

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 22, 2020**

BIOGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-19311
(Commission File Number)

33-0112644
(IRS Employer Identification No.)

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

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

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

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0005 par value	BIIB	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On April 22, 2020, Biogen Inc. issued a press release announcing its results of operations and financial condition for the quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

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

Item 9.01 Financial Statements and Exhibits.

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 April 22, 2020

SIGNATURES

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

BIOGEN INC.

By: /s/F. Ty Edmondson

F. Ty Edmondson

Chief Corporate and Compliance Counsel and Assistant Secretary

Date: April 22, 2020



BIOGEN REPORTS Q1 2020 REVENUES OF \$3.5 BILLION

GAAP diluted EPS increased 13%; Non-GAAP diluted EPS increased 31%

Biogen has open BLA and has started to submit modules, expects to complete the U.S. filing for aducanumab in third quarter

Biogen initiated re-dosing study for aducanumab and higher dose study for SPINRAZA

Biogen entered collaboration with Sangamo Therapeutics for gene regulation therapies for neurological disease

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

“The COVID-19 pandemic has created a challenging situation for people and companies throughout the world, and Biogen personally felt the painful impact of this global crisis. During these challenging and unprecedented times, Biogen has continued to deliver on its mission and purpose,” said Michel Vounatsos, Biogen’s Chief Executive Officer. “We have continued to operate our business and deliver our therapies to patients across the world and are especially grateful to our dedicated employees as we continue to execute on our strategy.”

Mr. Vounatsos added, “We delivered strong financial results in the first quarter, and we continued to develop and expand our pipeline, including making good progress toward the U.S. regulatory filing for aducanumab, as well as bolstering our efforts in gene therapy through a collaboration with Sangamo. The magnitude and uncertainty surrounding this pandemic clearly introduce unanticipated and potentially unquantifiable risks to our business and results over the near-term. That said, we believe that compelling opportunities exist in the therapeutic areas we are pursuing. This crisis has had a profound impact on our organization and the world at large. We have taken a broad set of actions, and we will remain fully engaged.”

Financial Results

- First quarter total revenues were \$3,534 million, a 1% increase versus the first quarter of 2019.
 - Multiple sclerosis (MS) revenues, including \$162 million in royalties on the sales of OCREVUS[®], increased 9% versus the prior year to \$2,280 million.
 - SPINRAZA[®] revenues increased 9% versus the prior year to \$565 million.
 - Biosimilars revenues increased 25% versus the prior year to \$219 million.
 - Other revenues decreased 63% versus the prior year to \$109 million primarily due to the sale of approximately \$200 million of hemophilia inventory to Bioverativ Inc. in the first quarter of 2019.
- Biogen estimates that its first quarter product revenues benefitted by approximately \$100 million attributed to accelerated sales due to the COVID-19 pandemic, primarily in Europe.
- Additionally, Biogen’s MS revenues in the U.S. benefitted by approximately \$54 million due to extra shipping days versus the prior year and prior quarter.

- First quarter GAAP net income and diluted earnings per share (EPS) attributable to Biogen Inc. were \$1,399 million and \$8.08, respectively, compared to \$1,409 million and \$7.15, respectively, in the first quarter of 2019.
- First quarter Non-GAAP net income and diluted EPS attributable to Biogen Inc. were \$1,582 million and \$9.14, respectively, compared to \$1,374 million and \$6.98, respectively, in the first quarter of 2019.

(In millions, except per share amounts)	Q1 '20	Q1 '19	Q4 '19	Q1 '20 v. Q1 '19	Q1 '20 v. Q4 '19
Total revenues	\$ 3,534	\$ 3,490	\$ 3,671	1%	(4%)
GAAP net income [#]	\$ 1,399	\$ 1,409	\$ 1,440	(1%)	(3%)
GAAP diluted EPS	\$ 8.08	\$ 7.15	\$ 8.08	13%	0%
Non-GAAP net income [#]	\$ 1,582	\$ 1,374	\$ 1,486	15%	6%
Non-GAAP diluted EPS	\$ 9.14	\$ 6.98	\$ 8.34	31%	10%

[#] 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.

