

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): **October 22, 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 October 22, 2019, Biogen Inc. issued a press release announcing its results of operations and financial condition for the third quarter ended September 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 October 22, 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: October 22, 2019



BIOGEN REPORTS Q3 2019 REVENUES OF \$3.6 BILLION

GAAP diluted EPS increased 17%; Non-GAAP diluted EPS increased 24%

SPINRAZA revenues grew 17% versus prior year and 12% versus prior quarter

VUMERITY demonstrated superior gastrointestinal tolerability versus TECFIDERA

Biogen added two new clinical programs in Parkinson's disease and brain contusion

Cambridge, Mass., October 22, 2019 -- Biogen Inc. (Nasdaq: BIIB) today reported third quarter 2019 financial results.

“Biogen delivered solid performance in the third quarter driven by continued resilience from our MS core business and growth from SPINRAZA and biosimilars,” said Michel Vounatsos, Biogen’s Chief Executive Officer. “SPINRAZA continued on a strong trajectory, particularly outside the U.S., and we are preparing for the expected launch of VUMERITY, which we believe will be an important addition to our market-leading multiple sclerosis portfolio. In addition to the recent news on aducanumab, we made strong progress in our pipeline as we initiated new clinical programs targeting Parkinson’s disease and brain contusion, and we look forward to nine important data readouts by the end of next year. We continue to believe that our core focus on neuroscience will lead to new innovative treatments for patients and will maximize long-term returns for our shareholders.”

Financial Results

- Third quarter total revenues were \$3,600 million, a 5% increase versus the third quarter of 2018.
 - Multiple sclerosis (MS) revenues, including \$188 million in royalties on the sales of OCREVUS[®], increased 2% versus the prior year to \$2,348 million.
 - Revenue growth was driven in part by the continued global launch of SPINRAZA[®], which contributed \$547 million in revenues in the third quarter of 2019 compared to \$468 million in the third quarter of 2018.
 - Revenue growth was also driven by biosimilars revenues, which increased to \$184 million compared to \$135 million in the third quarter of 2018, primarily driven by IMRALDI[™].
 - Third quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$1,546 million and \$8.39, respectively, compared to \$1,444 million and \$7.15, respectively, in the third quarter of 2018.
 - Third quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$1,689 million and \$9.17, respectively, compared to \$1,494 million and \$7.40, respectively, in the third quarter of 2018.
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(In millions, except per share amounts)	Q3 '19	Q3 '18	Q2 '19	Q3 '19 v. Q3 '18	Q3 '19 v. Q2 '19
Total revenues	\$ 3,600	\$ 3,439	\$ 3,617	5%	(0%)
GAAP net income [#]	\$ 1,546	\$ 1,444	\$ 1,494	7%	3%
GAAP diluted EPS	\$ 8.39	\$ 7.15	\$ 7.85	17%	7%
Non-GAAP net income [#]	\$ 1,689	\$ 1,494	\$ 1,742	13%	(3%)
Non-GAAP diluted EPS	\$ 9.17	\$ 7.40	\$ 9.15	24%	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.

