

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 21, 2020**

BIOPEN 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 21, 2020, Biogen Inc. (the "Company") issued a press release announcing its results of operations and financial condition for the third quarter ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

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

Item 8.01 Other Events.

On October 20, 2020, the Board of Directors of the Company authorized a program to repurchase up to \$5.0 billion of the Company's common stock (the "2020 Share Repurchase Program"). The 2020 Share Repurchase Program does not have an expiration date. All share repurchases under the 2020 Share Repurchase Program will be retired.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Biogen's press release dated October 21, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

BIOGEN INC.

By: /s/ Suzanne Murray
Suzanne Murray

Corporation Counsel and Assistant Secretary

Date: October 21, 2020



BIOGEN REPORTS Q3 2020 RESULTS

*Third quarter revenue \$3,376 million; GAAP diluted EPS \$4.46;
Non-GAAP diluted EPS \$8.84*

FDA accepted Biologics License Application for aducanumab with Priority Review

Marketing Authorization Application for aducanumab submitted in Europe

New collaboration with Denali Therapeutics bolsters pipeline for Parkinson's disease

Company announces new \$5.0 billion share repurchase authorization

Cambridge, Mass., October 21, 2020 -- Biogen Inc. (Nasdaq: BIIB) today reported third quarter 2020 financial results.

“In the third quarter, Biogen continued to execute on its strategy and delivered solid performance, although we began to face the launch of multiple generics of TECFIDERA® in the U.S.,” said Michel Vounatsos, Biogen’s Chief Executive Officer. “We look forward to participating in the aducanumab Advisory Committee meeting on November 6th, and we are excited about the prospect of aducanumab as a short- and long-term value creation opportunity. We have continued to allocate capital to create the opportunity for long-term shareholder value, including business development with our new collaboration in Parkinson’s disease.”

Financial Results

- Third quarter total revenues were \$3,376 million, a 6% decrease versus the third quarter of 2019, inclusive of a 1% unfavorable currency impact.
 - Multiple sclerosis (MS) revenues, including \$272 million in royalties on sales of OCREVUS®, decreased 4% versus the prior year to \$2,257 million.
 - SPINRAZA® revenues decreased 10% versus the prior year to \$495 million.
 - Biosimilars revenues increased 13% versus the prior year to \$208 million.
- Third quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$702 million and \$4.46, respectively.
- Third quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$1,390 million and \$8.84, respectively.

(In millions, except per share amounts)	Q3 '20	Q3 '19	Q3 '20 v. Q3 '19
Total revenues	\$ 3,376	\$ 3,600	(6%)
GAAP net income [#]	\$ 702	\$ 1,546	(55%)
GAAP diluted EPS	\$ 4.46	\$ 8.39	(47%)
Non-GAAP net income [#]	\$ 1,390	\$ 1,689	(18%)
Non-GAAP diluted EPS	\$ 8.84	\$ 9.17	(4%)

[#] Net income attributable to Biogen Inc.

Note: Percent changes represented as favorable/(unfavorable)

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

Revenue Highlights

(In millions)	Q3 '20	Q3 '19	Q3 '20 v. Q3 '19
Multiple Sclerosis:			
Total Fumarate	\$ 968	\$ 1,122	(14%)
TECFIDERA	\$ 953	\$ 1,122	(15%)
VUMERITY®	\$ 15	\$ —	NMF
Total Interferon	\$ 474	\$ 530	(11%)
AVONEX®	\$ 381	\$ 420	(9%)
PLEGRIDY®	\$ 93	\$ 110	(15%)
TYSABRI®	\$ 516	\$ 484	7%
FAMPYRA™	\$ 27	\$ 24	10%
Spinal Muscular Atrophy:			
SPINRAZA	\$ 495	\$ 547	(10%)
Biosimilars:			
BENEPALI™	\$ 124	\$ 116	7%
IMRALDI™	\$ 56	\$ 49	14%
FLIXABI™	\$ 27	\$ 18	49%
Other Product Revenues:			
FUMADERM™	\$ 3	\$ 4	(16%)
Total Product Revenues:	\$ 2,690	\$ 2,895	(7%)
OCREVUS Royalties	\$ 272	\$ 188	45%
RITUXAN®/GAZYVA® Revenues	\$ 288	\$ 408	(29%)
Other Revenues	\$ 126	\$ 110	15%
Total Revenues	\$ 3,376	\$ 3,600	(6%)
MS Product Revenues + OCREVUS Royalties	\$ 2,257	\$ 2,348	(4%)