Aducanumab Update

Biogen provided the following update regarding aducanumab, an anti-amyloid beta antibody candidate for the potential treatment of Alzheimer's disease that Biogen is developing in collaboration with Eisai Co., Ltd.:

- Biogen has an open Biological License Application (BLA) with the U.S. Food and Drug Administration (FDA) and has started to submit modules of the filing.
- Biogen has participated in additional formal interactions with the FDA using mechanisms such as Type C meetings and is preparing for a pre-BLA meeting, currently scheduled for the summer of 2020.
- Following the pre-BLA meeting, Biogen expects to complete the U.S. filing in the third quarter of 2020.

Revenue Highlights

(In millions)	Q1 '20	Q1 '19	Q4 '19	Q1 '20 v. Q1 '19	Q1 '20 v. Q4 '19
Multiple Sclerosis:					
Total Fumarate	\$ 1,101	\$ 999	\$ 1,167	10%	(6%)
TECFIDERA®	\$ 1,098	\$ 999	\$ 1,161	10%	(5%)
VUMERITY®	\$ 2	\$ —	\$ 5	NMF	NMF
Total Interferon	\$ 466	\$ 501	\$ 516	(7%)	(10%)
AVONEX®	\$ 366	\$ 397	\$ 411	(8%)	(11%)
PLEGRIDY®	\$ 100	\$ 104	\$ 106	(4%)	(6%)
TYSABRI®	\$ 522	\$ 460	\$ 473	13%	10%
FAMPYRA™	\$ 28	\$ 23	\$ 26	24%	10%
Spinal Muscular Atrophy:					
SPINRAZA	\$ 565	\$ 518	\$ 543	9%	4%
Biosimilars:					
BENEPALI™	\$ 133	\$ 124	\$ 126	8%	6%
IMRALDI™	\$ 62	\$ 36	\$ 52	72%	19%
FLIXABI™	\$ 24	\$ 15	\$ 18	61%	30%
Other Product Revenues:					
FUMADERM™	\$ 3	\$ 4	\$ 4	(20%)	(9%)
Total Product Revenues:	\$ 2,905	\$ 2,680	\$ 2,925	8%	(1%)
OCREVUS Royalties	\$ 162	\$ 112	\$ 205	45%	(21%)
RITUXAN®/GAZYVA® Revenues	\$ 358	\$ 405	\$ 395	(12%)	(9%)
Other Revenues	\$ 109	\$ 292	\$ 146	(63%)	(25%)
Total Revenues	\$ 3,534	\$ 3,490	\$ 3,671	1%	(4%)
MS Product Revenues + OCREVUS Royalties	\$ 2,280	\$ 2,095	\$ 2,388	9%	(5%)

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

- In the first quarter of 2020 channel inventory levels in the U.S. decreased by approximately \$115 million for TECFIDERA, VUMERITY, AVONEX, PLEGRIDY, and TYSABRI combined. This compares to a decrease in inventory levels of approximately \$170 million in the first quarter of 2019 and an increase of approximately \$145 million in the fourth quarter of 2019.
- In the first quarter of 2020 SPINRAZA revenues comprised \$235 million in sales in the U.S. and \$330 million in sales outside the U.S. The number of commercial patients receiving SPINRAZA grew approximately 1% in the U.S. and approximately 10% outside the U.S. versus the fourth quarter of 2019.

Expense Highlights

(In millions)	Q1 '20	Q1 '19	Q4 '19	Q1 '20 v. Q1 '19	Q1 '20 v. Q4 '19
GAAP cost of sales	\$ 454	\$ 602	\$ 447	25%	(2%)
Non-GAAP cost of sales	\$ 454	\$ 602	\$ 447	25%	(2%)
GAAP R&D	\$ 476	\$ 564	\$ 692	16%	31%
Non-GAAP R&D	\$ 476	\$ 564	\$ 692	15%	31%
GAAP SG&A	\$ 570	\$ 568	\$ 665	(0%)	14%
Non-GAAP SG&A	\$ 569	\$ 563	\$ 662	(1%)	14%

Note: Percent changes represented as favorable/(unfavorable)

- R&D expense in the first quarter of 2019 included approximately \$39 million related to Biogen's agreement with Skyhawk Therapeutics, Inc. and approximately \$45 million in net closeout costs for the Phase 3 studies of aducanumab in Alzheimer's disease.
- R&D expense in the fourth quarter of 2019 included \$63 million related to the transaction with Samsung Bioepis Co., Ltd., \$45 million related to the option exercise for BIIB080 (tau ASO), and \$30 million related to collaboration agreements with CAMP4 Therapeutics and Catalyst Biosciences, Inc.

