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): **April 24, 2019**

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-19311**	**33-0112644**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

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

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

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

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

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

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 April 24, 2019, Biogen Inc. issued a press release announcing its results of operations and financial condition for the first quarter ended March 31, 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.

Exhibit Number	Description
99.1	Biogen's press release dated April 24, 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: April 24, 2019

BIOGEN Q1 2019 REVENUES INCREASED 11% TO $3.5 BILLION

GAAP diluted EPS increased 29%; Non-GAAP diluted EPS increased 15%

First patient dosed in Phase 3 study of BIIB067 for SOD1 amyotrophic lateral sclerosis

New Drug Application for BIIB098 (diroximel fumarate) accepted for review by FDA

Company announced agreement to acquire Nightstar Therapeutics

Cambridge, Mass., April 24, 2019 -- Biogen Inc. (Nasdaq: BIIB) today reported first quarter 2019 financial results.

"Biogen delivered strong financial results in the first quarter driven by the solid operational performance of our MS, SMA, and biosimilars franchises," said Michel Vounatsos, Biogen's chief executive officer. "However, we are deeply disappointed with the discontinuation of aducanumab for Alzheimer's disease. We followed the science, and unfortunately the outcome was not as we had hoped. We continue to believe we can create value for patients and investors by capitalizing on opportunities in neuroscience, and we remain focused on allocating capital to the areas we believe have the highest potential return for shareholders."

Financial Results

- First quarter total revenues were $3.5 billion, an 11% increase versus the first quarter of 2018.
  - Multiple sclerosis (MS) revenues, including $112 million in royalties on the sales of OCREVUS®, were relatively stable in the first quarter versus the prior year at $2.1 billion.
  - Revenue growth was driven in part by the continued global launch of SPINRAZA®, which contributed $518 million in revenues in the first quarter compared to $364 million in the first quarter of 2018.
  - Biosimilars revenues increased to $175 million compared to $128 million in the first quarter of 2018, driven by the launch of IMRALDI™.
  - Other revenues in the first quarter increased to $292 million compared to $164 million in the first quarter of 2018, primarily due to the sale of most of the remaining hemophilia inventory on hand to Bioverativ Inc.
- First quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were $1.4 billion and $7.15, respectively, compared to $1.2 billion and $5.54, respectively, in the first quarter of 2018.
- First quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were $1.4 billion and $6.98, respectively, compared to $1.3 billion and $6.05, respectively in the first quarter of 2018.

(In millions, except per share amounts)	Q1 '19	Q1 '18	Q4 '18	Q1 '19 v. Q1 '18	Q1 '19 v. Q4 '18
Total revenues	$ 3,490	$ 3,131	$ 3,526	11%	(1%)
GAAP net income#	$ 1,409	$ 1,173	$ 947	20%	49%
GAAP diluted EPS	$ 7.15	$ 5.54	$ 4.73	29%	51%
Non-GAAP net income#	$ 1,374	$ 1,282	$ 1,400	7%	(2%)
Non-GAAP diluted EPS	$ 6.98	$ 6.05	$ 6.99	15%	(0%)

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.

Mr. Vounatsos added, “We continued to make meaningful progress diversifying our pipeline. We are building depth in neuromuscular diseases and movement disorders, and our proposed acquisition of Nightstar Therapeutics would provide us with two potentially first-in-class mid- to late-stage clinical assets in specialty ophthalmology. By the end of 2020 we expect readouts across our clinical programs in MS, progressive supranuclear palsy, ALS, Parkinson’s disease, pain, cognitive impairment associated with schizophrenia, epilepsy, stroke, and lupus.”

