and other assets	4,126.1	3,844.5
TOTAL ASSETS	\$ 26,287.6	\$ 25,288.9
LIABILITIES AND EQUITY		
Liabilities held for sale	\$ 88.6	\$ —
Other current liabilities	3,122.3	3,295.2
Total current liabilities	3,210.9	3,295.2
Notes payable	5,948.5	5,936.5
Long-term operating lease liabilities	423.0	—
Other long-term liabilities	3,756.4	3,025.6
Equity	12,948.8	13,031.6
TOTAL LIABILITIES AND EQUITY	\$ 26,287.6	\$ 25,288.9

TABLE 3

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)

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, 2019	June 30, 2018	March 31, 2019
GAAP earnings per share - Diluted	\$ 7.85	\$ 4.18	\$ 7.15
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	1.30	1.62	(0.17)
Non-GAAP earnings per share - Diluted	<u>\$ 9.15</u>	<u>\$ 5.80</u>	<u>\$ 6.98</u>

	For the Six Months Ended	
	June 30, 2019	June 30, 2018
GAAP earnings per share - Diluted	\$ 14.99	\$ 9.73
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	1.10	2.12
Non-GAAP earnings per share - Diluted	<u>\$ 16.09</u>	<u>\$ 11.85</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, 2019	June 30, 2018	March 31, 2019
GAAP net income attributable to Biogen Inc.	\$ 1,494.1	\$ 866.6	\$ 1,408.8
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets A	70.1	107.4	68.2
Acquired in-process research and development	—	75.0	—
(Gain) loss on fair value remeasurement of contingent consideration	(20.0)	1.9	11.5
Loss on assets and liabilities held for sale B	(2.3)	—	115.5
Net distribution to noncontrolling interests C	—	48.5	—
Stock option expense D	26.2	—	—
Acquisition-related transaction and integration costs	19.4	—	4.3
Subtotal: Acquisition and divestiture related costs	<u>93.4</u>	<u>232.8</u>	<u>199.5</u>
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation E	0.7	4.0	1.0
Restructuring charges E	0.8	1.6	0.4
Subtotal: Restructuring, business transformation and other cost saving initiatives	<u>1.5</u>	<u>5.6</u>	<u>1.4</u>
Premium paid on purchase of Ionis common stock F	—	162.1	—
(Gain) loss on equity security investments	174.2	(5.4)	(376.1)
Income tax effect related to reconciling items	(43.1)	(60.2)	126.1
Amortization included in Equity in loss of investee, net of tax G	21.7	—	14.7
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 1,741.8</u>	<u>\$ 1,201.5</u>	<u>\$ 1,374.4</u>

	For the Six Months Ended	
	June 30, 2019	June 30, 2018
GAAP net income attributable to Biogen Inc.	\$ 2,902.9	\$ 2,039.5
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets A	138.3	211.3
Acquired in-process research and development	—	85.0
(Gain) loss on fair value remeasurement of contingent consideration	(8.5)	(3.7)
Loss on assets and liabilities held for sale B	113.2	—
Net distribution to noncontrolling interests C	—	46.8
Stock option expense D	26.2	—
Acquisition-related transaction and integration costs	23.7	—
Subtotal: Acquisition and divestiture related costs	292.9	339.4
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation E	1.7	7.8
Restructuring charges E	1.2	3.2
Subtotal: Restructuring, business transformation and other cost saving initiatives	2.9	11.0
Premium paid on purchase of Ionis common stock F	—	162.1
(Gain) loss on equity security investments	(201.9)	1.0
Income tax effect related to reconciling items	83.0	(69.8)
Amortization included in Equity in loss of investee, net of tax G	36.4	—
Non-GAAP net income attributable to Biogen Inc.	\$ 3,116.2	\$ 2,483.2

2019 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:

	\$	Shares	Diluted EPS
GAAP net income attributable to Biogen Inc.	\$ 5,670	189	\$ 30.00
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets A	260		
(Gain) loss on fair value remeasurement of contingent consideration	(5)		
Loss on assets and liabilities held for sale B	113		
Stock option expense D	26		
Acquisition-related transaction and integration costs	20		
Subtotal: Acquisition and divestiture related costs	414		
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation E	5		
Restructuring charges E	5		
Subtotal: Restructuring, business transformation and other cost saving initiatives	10		
(Gain) loss on equity security investments	(220)		
Income tax effect related to reconciling items	75		
Amortization included in Equity in loss of investee, net of tax G	80		
Non-GAAP net income attributable to Biogen Inc.	\$ 6,029	189	\$ 31.90

Notes to GAAP to Non-GAAP Reconciliation

A For the three and six months ended June 30, 2019, compared to same periods in 2018, the decrease in amortization and impairment of acquired intangible assets was primarily due to a net overall decrease in our expected rate of amortization for acquired intangible assets. This decrease was primarily due to lower amortization subsequent to the impairment in the fourth quarter of 2018 of the U.S. license to Forward Pharma A/S' (Forward Pharma) intellectual property, including Forward Pharma's intellectual property related to TECFIDERA, and higher expected lifetime revenues of TYSABRI.

B In March 2019 we entered into a share purchase agreement with FUJIFILM Corporation (FUJIFILM) under which FUJIFILM will acquire all of the outstanding shares of our subsidiary that owns our biologics manufacturing operations in Hillerød, Denmark. Upon closing of the proposed transaction, we expect to receive up to \$890.0 million in cash, subject to certain working capital adjustments and other contractual terms.