Other Financial Highlights

- In the first quarter of 2020 Biogen recognized a GAAP-only charge of \$75 million related to its acquisition of BIIB118 (previously known as PF-05251749) from Pfizer Inc. (Pfizer).
- For the first quarter of 2020 GAAP and Non-GAAP collaboration profit sharing was \$72 million.
- For the first quarter of 2020 GAAP other expense was \$120 million, which included \$61 million in unrealized losses on investments, principally driven by a decrease in the fair value of Biogen's equity investment in Ionis Pharmaceuticals, Inc. Non-GAAP other expense for the first quarter of 2020 was \$60 million driven by net interest expense, foreign exchange losses, and losses on security sales.
- For the first quarter of 2020 the Company's effective GAAP tax rate was approximately 17%, a reduction from approximately 23% in the first quarter of 2019 due in part to the planned divestiture of our Hillerød, Denmark manufacturing operations and unrealized gains taxable at higher tax rates, both in Q1 2019. For the first quarter of 2020 the Company's effective Non-GAAP tax rate was approximately 17%, compared to approximately 18% in the first quarter of 2019.
- In the first quarter of 2020 Biogen repurchased approximately 7.3 million shares of the Company's common stock for a total value of approximately \$2,220 million.
 - As of March 31, 2020, the share repurchase program authorized in March 2019 had been completed, and approximately \$4,059 million remained under the share repurchase program authorized in December 2019.
- As of March 31, 2020, Biogen had cash, cash equivalents, and marketable securities totaling approximately \$4,830 million and approximately \$5,962 million in notes payable.
- In the first quarter of 2020 the Company generated approximately \$1,467 million in net cash flows from operations.
- For the first quarter of 2020 the Company's weighted average diluted shares were 173 million.

Biogen's Response to COVID-19

To help ensure the health and safety of all stakeholders and society, Biogen has taken several actions in response to the ongoing COVID-19 pandemic, including:

- Implementing policies and practices to safeguard employees and communities to reduce the spread of COVID-19, including asking almost all employees to work from home.
- Providing medical equipment and supplies to Partners Healthcare in Massachusetts to help diagnose COVID-19 in a greater number of people and donating 3D-printed personal protective equipment in Massachusetts and North Carolina.
- Committing \$10 million from the Biogen Foundation to support global response efforts and communities around the world.
- Facilitating volunteer efforts by medically trained employees to serve as healthcare workers on the front lines and by other employees to serve the community.
- Engaging with investigators who may want to evaluate the potential of our interferon therapies to treat COVID-19.
- Launching a consortium with the Broad Institute of MIT and Harvard and Partners Healthcare to build and share a COVID-19 biobank and giving Biogen employees who have recovered from COVID-19, as well as their close contacts, the opportunity to donate samples and medical data.
- Pursuing a process development and manufacturing collaboration with Vir Biotechnology, Inc., which is developing potential antibody therapies for COVID-19.

Potential Business Impacts of COVID-19

Biogen has continued to operate its business to serve the needs of patients and has been continually monitoring for potential impacts:

- **Supply chain:** Biogen has continued to operate its manufacturing facilities and is working with organizations across its supply chain to maintain continuity, while continuing to closely monitor the evolving situation
- **Regulatory interactions:** Biogen is continuing its frequent interactions with regulatory authorities including for aducanumab.
- **Clinical trials:** Biogen is working on a case-by-case basis to continue safely advancing as many of its clinical trials as possible. To help mitigate the impact to its clinical trials, the Company is pursuing innovative approaches such as remote monitoring, remote patient visits, and supporting home infusions. While Biogen does expect there will be some impact to timelines for some of its clinical programs, it still expects the vast majority of the 10 remaining near-term readouts to occur before the end of 2021.

Recent Events

- In April 2020 Biogen, Broad Institute of MIT and Harvard, and Partners HealthCare announced a consortium that will build and share a COVID-19 biobank. The biobank will help scientists study a large collection of de-identified biological and medical data to advance scientific knowledge and search for potential vaccines and treatments for COVID-19. Biogen will help employees who wish to volunteer connect with the project. The initial volunteers are among the first people in Massachusetts to be diagnosed with and recover from COVID-19, as well as close contacts of those individuals.