Revenue Highlights

(In millions)	Q1 '19	Q1 '18	Q4 '18	Q1 '19 v. Q1 '18	Q1 '19 v. Q4 '18
Multiple Sclerosis:					
TECFIDERA®	$ 999	$ 987	$ 1,110	1%	(10%)
Total Interferon	$ 501	$ 550	$ 597	(9%)	(16%)
AVONEX®	*$ 397*	*$ 451*	*$ 481*	*(12%)*	*(17%)*
PLEGRIDY®	*$ 104*	*$ 100*	*$ 116*	*4%*	*(11%)*
TYSABRI®	$ 460	$ 462	$ 464	(0%)	(1%)
FAMPYRA™	$ 23	$ 24	$ 23	(6%)	1%
ZINBRYTA®	$ —	$ 1	$ 0	(100%)	NMF
Spinal Muscular Atrophy:					
SPINRAZA	$ 518	$ 364	$ 470	42%	10%
Biosimilars:					
BENEPALI™	$ 124	$ 121	$ 125	3%	(1%)
IMRALDI	$ 36	$ —	$ 17	NMF	114%
FLIXABI™	$ 15	$ 7	$ 14	123%	4%
Other Product Revenues:					
FUMADERM™	$ 4	$ 7	$ 5	(41%)	(18%)
Total Product Revenues:	**$ 2,680**	**$ 2,523**	**$ 2,826**	**6%**	**(5%)**
OCREVUS Royalties	$ 112	$ 77	$ 152	46%	(26%)
RITUXAN®/GAZYVA® Revenues	$ 405	$ 366	$ 383	11%	6%
Other Revenues	$ 292	$ 164	$ 166	78%	76%
Total Revenues	**$ 3,490**	**$ 3,131**	**$ 3,526**	**11%**	**(1%)**
MS Product Revenues + OCREVUS Royalties	**$ 2,095**	**$ 2,101**	**$ 2,346**	**(0%)**	**(11%)**

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

- In the first quarter of 2019 channel inventory levels in the U.S. decreased by approximately $170 million for TECFIDERA, AVONEX, PLEGRIDY, and TYSABRI combined. This compares to an increase in inventory levels of approximately $105 million in the fourth quarter of 2018 and a decrease of approximately $140 million in the first quarter of 2018.
- In the first quarter of 2019 SPINRAZA revenues comprised $223 million in sales in the U.S. and $295 million in sales outside the U.S. The number of commercial patients receiving SPINRAZA grew approximately 5% in the U.S. and approximately 24% outside the U.S. versus the fourth quarter of 2018. In the first quarter of 2019 Biogen recorded SPINRAZA revenues in over 40 countries.

Expense Highlights

(In millions)	Q1 '19	Q1 '18	Q4 '18	Q1 '19 v. Q1 '18	Q1 '19 v. Q4 '18
GAAP cost of sales	$ 602	$ 446	$ 489	(35%)	(23%)
Non-GAAP cost of sales	$ 602	$ 446	$ 489	(35%)	(23%)
GAAP R&D	$ 564	$ 497	$ 612	(13%)	8%
Non-GAAP R&D	$ 564	$ 497	$ 602	(13%)	6%
GAAP SG&A	$ 568	$ 501	$ 591	(13%)	4%
Non-GAAP SG&A	$ 563	$ 497	$ 591	(13%)	5%

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.
- For the remainder of 2019 Biogen expects a reduction in operating expenses of approximately $125 million related to the discontinuation of aducanumab, with a net savings of approximately $80 million for the full year 2019.

Other Financial Highlights

- In the first quarter of 2019 Biogen booked a pre-tax GAAP loss of $116 million related to its share purchase agreement with FUJIFILM Corporation (FUJIFILM) under which FUJIFILM will acquire all of the outstanding shares of Biogen's subsidiary that owns its biologics manufacturing operations in Hillerød, Denmark.
- For the first quarter of 2019 pre-tax GAAP other income was $357 million, including $376 million in net gains on investments, principally driven by an increase in the fair value of our equity investment in Ionis Pharmaceuticals, Inc. Non-GAAP other expense was $19 million.
- For the first quarter of 2019 the Company's effective GAAP tax rate was 23%, and the Company's effective non-GAAP tax rate was 18%.
- In the first quarter of 2019 Biogen repurchased approximately 2.4 million shares of the Company's common stock for a total value of approximately $656 million. From April 1, 2019 through April 24, 2019, Biogen repurchased an additional approximately 2.1 million shares of the Company's common stock at a cost of approximately $492 million.
    - In the first quarter of 2019 Biogen's Board of Directors authorized a program to repurchase up to $5.0 billion of the Company's common stock. This is in addition to the approximately $1.0 billion remaining as of April 24, 2019, under the share repurchase program authorized in August 2018.
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- As of March 31, 2019, Biogen had cash, cash equivalents, and marketable securities totaling approximately $5.3 billion, and approximately $5.9 billion in notes payable.