Revenue Highlights

(In millions)	Q3 '19	Q3 '18	Q2 '19	Q3 '19 v. Q3 '18	Q3 '19 v. Q2 '19
Multiple Sclerosis:					
TECFIDERA®	\$ 1,122	\$ 1,090	\$ 1,150	3%	(2%)
Total Interferon	\$ 530	\$ 590	\$ 554	(10%)	(4%)
AVONEX®	\$ 420	\$ 482	\$ 438	(13%)	(4%)
PLEGRIDY®	\$ 110	\$ 108	\$ 117	2%	(5%)
TYSABRI®	\$ 484	\$ 470	\$ 475	3%	2%
FAMPYRA™	\$ 24	\$ 23	\$ 24	8%	1%
Spinal Muscular Atrophy:					
SPINRAZA	\$ 547	\$ 468	\$ 488	17%	12%
Biosimilars:					
BENEPALI™	\$ 116	\$ 123	\$ 120	(6%)	(4%)
IMRALDI	\$ 49	\$ 0	\$ 47	NMF	4%
FLIXABI™	\$ 18	\$ 11	\$ 17	63%	10%
Other Product Revenues:					
FUMADERM™	\$ 4	\$ 5	\$ 4	(22%)	(1%)
Total Product Revenues:	\$ 2,895	\$ 2,780	\$ 2,880	4%	1%
OCREVUS Royalties	\$ 188	\$ 137	\$ 183	37%	3%
RITUXAN®/GAZYVA® Revenues	\$ 408	\$ 375	\$ 394	9%	4%
Other Revenues	\$ 110	\$ 147	\$ 160	(26%)	(31%)
Total Revenues	\$ 3,600	\$ 3,439	\$ 3,617	5%	(0%)
MS Product Revenues + OCREVUS Royalties	\$ 2,348	\$ 2,310	\$ 2,387	2%	(2%)

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

- In the third quarter of 2019 channel inventory levels in the U.S. decreased by approximately \$30 million for TECFIDERA, 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 \$5 million in the third quarter of 2018.
- In the third quarter of 2019 SPINRAZA revenues comprised \$237 million in sales in the U.S. and \$310 million in sales outside the U.S. The number of commercial patients receiving SPINRAZA grew approximately 3% in the U.S. and approximately 18% outside the U.S. versus the second quarter of 2019.

Expense Highlights

(In millions)	Q3 '19	Q3 '18	Q2 '19	Q3 '19 v. Q3 '18	Q3 '19 v. Q2 '19
GAAP cost of sales	\$ 430	\$ 461	\$ 476	7%	10%
Non-GAAP cost of sales	\$ 430	\$ 461	\$ 476	7%	10%
GAAP R&D	\$ 540	\$ 508	\$ 485	(6%)	(11%)
Non-GAAP R&D	\$ 540	\$ 508	\$ 477	(6%)	(13%)
GAAP SG&A	\$ 555	\$ 498	\$ 588	(11%)	6%
Non-GAAP SG&A	\$ 547	\$ 495	\$ 553	(11%)	1%

Note: Percent changes represented as favorable/(unfavorable)

- R&D expense in the third quarter of 2019 included approximately \$58 million in net closeout costs for the Phase 3 studies of elenbecestat in early Alzheimer's disease (AD) and the Phase 2b study of BG00011 in idiopathic pulmonary fibrosis (IPF).

Other Financial Highlights

- In the third quarter of 2019 Biogen recognized a GAAP-only impairment charge of approximately \$216 million and a GAAP-only gain of \$61 million on fair value remeasurement of contingent consideration, both related to the discontinuation of BG00011.
 - For the third quarter of 2019 GAAP other expense was \$27 million. Non-GAAP other expense for the third quarter of 2019 was \$23 million.
 - For the third quarter of 2019 the Company's effective GAAP tax rate was approximately 12%, compared to approximately 20% in the third quarter of 2018. For the third quarter of 2019 the Company's effective Non-GAAP tax rate was approximately 16%, compared to approximately 21% in the third quarter of 2018.
 - Compared to the third quarter of 2018, the Company's GAAP effective tax rate for the third quarter of 2019 benefited from the remaining benefit realized from U.S. corporate tax reform, a change in our tax profile in the second quarter of 2019, and recently enacted tax reform in Switzerland.
 - In the third quarter of 2019 Biogen repurchased approximately 3.1 million shares of the Company's common stock for a total value of approximately \$718 million.
 - As of September 30, 2019, there was approximately \$3,372 million remaining under the share repurchase program authorized in March 2019.
 - As of September 30, 2019, Biogen had cash, cash equivalents, and marketable securities totaling approximately \$6,251 million, and approximately \$5,954 million in notes payable.
 - In the third quarter of 2019 the Company generated \$1,695 million in net cash flows from operations.
 - For the third quarter of 2019 the Company's weighted average diluted shares were 184 million.
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Recent Events