Expense Highlights

(In millions)	Q3 '20	Q3 '19	Q3 '20 v. Q3 '19
GAAP cost of sales	\$ 449	\$ 430	(4%)
Non-GAAP cost of sales	\$ 449	\$ 430	(4%)
GAAP R&D	\$ 1,141	\$ 540	(111%)
Non-GAAP R&D	\$ 540	\$ 540	—%
GAAP SG&A	\$ 573	\$ 555	(3%)
Non-GAAP SG&A	\$ 569	\$ 547	(4%)

Note: Percent changes represented as favorable/(unfavorable)

- GAAP R&D expenses in the third quarter of 2020 included a \$601 million charge related to Biogen's collaboration with Denali Therapeutics Inc. (Denali), which Biogen entered into in the third quarter of 2020 (\$560 million upfront and a \$41 million premium paid on Denali common stock purchased). These amounts are excluded from Non-GAAP R&D expense. Beginning in the third quarter of 2020, material upfront payments associated with significant collaboration and licensing arrangements are excluded from Non-GAAP R&D expense in order to better reflect the Company's core operating performance. Year-to-date Non-GAAP results also reflect this change as the \$125 million upfront payment related to the collaboration with Sangamo Therapeutics, Inc. (Sangamo) in the second quarter of 2020 has also now been excluded from Non-GAAP R&D expense.

Other Financial Highlights

- For the third quarter of 2020 GAAP and Non-GAAP net expense related to collaboration profit sharing was \$73 million.
- For the third quarter of 2020 GAAP other expense was \$129 million, primarily driven by net interest expense of \$50 million and unrealized losses on strategic equity investments of \$82 million. Non-GAAP other expense for the third quarter of 2020 was \$46 million, primarily driven by net interest expense of \$50 million partially offset by foreign exchange rate gains of \$3 million.
- For the third quarter of 2020 the Company's GAAP effective tax rate was approximately 25%, an increase from approximately 12% in the third quarter of 2019. This increase was primarily due to prior year favorability on Swiss tax reform as well as current year unfavorability, primarily driven by non-cash deferred tax adjustments related to TECFIDERA. For the third quarter of 2020 the Company's Non-GAAP effective tax rate was approximately 18%, an increase from approximately 16% in the third quarter of 2019.
- In the third quarter of 2020 Biogen repurchased approximately 4.5 million shares of the Company's common stock for a total value of approximately \$1,250 million. The share repurchase program authorized in December 2019 was completed as of September 30, 2020.
- On October 20, 2020, Biogen's Board of Directors authorized a program to repurchase up to \$5.0 billion of the Company's common stock (the 2020 Share Repurchase Program). The 2020 Share Repurchase Program does not have an expiration date. All shares repurchased under the 2020 Share Repurchase Program will be retired.
- As of September 30, 2020, Biogen had cash, cash equivalents, and marketable securities totaling \$4,590 million and \$7,425 million in notes payable. In the third quarter of 2020 the Company generated approximately \$1,181 million in net cash flow from operations. Capital expenditures were

\$84 million in the third quarter of 2020, and free cash flow, defined as net cash flow from operations less capital expenditures, was \$1,097 million.

- For the third quarter of 2020 the Company's weighted average diluted shares were 157 million.

2020 Financial Guidance

Biogen is providing an update to its full year 2020 financial guidance, which was last updated in July 2020 and assumed no generic entry for TECFIDERA. During the third quarter of 2020, the Company began to experience the impact of multiple TECFIDERA generic entrants in the U.S., and this financial guidance assumes significant erosion of TECFIDERA in the fourth quarter of 2020, the pace of which is difficult to predict. As a result, Biogen currently expects:

- 2020 Full Year Revenue to be approximately \$13.2 billion to \$13.4 billion, compared to the prior guidance range of \$13.8 billion to \$14.2 billion.
- 2020 Full Year GAAP diluted EPS to be between \$25.50 and \$26.50, compared to the prior guidance range of \$32.00 to \$34.00.
- 2020 Full Year Non-GAAP diluted EPS to be between \$32.50 and \$33.50, compared to the prior guidance range of \$34.00 to \$36.00. This range excludes the upfront payments associated with the Sangamo and Denali collaborations during the second and third quarters of 2020, respectively.