- In the first quarter of 2019 the Company generated $1.5 billion in net cash flows from operations.
- For the first quarter of 2019 the Company's weighted average diluted shares were 197 million.

Recent Events

- In April 2019 Biogen presented data on the rapidly progressive nature of spinal muscular atrophy (SMA) and the benefits of treatment with SPINRAZA at the Muscular Dystrophy Association (MDA) Clinical and Scientific Conference in Orlando, Florida (April 13-17, 2019). Presentations included data on the severity of disease progression in adults, adolescents, and older children, as well as data from the NURTURE study highlighting the benefits of pre-symptomatic treatment and findings on the role of neurofilament as a potential biomarker for predicting motor function in SMA.
- In March 2019 the first patient was dosed in the Phase 3 VALOR study of BIIB067 (tofersen), an antisense oligonucleotide for amyotrophic lateral sclerosis (ALS) with superoxide dismutase 1 (SOD1) mutations. VALOR is a continuation of the Phase 1/2 single- and multiple-ascending dose study and is designed to assess the efficacy and safety of BIIB067 versus placebo. The primary endpoint of this study is an analysis based on the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) Score. Biogen is collaborating with regulators to further define the scope of the clinical data package required to support the registration of BIIB067.
- In March 2019 Biogen and Eisai Co., Ltd. announced the decision to discontinue the global Phase 3 studies, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease dementia. The decision to stop the studies was based on results of a futility analysis conducted by an independent data monitoring committee, which indicated the studies were unlikely to meet their primary endpoint upon completion. The recommendation to stop the studies was not based on safety concerns. Biogen has also decided not to initiate a Phase 3 secondary prevention study to evaluate whether early use of aducanumab can prevent or delay the clinical onset of Alzheimer's disease at this time.
- In March 2019 Biogen announced that it has entered into a share purchase agreement with FUJIFILM under which FUJIFILM will acquire all of the outstanding shares of Biogen's subsidiary that owns its biologics manufacturing operations in Hillerød, Denmark, for up to $890 million in cash, subject to working capital adjustments and other contractual terms. Following the completion of the proposed transaction, FUJIFILM would use the Hillerød facility to produce commercial products for Biogen, such as TYSABRI, as well as other third-party products. The proposed transaction remains subject to customary closing conditions, including filings and clearances under the Danish Competition Act. The closing of the proposed transaction is expected to occur in the second half of 2019, after which Biogen will operate manufacturing facilities in Research Triangle Park, North Carolina and Solothurn, Switzerland, which Biogen expects to be operational by the end of 2020.
- In March 2019 Biogen announced that it had entered into an agreement to acquire Nightstar Therapeutics plc (NST), a clinical-stage gene therapy company focused on adeno-associated virus treatments for inherited retinal disorders. Under the terms of the proposed acquisition, Biogen would pay NST shareholders $25.50 in cash for each issued and outstanding NST share. This offer represents a total transaction value of approximately $800 million on a fully diluted basis, after taking into account expected transaction expenses and anticipated cash acquired at closing. NST has two potentially first-in-class mid- to late-stage clinical assets as well as preclinical programs. NST's lead asset NSR-REP1 is in Phase 3 development for choroideremia, a rare degenerative disorder that leads

to blindness and has no approved treatment options. The proposed acquisition of NST is planned to be funded through available cash and accounted for as an acquisition of a business. The closing of the proposed acquisition remains subject to customary closing conditions, including the approval by NST shareholders and the issuance of an order by the U.K. Court. Biogen expects to complete the acquisition by mid-year 2019.

- In February 2019 Biogen announced that SPINRAZA was approved by the China National Medical Products Association for the treatment of 5q SMA, expanding the Company's presence in China. Approximately 95% of all SMA cases are 5q SMA, making it the most common form of the disease. SPINRAZA is the first approved treatment in China for SMA. SPINRAZA will initially be available in China for self-paying patients as the Company works to secure provincial and national reimbursement.