- This week Biogen is presenting new data from the Company's anti-TNF biosimilar portfolio, which includes FLIXABI (infliximab) and IMRALDI (adalimumab), highlighting real-world evidence confirming the safety and efficacy of anti-TNF biosimilars for patients with inflammatory bowel disease. These data are being presented at the United European Gastroenterology (UEG) Week 2019.
 - In October 2019 the U.S. Food and Drug Administration (FDA) issued a tentative approval for VUMERITY™ (diroximel fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of MS. Additionally, in July 2019 Biogen and Alkermes plc announced positive topline results from EVOLVE-MS-2, a large, randomized, double-blind, five-week, Phase 3 study of VUMERITY for relapsing-remitting MS, compared to TECFIDERA (dimethyl fumarate). VUMERITY was statistically superior to TECFIDERA on the study's pre-specified primary endpoint, with patients treated with VUMERITY self-reporting significantly fewer days of key gastrointestinal symptoms with intensity scores ≥ 2 on the Individual Gastrointestinal Symptom and Impact Scale (IGISIS), as compared to TECFIDERA ($p=0.0003$).
 - In October 2019 Biogen dosed the first patient in a Phase 2 study of BIIB093 (glibenclamide IV) for brain contusion.
 - In October 2019 Biogen announced that the journal *Neuromuscular Disorders* published data from NURTURE, the first study investigating a treatment targeting the underlying cause of spinal muscular atrophy (SMA) in infants treated pre-symptomatically. Data from the NURTURE study demonstrated that infants who initiated treatment with SPINRAZA prior to the onset of clinical symptoms attained unparalleled results compared to the natural history of the disease. As of March 2019 all participants were alive, without the need for permanent ventilation, and experienced continuous improvements with the majority achieving motor milestones in timelines consistent with normal development. The results also demonstrated durability of effect with children making progress throughout the study. These published results from the NURTURE study were previously presented at the 2019 Cure SMA Annual SMA Conference and the 5th Congress of the European Academy of Neurology.
 - In October 2019 the European Medicines Agency updated the summaries of product characteristics (SmPCs) for AVONEX and PLEGRIDY to remove pregnancy contraindications and, where clinically needed, to allow use during pregnancy and breastfeeding in women with relapsing MS.
 - In September 2019 Biogen presented new data further demonstrating the safety and efficacy of treatment with SPINRAZA in individuals with later-onset SMA at the 13th Congress of the European Paediatric Neurology Society. An integrated analysis from SHINE, an open-label extension study for patients with SMA who participated in prior SPINRAZA studies, found that children with later-onset SMA (Type 2 or Type 3) experienced improvements or stabilization in one or more measures of motor function for up to nearly six years, in contrast to the expected decline observed in natural history cohorts.
 - In September 2019 Biogen announced that it plans to initiate a new study evaluating whether a higher dose of SPINRAZA can offer even greater efficacy in treating SMA. DEVOTE is a Phase 2/3 randomized, controlled dose-escalating study that will be conducted at 50 sites around the world with a projected enrollment of 126 individuals with SMA of all ages, including adults.
 - In September 2019 Roche announced that the FDA granted Breakthrough Therapy Designation to GAZYVA for adults with lupus nephritis. This designation was granted based on data from the Phase 2
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NOBILITY study in adult patients with proliferative lupus nephritis which showed 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 the U.S., GAZYVA is part of a collaboration between Biogen and Genentech, Inc., a wholly-owned member of the Roche Group.