This financial guidance does not include potential impacts from new acquisitions or large business development transactions, as both have elements that are hard to predict. This financial guidance assumes that foreign exchange rates as of September 30, 2020, remain in effect for the remainder of the year.

Biogen may incur charges, realize gains or losses, or experience other events or circumstances in 2020 that could cause actual results to vary from this financial guidance.

Recent Events

- In October 2020 Biogen submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the review of aducanumab, an investigational treatment for Alzheimer's disease. This MAA is subject to validation of whether the EMA accepts the application for review, which Biogen plans to announce when notified. Biogen is collaborating with Eisai Co., Ltd. (Eisai) on the development of aducanumab.
- In October 2020 Biogen entered into a collaboration with Scribe Therapeutics (Scribe) to develop and commercialize CRISPR-based therapies for the potential treatment of amyotrophic lateral sclerosis (ALS). Under the collaboration, Scribe will receive a \$15 million upfront payment and may be eligible to receive up to \$400 million in milestones as well as tiered high single digit to sub-teen royalties.
- In October 2020 Samsung Bioepis Co., Ltd. and Biogen announced that the EMA accepted for review the MAA for SB11, a proposed biosimilar referencing LUCENTIS® (ranibizumab). Ranibizumab is an anti-VEGF (vascular endothelial growth factor) for retinal vascular disorders, which are a leading cause of blindness.
- In October 2020 Biogen announced that the Phase 2 AFFINITY study of opicinumab (anti-LINGO) in MS did not meet its primary or secondary endpoints and that Biogen has discontinued development of opicinumab.

- In September 2020 the U.S. Food and Drug Administration (FDA) announced that an advisory committee meeting of the Peripheral and Central Nervous System Drugs Advisory Committee will be held virtually on November 6, 2020, to review data supporting the Biologics License Application (BLA) for aducanumab. Background material and the link to the online teleconference meeting room will be available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.
- In September 2020 Biogen dosed the first patient in a Phase 1 study of BIIB105, an antisense oligonucleotide targeting ataxin-2, in ALS.
- In September 2020 the first patient was dosed in Phase 3 AHEAD 3-45 clinical study of BAN2401, an anti-amyloid beta (A β) antibody, in individuals with preclinical Alzheimer's disease who have intermediate or elevated levels of amyloid in their brains. Biogen is collaborating with Eisai on the development of BAN2401.
- In September 2020 Biogen announced *Healthy Climate, Healthy LivesTM*, a groundbreaking \$250 million, 20-year initiative to eliminate fossil fuels across its operations and collaborate with renowned institutions with the aim to improve health, especially for the world's most vulnerable populations. Building on its long-standing commitment to corporate responsibility, Biogen's goal is to eliminate its fossil fuel emissions by 2040 as well as be a catalyst for positive change by advancing the science around how fossil fuels impact human health and taking action to promote climate and health equity.
- In September 2020 Biogen presented new data underscoring the efficacy and safety of its broad portfolio of MS therapies at MSVirtual2020, the eighth joint meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS). These presentations included new data further defining the effectiveness and safety profile of VUMERITY as well as new real-world MRI data suggesting that the effectiveness of extended interval dosing of TYSABRI is similar to the approved every-four-week dosing.
- In September 2020, also at MSVirtual2020, Biogen announced findings from a large, real-world study that provided insight into the clinical and health disparities that exist for people living with MS. Real-world data from the NARCRMS registry, a longitudinal database of more than 700 people living with MS in the U.S. and Canada, show that ethnic and racial disparities exist related to occupation, income status, MS-related disability, and type of treatment used.
- In August 2020 the first patient was dosed in the Phase 3 program for dapirolizumab pegol in patients with active systemic lupus erythematosus despite being treated by standard of care therapies. Dapirolizumab pegol is being developed in collaboration with UCB.
- In August 2020 the FDA accepted the BLA for aducanumab. The application was granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date on March 7, 2021, and the FDA has stated that, if possible, it plans to act early on this application under an expedited review.
- In August 2020 Biogen and Denali announced a collaboration to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2), expanding Biogen's pipeline of potential therapies in Parkinson's disease. Biogen also received rights to opt into two programs and a right of first negotiation for two additional programs, in each case for neurodegenerative diseases leveraging Denali's Transport Vehicle technology platform to cross the blood-brain barrier. Under the agreements, Denali received a \$560 million upfront payment and an equity investment of \$465 million and may be eligible to receive up to \$1.125 billion in potential

milestone payments, profit sharing, and royalties. The share purchase agreement and collaboration agreement subsequently closed in September 2020 and October 2020, respectively.