- In April 2020 the previously announced collaboration between Biogen and Sangamo Therapeutics, Inc. (Sangamo) to develop gene regulation therapies for Alzheimer's disease, Parkinson's disease, neuromuscular disease, and other neurological diseases became effective. The companies will leverage Sangamo's proprietary zinc finger protein technology delivered via adeno-associated virus to modulate the expression of key genes involved in neurological diseases. Upon closing of this transaction, Biogen paid Sangamo \$225 million for the purchase of new Sangamo stock, or approximately 24 million shares at \$9.21 per share, and will pay a \$125 million license fee in the second quarter of 2020. In addition, Biogen may pay Sangamo up to \$2.37 billion in other milestone payments as well as tiered high single digit to sub-teen double-digit royalties.
- In April 2020 Biogen delivered an encore presentation of the Phase 3 topline results for aducanumab at the virtual AAT-AD/PD™ focus meeting. The data in this presentation were previously presented at the Clinical Trials on Alzheimer's Disease (CTAD) annual congress in December 2019.
- In March 2020 the first patient was dosed in the global clinical study, DEVOTE, which is evaluating the safety, tolerability, and potential for even greater efficacy of SPINRAZA when administered at a higher dose than currently approved for the treatment of spinal muscular atrophy (SMA). The Phase 2/3 randomized, controlled, dose-escalating study will be conducted at approximately 50 sites around the world and aims to enroll individuals of all ages with SMA.
- In March 2020 Biogen received the topline data from OPUS, a randomized Phase 2 study exploring the efficacy, safety, and tolerability of natalizumab as an adjunctive therapy in adults with drug-resistant focal epilepsy. Though safety data were in-line with the known safety profile of natalizumab, and target engagement as assessed by alpha-4 integrin saturation was achieved, the primary endpoint was not met. As a result, Biogen has decided to discontinue development of natalizumab in drug-resistant focal epilepsy.
- In March 2020 a study on the efficacy and safety of SPINRAZA in teen and adult patients was published in *Lancet Neurology*, showing clinically meaningful improvements in motor function in a real-world cohort. This study included 139 teens and adults with later-onset SMA (age 16-65 years) from 10 neuromuscular treatment centers in Germany. Patients were followed for 6-14 months and experienced statistically significant increases in HFMSE (Hammersmith Functional Motor Scale Expanded) scores compared to baseline at 6 months, 10 months, and 14 months. Clinically meaningful improvements (≥3 points increase) in HFMSE scores were seen in 28% of patients at 6 months, 35% of patients at 10 months, and 40% of patients at 14 months. The most frequent adverse events were headache, back pain, and nausea.
- In March 2020 the first patient was dosed in the aducanumab re-dosing study, EMBARK, in line with Biogen's commitment to offer aducanumab to eligible patients who were previously in aducanumab clinical studies. EMBARK is a global re-dosing clinical study designed to evaluate aducanumab in eligible Alzheimer's disease patients who were actively enrolled in aducanumab studies (PRIME, EVOLVE, EMERGE, and ENGAGE) in March 2019.
- In March 2020 Biogen completed its acquisition of BIIB118 from Pfizer. BIIB118 is a novel CNS-penetrant small molecule inhibitor of casein kinase 1 (CK1), for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases. In particular, Biogen plans to develop the Phase 1 asset for the treatment of sundowning in Alzheimer's disease and irregular sleep wake rhythm disorder in Parkinson's disease. The purchase included an upfront payment of \$75 million with up to \$635 million in potential additional development and commercialization milestone payments, as well as tiered royalties in the high single digits to sub-teens.

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 22, 2020, and will be accessible through the Investors section of Biogen's website, www.biogen.com. Supplemental information in the form of a slide presentation is also accessible at the same location on the internet and will be subsequently available on the website for at least one month.

About Biogen

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

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

Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our strategy and plans; potential of our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; risks and uncertainties associated with drug development and commercialization; 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; and the direct and indirect impact of COVID-19 on our business and operations, including sales, expenses, supply chain, manufacturing, research and development costs, clinical trials, and employees. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; failure to protect and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations, and financial condition; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; the risk that positive results in a clinical trial may not be replicated in subsequent or

confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; risks relating to technology failures or breaches; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks relating to management and key personnel changes, including attracting and retaining key personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; risks related to commercialization of biosimilars; fluctuations in our operating results; fluctuations in our effective tax rate; risks related to investment in properties; the market, interest, and credit risks associated with our portfolio of marketable securities; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; environmental risks; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; change in control provisions in certain of our collaboration agreements; and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission.