As part of the proposed transaction, we have provided FUJIFILM with certain minimum batch production commitment guarantees. There is a risk that the minimum contractual batch production commitments will not be met. Based upon current estimates we expect to incur an adverse commitment obligation of approximately \$120.0 million associated with such guarantees. We may adjust this estimate based upon changes in business conditions, which may result in the recognition of additional losses. We are also obligated to indemnify FUJIFILM for liabilities that may exist relating to certain business activities incurred prior to the closing of the proposed transaction.

In February 2019 the assets and liabilities related to our Hillerød, Denmark manufacturing operations met the criteria to be classified as held for sale and were reclassified as assets held for sale and liabilities held for sale, respectively, in our condensed consolidated balance sheets.

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 includes a pre-tax loss of \$113.2 million, which reflects a \$2.3 million decrease to our original estimate as of March 31, 2019, reflecting our current estimated fair value of the assets and liabilities held for sale, adjusting for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately \$10.0 million and our 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 proposed transaction. Our total estimated loss is based on current exchange rates and business conditions, and any changes to these factors through the closing date of the transaction will result in adjustments to the carrying values of the related assets and liabilities as well as a corresponding adjustment to the loss amount recognized on the sale.

Following the closing of the proposed transaction, the final purchase price will be adjusted by an amount equal to the difference between our current estimates of working capital and inventory balances that will be transferred to FUJIFILM and the amounts that are ultimately transferred.

The proposed transaction remains subject to customary closing conditions. We expect to complete the proposed transaction in the third quarter of 2019.

C Net distribution to noncontrolling interests reflects the \$50.0 million payment to Neurimmune SubOne AG (Neurimmune), net of Neurimmune's tax, to further reduce the previously negotiated royalty rates payable on products developed under our amended collaboration and license agreement with Neurimmune, by an additional 5%.

D 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.

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

F In June 2018 we closed the 2018 Ionis Agreement, which is a 10-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases for a total payment of \$1.0 billion, consisting of an upfront payment of \$375.0 million and the purchase of approximately 11.5 million shares of Ionis common stock at a cost of \$625.0 million.

The 11.5 million shares of Ionis common stock were purchased at a premium to their fair value at the transaction closing date. The premium consisted of acquiring the shares at a price above the fair value based on the trailing 10-day weighted-average close price prior to entering into the 2018 Ionis Agreement in April 2018 and the effect of certain holding period restrictions. We recorded an asset of \$462.9 million in investments and other assets in our condensed consolidated balance sheets reflecting the fair value of the common stock as of the purchase date and a charge of \$162.1 million to research and development expense in our condensed consolidated statements of income in the second quarter of 2018 reflecting the premium paid for the common stock.

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 R&D 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, 2019			June 30, 2018			March 31, 2019		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	\$ 869.8	\$ 280.4	\$ 1,150.2	\$ 825.8	\$ 261.0	\$ 1,086.8	\$ 717.7	\$ 281.1	\$ 998.8
Interferon*	379.7	174.7	554.4	444.7	180.8	625.5	327.3	173.6	500.9
TYSABRI	264.3	211.0	475.3	265.5	201.7	467.2	245.0	215.4	460.4
FAMPYRA	—	24.1	24.1	—	23.0	23.0	—	22.9	22.9
Spinal Muscular Atrophy:									
SPINRAZA	230.6	257.6	488.2	205.9	216.8	422.7	223.3	295.2	518.5
Biosimilars:									
BENEPALI	—	120.3	120.3	—	115.6	115.6	—	124.0	124.0
IMRALDI	—	47.3	47.3	—	—	—	—	35.7	35.7
FLIXABI	—	16.8	16.8	—	11.2	11.2	—	14.7	14.7
Other Product Revenues:									
FUMADERM	—	3.7	3.7	—	5.5	5.5	—	4.1	4.1
Total product revenues	<u>\$ 1,744.4</u>	<u>\$ 1,135.9</u>	<u>\$ 2,880.3</u>	<u>\$ 1,741.9</u>	<u>\$ 1,015.6</u>	<u>\$ 2,757.5</u>	<u>\$ 1,513.3</u>	<u>\$ 1,166.7</u>	<u>\$ 2,680.0</u>

	For the Six Months Ended					
	June 30, 2019			June 30, 2018		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 1,587.5	\$ 561.5	\$ 2,149.0	\$ 1,554.7	\$ 519.0	\$ 2,073.7
Interferon*	707.0	348.3	1,055.3	816.0	359.8	1,175.8
TYSABRI	509.3	426.4	935.7	515.2	414.1	929.3
FAMPYRA	—	47.0	47.0	—	47.4	47.4
ZINBRYTA	—	—	—	—	1.4	1.4
Spinal Muscular Atrophy:						
SPINRAZA	453.9	552.8	1,006.7	393.9	392.7	786.6
Biosimilars:						
BENEPALI	—	244.3	244.3	—	236.5	236.5
IMRALDI	—	83.0	83.0	—	—	—
FLIXABI	—	31.5	31.5	—	17.8	17.8
Other Product Revenues:						
FUMADERM	—	7.8	7.8	—	12.5	12.5
Total product revenues	<u>\$ 3,257.7</u>	<u>\$ 2,302.6</u>	<u>\$ 5,560.3</u>	<u>\$ 3,279.8</u>	<u>\$ 2,001.2</u>	<u>\$ 5,281.0</u>

* Interferon includes AVONEX and PLEGRIDY