Conference Call and Webcast

The Company's earnings conference call for the third quarter will be broadcast via the internet at 8:00 a.m. ET on October 21, 2020, and will be accessible through the Investors section of Biogen's website, www.biogen.com. Supplemental information in the form of a slide presentation is also accessible at the same location on the internet and will be subsequently available on the website for at least one month.

About Biogen

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

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

Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our strategy and plans; potential of our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations, and business development activities; our future financial and operating results; 2020 financial guidance; potential benefits and results that may be achieved through our *Healthy Climate, Healthy Lives* initiative; and the anticipated timeline of our *Healthy Climate, Healthy Lives* initiative. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; failure to protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for

existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; risks relating to technology failures or breaches; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks relating to management and key personnel changes, including attracting and retaining key personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; risks related to commercialization of biosimilars; fluctuations in our operating results; fluctuations in our effective tax rate; risks related to investment in properties; the market, interest, and credit risks associated with our portfolio of marketable securities; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; environmental risks; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; change in control provisions in certain of our collaboration agreements; risks that the goals of our *Healthy Climate, Healthy Lives* initiative will be completed in a timely manner or at all; uncertainty as to whether the anticipated benefits of our *Healthy Climate, Healthy Lives* initiative 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:
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Biogen Inc.	Biogen Inc.
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TABLE 1

BIOPEN 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,	
	2020	2019	2020	2019
Revenues:				
Product, net	\$ 2,690.3	\$ 2,894.7	\$ 8,390.6	\$ 8,455.0
Revenues from anti-CD20 therapeutic programs	560.1	595.8	1,558.8	1,689.6
Other	125.7	109.6	642.6	562.0
Total revenues	<u>3,376.1</u>	<u>3,600.1</u>	<u>10,592.0</u>	<u>10,706.6</u>
Cost and expenses:				
Cost of sales, excluding amortization and impairment of acquired intangible assets	449.1	430.0	1,314.6	1,508.3
Research and development	1,140.9	540.4	2,264.8	1,588.9
Selling, general and administrative	573.1	554.5	1,698.3	1,709.8
Amortization and impairment of acquired intangible assets	82.6	283.9	215.6	422.2
Collaboration profit (loss) sharing	73.0	60.2	166.5	181.8
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	(17.7)	—	95.5
(Gain) loss on fair value remeasurement of contingent consideration	(29.0)	(57.8)	(23.5)	(66.3)
Restructuring charges	—	0.3	—	1.5
Acquired in-process research and development	—	—	75.0	—
Total cost and expenses	<u>2,289.7</u>	<u>1,793.8</u>	<u>5,711.3</u>	<u>5,441.7</u>
Income from operations	1,086.4	1,806.3	4,880.7	5,264.9
Other income (expense), net	(128.6)	(27.3)	(186.1)	132.6
Income before income tax expense and equity in loss of investee, net of tax	957.8	1,779.0	4,694.6	5,397.5
Income tax expense	240.8	211.3	979.0	881.9
Equity in loss of investee, net of tax	13.1	21.8	12.7	66.8
Net income	703.9	1,545.9	3,702.9	4,448.8
Net income (loss) attributable to noncontrolling interests, net of tax	2.4	—	60.2	—
Net income attributable to Biogen Inc.	<u>\$ 701.5</u>	<u>\$ 1,545.9</u>	<u>\$ 3,642.7</u>	<u>\$ 4,448.8</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	\$ 4.47	\$ 8.40	\$ 22.29	\$ 23.38
Diluted earnings per share attributable to Biogen Inc.	\$ 4.46	\$ 8.39	\$ 22.25	\$ 23.35
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	156.9	184.0	163.4	190.3
Diluted earnings per share attributable to Biogen Inc.	157.2	184.2	163.7	190.5