- In September 2019 Biogen announced that it has been ranked the #1 biotechnology company on the Dow Jones Sustainability World Index for the fourth time, after being the first U.S.-based biotech company to ever make the list in 2013.
- In September 2019 Eisai Co., Ltd. and Biogen announced the decision to discontinue the Phase 3 clinical studies (MISSION AD1 and MISSION AD2) of the investigational oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) in patients with early AD.
- In September 2019 Biogen presented new data at the 35th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) and 24th Annual Conference of Rehabilitation in MS. Key data included new 10-year results from the ongoing Phase 3 ENDORSE extension study and comparative effectiveness analyses of TECFIDERA, interim data from the Phase 3 EVOLVE-MS-1 study evaluating the safety and efficacy of VUMERITY, data from the TYSABRI Observational Program evaluating the effectiveness of every six weeks (Q6W) dosing, and data supporting that exposure to interferon beta treatment, including PLEGRIDY and AVONEX, before conception and/or during pregnancy is not expected to have an adverse effect on pregnancy or infant growth outcomes.
- In August 2019 Biogen dosed the first patient in the Phase 1 study of BIIB094 (ION859), an antisense oligonucleotide targeting leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease.
- In August 2019 Biogen discontinued the Phase 2b study of BG00011 for IPF due to safety concerns.

Leadership Updates

- In October 2019 Biogen announced that Alfred Sandrock, Jr., M.D., Ph.D., has been named Executive Vice President, Research and Development, in addition to his responsibilities as Chief Medical Officer, and Alphonse Galdes, Ph.D., has been appointed Executive Vice President, Pharmaceutical Operations and Technology. Michael D. Ehlers, M.D., Ph.D., has stepped down as Executive Vice President, Research and Development to pursue a new external career opportunity.

Conference Call and Webcast

The Company's earnings conference call for the third quarter, which will include an update on aducanumab, will be broadcast via the internet at 8:00 a.m. ET on October 22, 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. 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, 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; and the anticipated benefits and potential of investments, collaborations, and business development activities. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “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; 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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product, net	\$ 2,894.7	\$ 2,780.1	\$ 8,455.0	\$ 8,061.1
Revenues from anti-CD20 therapeutic programs	595.8	511.7	1,689.6	1,445.3
Other	109.6	147.2	562.0	420.2
Total revenues	<u>3,600.1</u>	<u>3,439.0</u>	<u>10,706.6</u>	<u>9,926.6</u>
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	430.0	460.8	1,508.3	1,327.8
Research and development	540.4	507.9	1,588.9	1,985.6
Selling, general and administrative	554.5	497.7	1,709.8	1,515.2
Amortization and impairment of acquired intangible assets	283.9	281.9	422.2	493.2
Collaboration profit (loss) sharing	60.2	47.5	181.8	129.2
Loss on divestiture of Hillerød, Denmark manufacturing operations	(17.7)	—	95.5	—
(Gain) loss on fair value remeasurement of contingent consideration	(57.8)	(87.9)	(66.3)	(91.6)
Restructuring charges	0.3	6.0	1.5	9.2
Acquired in-process research and development	—	27.5	—	112.5
Total cost and expenses	<u>1,793.8</u>	<u>1,741.4</u>	<u>5,441.7</u>	<u>5,481.1</u>
Income from operations	1,806.3	1,697.6	5,264.9	4,445.5
Other income (expense), net	(27.3)	115.1	132.6	39.6
Income before income tax expense and equity in loss of investee, net of tax	1,779.0	1,812.7	5,397.5	4,485.1
Income tax expense	211.3	369.8	881.9	956.0
Equity in loss of investee, net of tax	21.8	—	66.8	—
Net income	1,545.9	1,442.9	4,448.8	3,529.1
Net income (loss) attributable to noncontrolling interests, net of tax	—	(1.5)	—	45.2
Net income attributable to Biogen Inc.	<u>\$ 1,545.9</u>	<u>\$ 1,444.4</u>	<u>\$ 4,448.8</u>	<u>\$ 3,483.9</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 8.40	\$ 7.17	\$ 23.38	\$ 16.86
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 8.39</u>	<u>\$ 7.15</u>	<u>\$ 23.35</u>	<u>\$ 16.83</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	184.0	201.4	190.3	206.6
Diluted earnings per share attributable to Biogen Inc.	<u>184.2</u>	<u>201.9</u>	<u>190.5</u>	<u>207.0</u>