- In February 2019 Alkermes plc and Biogen announced that the U.S. Food and Drug Administration (FDA) had accepted for review the New Drug Application (NDA) for diroximel fumarate (BIIB098), a novel oral fumarate in development for the treatment of relapsing forms of MS. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY, which has been conditionally accepted by the FDA and will be confirmed upon approval. The NDA has been assigned a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019.

Conference Call and Webcast
The Company's earnings conference call for the first quarter will be broadcast via the internet at 8:00 a.m. ET on April 24, 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 and only approved treatment for spinal muscular atrophy, and is focused on advancing neuroscience research programs in MS and neuroimmunology, Alzheimer's disease and dementia, movement disorders, neuromuscular disorders, acute neurology, neurocognitive disorders, pain, and ophthalmology. Biogen also commercializes biosimilars of advanced biologics.

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; the anticipated completion and operational status of Biogen's large-scale biologics manufacturing facility in Solothurn, Switzerland; the potential benefits that may be achieved through our proposed acquisition of NST; the anticipated timing of our proposed acquisition of NST; and the anticipated timing of the proposed transaction with FUJIFILM.

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 growth and strategic 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 and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our 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 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 sale and distribution 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 relating to the spin-off of our hemophilia business, including exposure to claims and liabilities; risks that our proposed acquisition of NST will not be completed in a timely manner or at all; the possibility that certain closing conditions to our proposed acquisition of NST will not be satisfied; uncertainty as to whether the anticipated benefits of our proposed acquisition of NST can be achieved; risks that our proposed transaction with FUJIFILM will not be completed in a timely manner or at all; the possibility that certain closing conditions to our proposed transaction with FUJIFILM will not be satisfied; uncertainty as to whether the anticipated benefits of our proposed transaction with FUJIFILM 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 Securities and Exchange Commission.

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

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TABLE 1

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

	For the Three Months Ended March 31,	
	2019	2018
Revenues:		
Product, net	$ 2,680.0	$ 2,523.5
Revenues from anti-CD20 therapeutic programs	517.4	443.2
Other	292.4	164.4
Total revenues	3,489.8	3,131.1
Cost and expenses:		
Cost of sales, excluding amortization and impairment of acquired intangible assets	602.0	446.0
Research and development	563.7	496.7
Selling, general and administrative	567.7	501.3
Loss on assets and liabilities held for sale	115.5	—
Amortization and impairment of acquired intangible assets	68.2	103.9
Collaboration profit (loss) sharing	58.1	42.5
Acquired in-process research and development	—	10.0
Loss (gain) on fair value remeasurement of contingent consideration	11.5	(5.6)
Restructuring charges	0.4	1.6
Total cost and expenses	1,987.1	1,596.4
Income from operations	1,502.7	1,534.7
Other income (expense), net	357.3	(41.0)
Income before income tax expense and equity in loss of investee, net of tax	1,860.0	1,493.7
Income tax expense	422.5	322.5
Equity in loss of investee, net of tax	28.7	—
Net income	1,408.8	1,171.2
Net income (loss) attributable to noncontrolling interests, net of tax	—	(1.7)
Net income attributable to Biogen Inc.	$ 1,408.8	$ 1,172.9
Net income per share:		
Basic earnings per share attributable to Biogen Inc.	$ 7.17	$ 5.55
Diluted earnings per share attributable to Biogen Inc.	$ 7.15	$ 5.54
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	196.6	211.4
Diluted earnings per share attributable to Biogen Inc.	197.0	211.7