TABLE 2

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

	As of September 30, 2020	As of December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	\$ 3,579.8	\$ 4,475.9
Accounts receivable, net	2,024.9	1,880.5
Inventory	1,027.7	804.2
Other current assets	1,210.7	1,221.2
Total current assets	7,843.1	8,381.8
Marketable securities	1,009.8	1,408.1
Property, plant and equipment, net	3,359.9	3,247.3
Operating lease assets	434.2	427.0
Intangible assets, net	3,323.6	3,527.4
Goodwill	5,755.7	5,757.8
Investments and other assets	3,207.8	4,484.9
TOTAL ASSETS	\$ 24,934.1	\$ 27,234.3
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ —	\$ 1,495.8
Other current liabilities	3,804.0	3,368.0
Total current liabilities	3,804.0	4,863.8
Notes payable	7,425.0	4,459.0
Long-term operating lease liabilities	409.1	412.7
Other long-term liabilities	2,551.5	4,159.7
Equity	10,744.5	13,339.1
TOTAL LIABILITIES AND EQUITY	\$ 24,934.1	\$ 27,234.3

TABLE 3

BIOPEN INC. AND SUBSIDIARIES
GAAP TO NON-GAAP RECONCILIATION:
NET INCOME ATTRIBUTABLE TO BIOPEN INC., DILUTED EARNINGS PER SHARE AND FREE CASH FLOW
(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,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP earnings per share - Diluted	\$ 4.46	\$ 8.39	\$ 22.25	\$ 23.35
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	4.38	0.78	6.64	1.87
Non-GAAP earnings per share - Diluted	\$ 8.84	\$ 9.17	\$ 28.89	\$ 25.22

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,	
	2020	2019
GAAP net income attributable to Biogen Inc.	\$ 701.5	\$ 1,545.9
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets ^A	82.6	283.9
Acquired in-process research and development	—	—
(Gain) loss on fair value remeasurement of contingent consideration ^A	(29.0)	(57.8)
Loss on divestiture of Hillerød, Denmark manufacturing operations ^B	—	(17.7)
Net distribution to noncontrolling interests	7.4	—
Acquisition-related transaction and integration costs	4.2	(0.3)
Accelerated share-based compensation expense	—	6.7
Subtotal: Acquisition and divestiture related costs	65.2	214.8
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation ^C	—	1.3
Restructuring charges ^C	—	0.3
Subtotal: Restructuring, business transformation and other cost saving initiatives	—	1.6
(Gain) loss on equity security investments	82.2	4.6
Sangamo upfront payment and premium paid on the purchase of Sangamo common stock ^D	—	—
Denali upfront payment and premium paid on the purchase of Denali common stock ^E	601.3	—
Premium paid on early debt redemption	—	—
Valuation allowance associated with deferred tax assets ^F	33.3	—
Income tax effect related to reconciling items	(103.4)	(44.8)
Swiss tax reform ^G	—	(54.3)
Amortization included in equity in loss of investee, net of tax ^H	10.3	21.2
Non-GAAP net income attributable to Biogen Inc.	\$ 1,390.4	\$ 1,689.0

	For the Nine Months Ended September 30,	
	2020*	2019
GAAP net income attributable to Biogen Inc.	\$ 3,642.7	\$ 4,448.8
Adjustments:		
Acquisition and divestiture related costs:		
Amortization and impairment of acquired intangible assets ^A	215.6	422.2
Acquired in-process research and development	75.0	—
(Gain) loss on fair value remeasurement of contingent consideration ^A	(23.5)	(66.3)
Loss on divestiture of Hillerød, Denmark manufacturing operations ^B	—	95.5
Net distribution to noncontrolling interests	0.3	—
Stock option expense ^I	—	26.2
Acquisition-related transaction and integration costs	9.4	23.4
Accelerated share-based compensation expense	—	6.7
Subtotal: Acquisition and divestiture related costs	276.8	507.7
Restructuring, business transformation and other cost saving initiatives:		
2017 corporate strategy implementation ^C	—	3.0
Restructuring charges ^C	—	1.5
Subtotal: Restructuring, business transformation and other cost saving initiatives	—	4.5
(Gain) loss on equity security investments	40.2	(197.3)
Sangamo upfront payment and premium paid on the purchase of Sangamo common stock ^D	208.2	—
Denali upfront payment and premium paid on the purchase of Denali common stock ^E	601.3	—
Premium paid on early debt redemption	9.4	—
Valuation allowance associated with deferred tax assets ^F	89.3	—
Income tax effect related to reconciling items	(171.2)	38.2
Swiss tax reform ^G	—	(54.3)
Amortization included in equity in loss of investee, net of tax ^H	33.2	57.6
Non-GAAP net income attributable to Biogen Inc.	\$ 4,729.9	\$ 4,805.2