TABLE 2

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

	As of September 30, 2019	As of December 31, 2018
ASSETS		
Cash, cash equivalents and marketable securities	\$ 4,437.4	\$ 3,538.0
Accounts receivable, net	1,933.5	1,958.5
Inventory	751.8	929.9
Other current assets	1,325.5	1,214.5
Total current assets	8,448.2	7,640.9
Marketable securities	1,813.9	1,375.9
Property, plant and equipment, net	3,138.1	3,601.2
Operating lease assets	422.0	—
Intangible assets, net	3,392.4	3,120.0
Goodwill	5,746.1	5,706.4
Investments and other assets	4,523.3	3,844.5
TOTAL ASSETS	\$ 27,484.0	\$ 25,288.9
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ 1,495.3	\$ —
Other current liabilities	2,936.9	3,295.2
Total current liabilities	4,432.2	3,295.2
Notes payable	4,458.2	5,936.5
Long-term operating lease liabilities	410.5	—
Other long-term liabilities	4,191.3	3,025.6
Equity	13,991.8	13,031.6
TOTAL LIABILITIES AND EQUITY	\$ 27,484.0	\$ 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		
	September 30, 2019	September 30, 2018	June 30, 2019
GAAP earnings per share - Diluted	\$ 8.39	\$ 7.15	\$ 7.85
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.78	0.25	1.30
Non-GAAP earnings per share - Diluted	<u>\$ 9.17</u>	<u>\$ 7.40</u>	<u>\$ 9.15</u>

	For the Nine Months Ended	
	September 30, 2019	September 30, 2018
GAAP earnings per share - Diluted	\$ 23.35	\$ 16.83
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	1.87	2.39
Non-GAAP earnings per share - Diluted	<u>\$ 25.22</u>	<u>\$ 19.22</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		
	September 30, 2019	September 30, 2018	June 30, 2019
GAAP net income attributable to Biogen Inc.	\$ 1,545.9	\$ 1,444.4	\$ 1,494.1
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets A	283.9	281.9	70.1
Acquired in-process research and development	—	27.5	—
(Gain) loss on fair value remeasurement of contingent consideration A	(57.8)	(87.9)	(20.0)
Loss on divestiture of Hillerød, Denmark manufacturing operations B	(17.7)	—	(2.3)
Net distribution to noncontrolling interests	—	(1.5)	—
Stock option expense D	—	—	26.2
Acquisition-related transaction and integration costs	(0.3)	—	19.4
Accelerated share-based compensation expense	6.7	—	—
Subtotal: Acquisition and divestiture related costs	<u>214.8</u>	<u>220.0</u>	<u>93.4</u>
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation E	1.3	3.1	0.7
Restructuring charges E	0.3	6.0	0.8
Subtotal: Restructuring, business transformation and other cost saving initiatives	<u>1.6</u>	<u>9.1</u>	<u>1.5</u>
(Gain) loss on equity security investments	4.6	(141.2)	174.2
Income tax effect related to reconciling items	(44.8)	(19.3)	(43.1)
U.S. tax reform	—	(18.5)	—
Swiss tax reform F	(54.3)	—	—
Amortization included in Equity in loss of investee, net of tax G	21.2	—	21.7
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 1,689.0</u>	<u>\$ 1,494.5</u>	<u>\$ 1,741.8</u>