TABLE 2

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

	As of March 31, 2019	As of December 31, 2018
ASSETS		
Cash, cash equivalents and marketable securities	$ 3,909.0	$ 3,538.0
Accounts receivable, net	2,088.9	1,958.5
Inventory	770.2	929.9
Assets held for sale	682.0	—
Other current assets	1,492.5	1,214.5
Total current assets	8,942.6	7,640.9
Marketable securities	1,372.7	1,375.9
Property, plant and equipment, net	3,013.8	3,601.2
Operating lease assets	447.8	—
Intangible assets, net	3,056.2	3,120.0
Goodwill	5,639.7	5,706.4
Investments and other assets	3,972.7	3,844.5
TOTAL ASSETS	$ 26,445.5	$ 25,288.9
LIABILITIES AND EQUITY		
Liabilities held for sale	$ 97.2	$ —
Other current liabilities	3,051.5	3,295.5
Total current liabilities	3,148.7	3,295.5
Notes payable	5,943.2	5,936.5
Long-term operating lease liabilities	436.1	—
Other long-term liabilities	3,095.5	3,025.6
Equity	13,822.0	13,031.6
TOTAL LIABILITIES AND EQUITY	$ 26,445.5	$ 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		
	March 31, 2019	March 31, 2018	December 31, 2018
GAAP earnings per share - Diluted	$ 7.15	$ 5.54	$ 4.73
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	(0.17)	0.51	2.26
Non-GAAP earnings per share - Diluted	$ 6.98	$ 6.05	$ 6.99

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		
	March 31, 2019	March 31, 2018	December 31, 2018
GAAP net income attributable to Biogen Inc.	$ 1,408.8	$ 1,172.9	$ 946.8
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets [A]	68.2	103.9	254.1
Acquired in-process research and development	—	10.0	—
Research and development [B]	—	—	10.0
Loss (gain) on fair value remeasurement of contingent consideration [C]	11.5	(5.6)	79.3
Loss on assets and liabilities held for sale [D]	115.5	—	—
Net distribution to noncontrolling interests	—	—	(1.6)
Acquisition-related transaction and integration costs	4.3	—	—
Subtotal: Acquisition and divestiture related costs	199.5	108.3	341.8
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation [E]	1.0	3.8	—
Restructuring charges [E]	0.4	1.6	2.8
Subtotal: Restructuring, business transformation and other cost saving initiatives	1.4	5.4	2.8
(Gain) loss on equity security investments	(376.1)	6.4	12.2
Income tax effect related to reconciling items	126.1	(11.3)	(49.8)
Amortization included in Equity in loss of investee, net of tax [F]	14.7	—	—
Elimination of deferred tax asset [G]	—	—	10.6
Tax reform [H]	—	—	135.8
Non-GAAP net income attributable to Biogen Inc.	$ 1,374.4	$ 1,281.7	$ 1,400.2

Notes to GAAP to Non-GAAP Reconciliation

A In January 2017 we entered into a settlement and license agreement among Biogen Swiss Manufacturing GmbH, Biogen International Holding Ltd., Forward Pharma A/S (Forward Pharma) and certain related parties, which was effective February 1, 2017. Pursuant to this agreement, we obtained U.S. and rest of world licenses to Forward Pharma's intellectual property, including Forward Pharma's intellectual property related to TECFIDERA. In exchange, we paid Forward Pharma $1.25 billion in cash, of which $795.2 million was recognized as an intangible asset in the first quarter of 2017.

We have two intellectual property disputes with Forward Pharma, one in the U.S. and one in the European Union, concerning intellectual property related to TECFIDERA.

In March 2017 the U.S. intellectual property dispute was decided in our favor. Forward Pharma appealed to the U.S. Court of Appeals for the Federal Circuit. We evaluated the recoverability of the U.S. asset acquired from Forward Pharma and recorded a $328.2 million impairment charge in the first quarter of 2017 to adjust the carrying value of the acquired U.S. asset to fair value reflecting the impact of the developments in the U.S. legal dispute and continued to amortize the remaining net book value of the U.S. intangible asset in our consolidated statements of income utilizing an economic consumption model. The U.S. Court of Appeals for the Federal Circuit upheld the U.S. Patent and Trademark Office's March 2017 ruling and in January 2019 denied Forward Pharma's petition for rehearing. We evaluated the recoverability of the U.S. asset based upon these most recent developments and recorded a $176.8 million impairment charge in the fourth quarter of 2018 to reduce the remaining net book value of the U.S. asset to zero.