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

Biogen Media Contact: **Biogen Investor Contact:**

David Caouette

Joe Mara

Biogen Inc.

Biogen Inc.

Tel: (781) 464-3260

Tel: (781) 464-2442

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TABLE 1

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

	For the Three Months Ended March 31,	
	2020	2019
Revenues:		
Product, net	\$ 2,904.6	\$ 2,680.0
Revenues from anti-CD20 therapeutic programs	520.4	517.4
Other	109.3	292.4
Total revenues	<u>3,534.3</u>	<u>3,489.8</u>
Cost and expenses:		
Cost of sales, excluding amortization and impairment of acquired intangible assets	454.3	602.0
Research and development	476.3	563.7
Selling, general and administrative	570.1	567.7
Amortization and impairment of acquired intangible assets	71.5	68.2
Collaboration profit (loss) sharing	71.8	58.1
Loss on divestiture of Hillerød, Denmark manufacturing operations	—	115.5
(Gain) loss on fair value remeasurement of contingent consideration	(4.6)	11.5
Restructuring charges	—	0.4
Acquired in-process research and development	75.0	—
Total cost and expenses	<u>1,714.4</u>	<u>1,987.1</u>
Income from operations	1,819.9	1,502.7
Other income (expense), net	(120.5)	357.3
Income before income tax expense and equity in loss of investee, net of tax	1,699.4	1,860.0
Income tax expense	292.0	422.5
Equity in loss of investee, net of tax	14.8	28.7
Net income	1,392.6	1,408.8
Net income (loss) attributable to noncontrolling interests, net of tax	(6.5)	—
Net income attributable to Biogen Inc.	<u>\$ 1,399.1</u>	<u>\$ 1,408.8</u>
Net income per share:		
Basic earnings per share attributable to Biogen Inc.	\$ 8.10	\$ 7.17
Diluted earnings per share attributable to Biogen Inc.	\$ 8.08	\$ 7.15
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	172.8	196.6
Diluted earnings per share attributable to Biogen Inc.	<u>173.1</u>	<u>197.0</u>

TABLE 2

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

	As of March 31, 2020	As of December 31, 2019
ASSETS		
Cash, cash equivalents and marketable securities	\$ 3,860.4	\$ 4,475.9
Accounts receivable, net	2,604.2	2,470.7
Inventory	858.8	804.2
Other current assets	683.8	631.0
Total current assets	8,007.2	8,381.8
Marketable securities	969.5	1,408.1
Property, plant and equipment, net	3,281.6	3,247.3
Operating lease assets	422.0	427.0
Intangible assets, net	3,446.9	3,527.4
Goodwill	5,752.0	5,757.8
Investments and other assets	4,240.0	4,484.9
TOTAL ASSETS	\$ 26,119.2	\$ 27,234.3
LIABILITIES AND EQUITY		
Current portion of notes payable	\$ 1,501.8	\$ 1,495.8
Other current liabilities	3,136.8	3,368.0
Total current liabilities	4,638.6	4,863.8
Notes payable	4,459.9	4,459.0
Long-term operating lease liabilities	403.7	412.7
Other long-term liabilities	4,080.1	4,159.7
Equity	12,536.9	13,339.1
TOTAL LIABILITIES AND EQUITY	\$ 26,119.2	\$ 27,234.3

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, 2020	March 31, 2019	December 31, 2019
GAAP earnings per share - Diluted	\$ 8.08	\$ 7.15	\$ 8.08
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	1.06	(0.17)	0.26
Non-GAAP earnings per share - Diluted	<u>\$ 9.14</u>	<u>\$ 6.98</u>	<u>\$ 8.34</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		
	March 31, 2020	March 31, 2019	December 31, 2019
GAAP net income attributable to Biogen Inc.	\$ 1,399.1	\$ 1,408.8	\$ 1,439.7
Adjustments:			
Acquisition and divestiture related costs:			
Amortization and impairment of acquired intangible assets ^A	71.5	68.2	67.7
Acquired in-process research and development	75.0	—	—
(Gain) loss on fair value remeasurement of contingent consideration	(4.6)	11.5	2.6
Loss on divestiture of Hillerød, Denmark manufacturing operations ^B	—	115.5	(40.2)
Net distribution to noncontrolling interests	—	—	—
Acquisition-related transaction and integration costs	1.2	4.3	4.5
Subtotal: Acquisition and divestiture related costs	143.1	199.5	34.6
Restructuring, business transformation and other cost saving initiatives:			
2017 corporate strategy implementation ^C	—	1.0	0.5
Restructuring charges ^C	—	0.4	—
Subtotal: Restructuring, business transformation and other cost saving initiatives	—	1.4	0.5
(Gain) loss on equity security investments	60.9	(376.1)	(2.9)
Income tax effect related to reconciling items	(38.4)	126.1	(6.9)
Amortization included in equity in loss of investee, net of tax ^D	17.3	14.7	20.6
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 1,582.0</u>	<u>\$ 1,374.4</u>	<u>\$ 1,485.6</u>