	For the Nine Months Ended	
	September 30, 2019	September 30, 2018
GAAP net income attributable to Biogen Inc.	\$ 4,448.8	\$ 3,483.9
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets A	422.2	493.2
Acquired in-process research and development	—	112.5
(Gain) loss on fair value remeasurement of contingent consideration A	(66.3)	(91.6)
Loss on divestiture of Hillerød, Denmark manufacturing operations B	95.5	—
Net distribution to noncontrolling interests C	—	45.3
Stock option expense D	26.2	—
Acquisition-related transaction and integration costs	23.4	—
Accelerated share-based compensation expense	6.7	—
Subtotal: Acquisition and divestiture related costs	507.7	559.4
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation E	3.0	10.9
Restructuring charges E	1.5	9.2
Subtotal: Restructuring, business transformation and other cost saving initiatives	4.5	20.1
Premium paid on purchase of Ionis common stock H	—	162.1
(Gain) loss on equity security investments	(197.3)	(140.2)
Income tax effect related to reconciling items	38.2	(96.7)
Swiss tax reform F	(54.3)	—
U.S. tax reform	—	(10.9)
Amortization included in Equity in loss of investee, net of tax G	57.6	—
Non-GAAP net income attributable to Biogen Inc.	\$ 4,805.2	\$ 3,977.7

Notes to GAAP to Non-GAAP Reconciliation

A Amortization and impairment of acquired intangible assets for the three and nine months ended September 30, 2019, reflects the impact of a \$215.9 million impairment charge related to certain in-process research and development (IPR&D) assets associated with the Phase 2b study of BG00011 (STX-100) for the potential treatment of idiopathic pulmonary fibrosis, which was discontinued during the third quarter of 2019 due to safety concerns. We also adjusted the value of our contingent consideration obligations related to this asset resulting in a gain of \$61.2 million in the third quarter of 2019.

Amortization and impairment of acquired intangible assets for the three and nine months ended September 30, 2018, reflects the impact of impairment charges related to certain IPR&D assets associated with our vixotrigine (BIB074) program totaling \$189.3 million. During the third quarter of 2018 we completed the Phase 2b study for vixotrigine for the potential treatment of painful lumbosacral radiculopathy (PLSR). The study did not meet its primary or secondary efficacy endpoints and we discontinued development of vixotrigine for the potential treatment of PLSR. As a result, we recognized an impairment charge of approximately \$60.0 million during the third quarter of 2018 to reduce the fair value of the IPR&D intangible asset to zero.

In addition, we delayed the initiation of the Phase 3 studies of vixotrigine for the potential treatment of trigeminal neuralgia (TGN) as we awaited the outcome of ongoing interactions with the U.S. Food and Drug Administration regarding the design of the Phase 3 studies, a more detailed review of the data from the Phase 2b study of vixotrigine for the potential treatment of PLSR and insights from the Phase 2 study of vixotrigine for the potential treatment of small fiber neuropathy. We reassessed the fair value of the TGN program using reduced expected lifetime revenues, higher expected clinical development costs and a lower cumulative probability of success. As a result of that assessment, we recognized an impairment charge of \$129.3 million during the third quarter of 2018 to reduce the fair value of the TGN IPR&D intangible asset to \$41.8 million at that date. We also adjusted the value of our contingent consideration obligations related to the TGN program to reflect the lower cumulative probabilities of success resulting in a gain of \$89.6 million in the third quarter of 2018.

For the nine months ended September 30, 2019, compared to the prior year period, the decrease in amortization of acquired intangible assets, excluding impairment charges, 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 On August 1, 2019, we completed our sale of all of the outstanding shares of our subsidiary that owned our biologics manufacturing operations in Hillerød, Denmark to FUJIFILM Corporation (FUJIFILM). Upon the closing of this transaction, we received approximately \$881.9 million in cash, which is subject to the finalization of certain working capital adjustments and may be further adjusted based on other contractual terms, which are discussed below. 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.

As part of this 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 \$114.0 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 also may be obligated to indemnify FUJIFILM for liabilities that existed relating to certain business activities incurred prior to the closing of this transaction.

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. 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.

As part of this transaction, we entered into certain manufacturing services agreements with FUJIFILM pursuant to which FUJIFILM will use the Hillerød facility to produce commercial products for us, such as TYSABRI, as well as other third-party products.