In March 2018 the European Patent Office (EPO) revoked Forward Pharma's European Patent No. 2 801 355. Forward Pharma has filed an appeal to the Technical Boards of Appeal of the EPO and the appeal is pending. Based upon our assessment of this ruling, we continue to amortize the remaining net book value of the rest of world intangible asset in our consolidated statements of income utilizing an economic consumption model.

B GAAP research and development expense for the three months ended December 31, 2018, includes a $10.0 million contingent consideration payment accrued in relation to the acquisition of an asset.

C During the third quarter of 2018 we adjusted the fair value of our contingent consideration obligations related to our BIIB074 (vixotrigine) program for the treatment of trigeminal neuralgia (TGN) to reflect the lower cumulative probabilities of success, which resulted in a gain of $89.6 million.

In late December 2018 we received feedback from the U.S. Food and Drug Administration regarding the design of the Phase 3 studies of vixotrigine for the treatment of TGN. Following this feedback, we are now planning to initiate the Phase 3 studies for our vixotrigine program for the treatment of TGN and, as a result, we adjusted the fair value of our contingent consideration obligations related to our vixotrigine program for the treatment of TGN to reflect the increased probabilities of success and recognized a loss of $80.6 million in the fourth quarter of 2018.

D 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.

We determined that the operations to be disposed of in the proposed transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

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.

In the first quarter of 2019 we recorded a loss of approximately $174.6 million in our condensed consolidated statements of income. This estimated loss includes a pre-tax loss of $115.5 million 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 $59.1 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, including filings and clearances under the Danish Competition Act. We expect to complete the proposed transaction in the second half of 2019.

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

F 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. (Samsung Bioepis) and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life.

G Elimination of deferred tax asset due to Samsung Bioepis qualifying as a corporate joint venture for accounting purposes.

H The Tax Cuts and Jobs Act of 2017 (2017 Tax Act) resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as global intangible low-taxed income (GILTI). During the fourth quarter of 2018 we elected to recognize deferred taxes for the basis differences expected to reverse as GILTI is incurred and have established initial deferred tax balances, as of the enactment date of the 2017 Tax Act.

During the fourth quarter of 2017 we recognized within our provision for income taxes a $1.2 billion provisional estimate pursuant to the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 118. Our provisional estimate included an amount of $989.6 million associated with a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings (the Transition Toll Tax) and $184.0 million related to the impact of remeasuring our deferred tax balances to reflect the new federal statutory rate and other changes to U.S. tax law.

Tax reform amounts for the three months ended December 31, 2018, reflects the effect of an expense of $135.8 million related to the establishment of GILTI deferred taxes.

The final determination of the Transition Toll Tax and remeasurement of our deferred assets and liabilities was completed in the fourth quarter of 2018.

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								
	March 31, 2019			March 31, 2018			December 31, 2018		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	$ 717.7	$ 281.1	$ 998.8	$ 728.9	$ 258.0	$ 986.9	$ 856.3	$ 254.1	$ 1,110.4
Interferon*	327.3	173.6	500.9	371.4	178.9	550.3	430.9	166.3	597.2
TYSABRI	245.0	215.4	460.4	249.7	212.4	462.1	256.8	207.6	464.4
FAMPYRA	—	22.9	22.9	—	24.4	24.4	—	22.7	22.7
ZINBRYTA	—	—	—	—	1.4	1.4	—	—	—
Spinal Muscular Atrophy:									
SPINRAZA	223.3	295.2	518.5	188.0	175.9	363.9	236.2	233.7	469.9
Other Product Revenues:									
FUMADERM	—	4.1	4.1	—	7.0	7.0	—	5.0	5.0
BENEPALI	—	124.0	124.0	—	120.9	120.9	—	125.3	125.3
FLIXABI	—	14.7	14.7	—	6.6	6.6	—	14.1	14.1
IMRALDI	—	35.7	35.7	—	—	—	—	16.7	16.7
Total product revenues	$ 1,513.3	$ 1,166.7	$ 2,680.0	$ 1,538.0	$ 985.5	$ 2,523.5	$ 1,780.2	$ 1,045.5	$ 2,825.7

* Interferon includes AVONEX and PLEGRIDY