Notes to GAAP to Non-GAAP Reconciliation

^A Amortization and impairment of acquired intangible assets for the three months ended March 31, 2020, compared to the prior periods, increased primarily due to a net overall increase in our expected rate of amortization for acquired intangible assets.

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

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, which was subsequently remeasured each reporting period, included a pre-tax loss of \$115.5 million reflecting our estimated fair value of the assets and liabilities held for sale as of March 31, 2019, adjusted for our expected costs to sell our Hillerød, Denmark manufacturing operations of approximately \$10.0 million and includes our initial estimate of the fair value of an adverse commitment of approximately \$120.0 million associated with the guarantee of future minimum batch production at the Hillerød facility. The value of this adverse commitment was determined using a probability-weighted estimate of future manufacturing activity. In addition, we recorded a tax expense of \$59.1 million related to the planned transaction in the first quarter of 2019.

In August 2019 this transaction closed and we received approximately \$881.9 million in cash, which may be adjusted based on 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.

During the fourth quarter of 2019 we recorded a \$40.2 million reduction in our estimate of the future minimum batch commitment utilizing our revised manufacturing forecast, which reflects the impact of forecasted batches of aducanumab, an anti-amyloid beta antibody candidate for the potential treatment of AD that we are developing in collaboration with Eisai Co., Ltd., resulting in a reduction in the pre-tax loss on divestiture to \$55.3 million for 2019. Our estimate of the adverse commitment obligation is approximately \$74.0 million as of March 31, 2020 and December 31, 2019. We developed this estimate using a probability-weighted estimate of future manufacturing activity and may adjust this estimate based upon changes in business conditions, which may result in the increase or reduction of this adverse commitment obligation in subsequent periods. 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. 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 Amortization included in equity in loss of investee, net of tax represents the amortization of the differences between the fair value of our investment in Samsung Bioepis Co., Ltd. and the carrying value of our interest in the underlying net assets of the investee. These basis differences are amortized over their economic life.

Use of Non-GAAP Financial Measures

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

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

1. Acquisition and divestiture related costs

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

2. Restructuring, business transformation and other cost saving initiatives

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

3. (Gain) loss on equity security investments

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

4. Other items

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

TABLE 4

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

	For the Three Months Ended								
	March 31, 2020			March 31, 2019			December 31, 2019		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
Fumarates*	\$ 777.5	\$ 323.3	\$ 1,100.8	\$ 717.7	\$ 281.1	\$ 998.8	\$ 882.5	\$ 284.3	\$ 1,166.8
Interferon**	292.6	173.4	466.0	327.3	173.6	500.9	359.3	157.2	516.5
TYSABRI	277.7	244.7	522.4	245.0	215.4	460.4	269.5	203.4	472.9
FAMPYRA	—	28.3	28.3	—	22.9	22.9	—	25.9	25.9
Spinal Muscular Atrophy:									
SPINRAZA	235.4	329.6	565.0	223.3	295.2	518.5	242.8	300.4	543.2
Biosimilars:									
BENEPALI	—	133.5	133.5	—	124.0	124.0	—	126.0	126.0
IMRALDI	—	61.6	61.6	—	35.7	35.7	—	51.7	51.7
FLIXABI	—	23.7	23.7	—	14.7	14.7	—	18.2	18.2
Other Product Revenues:									
FUMADERM	—	3.3	3.3	—	4.1	4.1	—	3.6	3.6
Total product revenues	<u>\$ 1,583.2</u>	<u>\$ 1,321.4</u>	<u>\$ 2,904.6</u>	<u>\$ 1,513.3</u>	<u>\$ 1,166.7</u>	<u>\$ 2,680.0</u>	<u>\$ 1,754.1</u>	<u>\$ 1,170.7</u>	<u>\$ 2,924.8</u>

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

**Interferon includes AVONEX and PLEGRIDY.