In connection with this transaction we recognized a total net loss of approximately \$160.2 million in our condensed consolidated statements of income. This loss included a pre-tax loss of \$95.5 million, which reflects a decrease of \$17.7 million to our previously recorded pre-tax loss. The loss recognized was based on exchange rates and business conditions on the closing date of this transaction, and included costs to sell our Hillerød, Denmark manufacturing operations of approximately \$11.2 million and our estimate of the fair value of an adverse commitment of \$114.0 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. We also recorded a tax expense of \$64.7 million related to this transaction.

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, including royalties payable on potential commercial sales of aducanumab, an investigational treatment for early Alzheimer's disease, 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 During the third quarter of 2019 a new taxing regime in the country and certain cantons of Switzerland was enacted and we refer to this as Swiss Tax Reform. As a result of the impact of Swiss Tax Reform, we recorded an income tax benefit of approximately \$54.3 million resulting from a remeasurement of our deferred tax assets and liabilities in the three and nine months ended September 30, 2019.

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.

H In June 2018 we closed a 10-year exclusive agreement with Ionis Pharmaceuticals, Inc. (Ionis) to develop novel antisense oligonucleotide drug candidates for a broad range of neurological diseases (the 2018 Ionis Agreement) 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.

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								
	September 30, 2019			September 30, 2018			June 30, 2019		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	\$ 842.0	\$ 280.4	\$ 1,122.4	\$ 842.1	\$ 247.9	\$ 1,090.0	\$ 869.8	\$ 280.4	\$ 1,150.2
Interferon*	360.3	169.7	530.0	421.5	168.6	590.1	379.7	174.7	554.4
TYSABRI	263.0	220.6	483.6	253.0	217.2	470.2	264.3	211.0	475.3
FAMPYRA	—	24.2	24.2	—	22.5	22.5	—	24.1	24.1
Spinal Muscular Atrophy:									
SPINRAZA	236.7	310.4	547.1	223.9	243.8	467.7	230.6	257.6	488.2
Biosimilars:									
BENEPALI	—	115.9	115.9	—	123.4	123.4	—	120.3	120.3
IMRALDI	—	49.3	49.3	—	—	—	—	47.3	47.3
FLIXABI	—	18.4	18.4	—	11.4	11.4	—	16.8	16.8
Other Product Revenues:									
FUMADERM	—	3.8	3.8	—	4.8	4.8	—	3.7	3.7
Total product revenues	<u>\$ 1,702.0</u>	<u>\$ 1,192.7</u>	<u>\$ 2,894.7</u>	<u>\$ 1,740.5</u>	<u>\$ 1,039.6</u>	<u>\$ 2,780.1</u>	<u>\$ 1,744.4</u>	<u>\$ 1,135.9</u>	<u>\$ 2,880.3</u>

	For the Nine Months Ended					
	September 30, 2019			September 30, 2018		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
TECFIDERA	\$ 2,429.5	\$ 841.9	\$ 3,271.4	\$ 2,396.8	\$ 766.9	\$ 3,163.7
Interferon*	1,067.3	518.0	1,585.3	1,237.5	528.4	1,765.9
TYSABRI	772.3	647.0	1,419.3	768.2	631.3	1,399.5
FAMPYRA	—	71.2	71.2	—	69.9	69.9
ZINBRYTA	—	—	—	—	1.4	1.4
Spinal Muscular Atrophy:						
SPINRAZA	690.6	863.2	1,553.8	617.8	636.5	1,254.3
Biosimilars:						
BENEPALI	—	360.2	360.2	—	359.9	359.9
IMRALDI	—	132.3	132.3	—	—	—
FLIXABI	—	49.9	49.9	—	29.2	29.2
Other Product Revenues:						
FUMADERM	—	11.6	11.6	—	17.3	17.3
Total product revenues	<u>\$ 4,959.7</u>	<u>\$ 3,495.3</u>	<u>\$ 8,455.0</u>	<u>\$ 5,020.3</u>	<u>\$ 3,040.8</u>	<u>\$ 8,061.1</u>

* Interferon includes AVONEX and PLEGRIDY