*Beginning in the third quarter of 2020, material upfront payments associated with significant collaboration and licensing arrangements are excluded from Non-GAAP R&D expense in order to better reflect the Company's core operating performance. Year-to-date Non-GAAP results also reflect this change as the \$125.0 million upfront payment related to the collaboration with Sangamo Therapeutics, Inc. in the second quarter of 2020 has also now been excluded from Non-GAAP R&D expense.

A reconciliation between net cash flow from operations and free cash flow is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Net cash flows provided by operating activities	\$ 1,181.1	\$ 1,694.9	\$ 4,596.9	\$ 5,118.4
Purchases of property, plant, and equipment	(84.1)	(90.1)	(338.8)	(404.1)
Free Cash Flow [^]	\$ 1,097.0	\$ 1,604.8	\$ 4,258.1	\$ 4,714.3

[^] Free cash flow is defined as net cash flow from operations less capital expenditures.

2020 Full Year Guidance: GAAP to Non-GAAP Reconciliation

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

	2020 Full Year Guidance		
	\$	Shares	Diluted EPS
GAAP net income attributable to Biogen Inc.	\$ 4,197.0	161.4	\$ 26.00
Adjustments:			
Amortization and impairment of acquired intangible assets ^A	279.0		
Gain (loss) on fair value remeasurement of contingent consideration ^A	(23.0)		
Acquired in-process research and development	75.0		
Payments related to license agreements ^{D E}	810.0		
Amortization included in equity in loss of investee, net of tax ^H	40.0		
Other	59.0		
Valuation allowance associated with deferred tax assets ^F	89.0		
Income tax effect related to reconciling items	(199.0)		
Non-GAAP net income attributable to Biogen Inc.	\$ 5,327.0	161.4	\$ 33.00

Notes to GAAP to Non-GAAP Reconciliation

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

For the three and nine months ended September 30, 2020, amortization and impairment of acquired intangible assets reflects the impact of a \$19.3 million impairment charge related to one of our in-process research and development (IPR&D) intangible assets. 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 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. We also adjusted the value of our contingent consideration obligations related to BG00011 resulting in a gain of \$61.2 million in the third quarter of 2019.

^B In August 2019 we completed the 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 may be adjusted based on contractual terms. We determined that the operations disposed of in this transaction did not meet the criteria to be classified as discontinued operations under the applicable guidance.

For the nine months ended September 30, 2019, we recorded a 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 reflected a \$17.7 million decrease to our previously recorded loss, reflecting our estimated fair value of the assets and liabilities held for sale as of September 30, 2019, adjusted for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately \$11.2 million and included our initial estimate of the fair value of an

adverse commitment of approximately \$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. In addition, we recorded a tax expense of \$64.7 million related to the transaction during the nine months ended September 30, 2019.

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

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

^d In February 2020 we entered into a collaboration and license agreement with Sangamo Therapeutics, Inc. (Sangamo) to develop and commercialize ST-501 for tauopathies, including Alzheimer's disease; ST-502 for synucleinopathies, including Parkinson's disease; a third neuromuscular disease target; and up to nine additional neurological disease targets to be identified and selected within a five-year period. In connection with the closing of this transaction in April 2020 we purchased \$225.0 million of Sangamo common stock, or approximately 24 million shares at approximately \$9.21 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Sangamo common stock acquired and a charge of approximately \$83.2 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Sangamo common stock. We also made an upfront payment of \$125.0 million that was recorded as research and development expense.

^e In August 2020 we entered into a collaboration and license agreement with Denali Therapeutics Inc. (Denali) to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich kinase 2 (LRRK2) for Parkinson's disease. As part of this collaboration we purchased approximately \$465.0 million of Denali common stock in September 2020, or approximately 13 million shares at approximately \$34.94 per share, which are subject to transfer restrictions. We recorded an asset in investments and other assets in our condensed consolidated balance sheets to reflect the initial fair value of the Denali common stock acquired and a charge of approximately \$41.3 million to research and development expense in our condensed consolidated statements of income to reflect the premium paid for the Denali common stock. We also made an upfront payment of \$560.0 million that was recorded as research and development expense.

^f Income tax expense for the three and nine months ended September 30, 2020, included \$33.3 million and \$89.3 million, respectively, in income tax expense related to a net valuation allowance against certain deferred tax assets, due to the decisions of the U.S. District Court of the Northern District of West Virginia and the U.S. District Court of the District of Delaware that the asserted claims of our U.S. patent No. 8,399,514, which cover the treatment of multiple sclerosis with 480 mg of dimethyl fumarate per day as provided for in our TECFIDERA label, are invalid.

^g During the third quarter of 2019 a new taxing regime in the country and certain cantons of Switzerland was enacted, which we refer to 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.

^h 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.

ⁱ 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.

Use of Non-GAAP Financial Measures

We supplement our GAAP consolidated financial statements and GAAP financial measures with other financial measures, such as free cash flow, adjusted net income and adjusted diluted earnings per share as well as “constant currency” measures that have been adjusted for the change in foreign exchange rates between periods. We believe that these and other Non-GAAP financial measures provide additional insight into the ongoing economics of our business and reflect how we manage our business internally, set operational goals and form the basis of our management incentive programs. Non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

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

1. Acquisitions, divestitures and significant collaboration and licensing arrangements

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

2. Restructuring, business transformation and other cost saving initiatives

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

3. (Gain) loss on equity security investments

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

4. Other items

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

TABLE 4

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

For the Three Months Ended September 30,

	2020			2019		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	\$ 684.2	\$ 283.3	\$ 967.5	\$ 842.0	\$ 280.4	\$ 1,122.4
Interferon**	327.3	146.8	474.1	360.3	169.7	530.0
TYSABRI	304.2	212.3	516.5	263.0	220.6	483.6
FAMPYRA	—	26.8	26.8	—	24.2	24.2
Spinal Muscular Atrophy:						
SPINRAZA	182.5	311.9	494.4	236.7	310.4	547.1
Biosimilars:						
BENEPALI	—	124.2	124.2	—	115.9	115.9
IMRALDI	—	56.2	56.2	—	49.3	49.3
FLIXABI	—	27.5	27.5	—	18.4	18.4
Other Product Revenues:						
FUMADERM	—	3.1	3.1	—	3.8	3.8
Total product revenues	<u>\$ 1,498.2</u>	<u>\$ 1,192.1</u>	<u>\$ 2,690.3</u>	<u>\$ 1,702.0</u>	<u>\$ 1,192.7</u>	<u>\$ 2,894.7</u>

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

**Interferon includes AVONEX and PLEGRIDY.

For the Nine Months Ended September 30,

	2020			2019		
	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):						
Fumarate*	\$ 2,383.4	\$ 875.2	\$ 3,258.6	\$ 2,429.5	\$ 841.9	\$ 3,271.4
Interferon**	965.5	456.0	1,421.5	1,067.3	518.0	1,585.3
TYSABRI	826.0	644.9	1,470.9	772.3	647.0	1,419.3
FAMPYRA	—	78.1	78.1	—	71.2	71.2
Spinal Muscular Atrophy:						
SPINRAZA	628.2	925.8	1,554.0	690.6	863.2	1,553.8
Biosimilars:						
BENEPALI	—	363.9	363.9	—	360.2	360.2
IMRALDI	—	162.6	162.6	—	132.3	132.3
FLIXABI	—	71.8	71.8	—	49.9	49.9
Other Product Revenues:						
FUMADERM	—	9.2	9.2	—	11.6	11.6
Total product revenues	<u>\$ 4,803.1</u>	<u>\$ 3,587.5</u>	<u>\$ 8,390.6</u>	<u>\$ 4,959.7</u>	<u>\$ 3,495.3</u>	<u>\$ 8,455.0</u>

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

**Interferon includes AVONEX and PLEGRIDY.