

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 21, 2016

**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))

## **Item 2.02 Results of Operations and Financial Condition.**

On April 21, 2016, Biogen Inc. issued a press release announcing its results of operations and financial condition for the first quarter ended March 31, 2016. 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 on the Exhibit Index immediately preceding such exhibit is furnished as part of this Current Report on Form 8-K.

## 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/Steven N. Avruch  
Steven N. Avruch  
Chief Corporation Counsel and Assistant Secretary

Date: April 21, 2016

## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Biogen's press release dated April 21, 2016.



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

Jason Glashow                      Matt Calistri  
 Biogen Inc.                              Biogen Inc.  
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**BIOGEN REPORTS FIRST QUARTER 2016 REVENUES OF \$2.7 BILLION**

*First quarter 2016 Non-GAAP diluted EPS rise 25%; GAAP diluted EPS rise 27%*

**Cambridge, Mass., April 21, 2016** -- Biogen Inc. (NASDAQ: BIIB) today reported first quarter 2016 financial results, including:

- Total revenues of \$2.7 billion, a 7% increase versus the same period in the prior year. Growth was driven by a 15% increase in worldwide TECFIDERA<sup>®</sup> revenues as well as increased revenues from ELOCTATE<sup>®</sup> and ALPROLIX<sup>®</sup>. Revenues were partially offset by a decrease in worldwide interferon sales.
  - Foreign exchange, including a \$26 million reduction in hedging gains, negatively impacted total revenues by approximately \$50 million compared to the first quarter of 2015.
- Non-GAAP diluted earnings per share (EPS) of \$4.79, a 25% increase versus the same period in the prior year. Growth was driven by a combination of increased revenues, lower SG&A and R&D expense, and a lower share count.
- Non-GAAP net income attributable to Biogen Inc. increased 17% to \$1.0 billion.
- GAAP diluted EPS of \$4.43, a 27% increase versus the same period in the prior year.
- GAAP net income attributable to Biogen Inc. increased 18% to \$971 million.

(In millions, except per share amounts)	Q1 '16	Q4 '15	Q1 '15	Q1 '16 v. Q4 '15	Q1 '16 v. Q1 '15
Total revenues	\$ 2,727	\$ 2,839	\$ 2,555	(4%)	7%
Non-GAAP net income*	\$ 1,049	\$ 995	\$ 900	5%	17%
Non-GAAP EPS	\$ 4.79	\$ 4.50	\$ 3.82	6%	25%
GAAP net income*	\$ 971	\$ 832	\$ 823	17%	18%
GAAP EPS	\$ 4.43	\$ 3.77	\$ 3.49	18%	27%

\*Net income attributable to Biogen Inc.

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

“Our leading multiple sclerosis portfolio, a growing hemophilia business, and our ongoing focus on managing expenses led to robust earnings growth in the first quarter,” said Chief Executive Officer George A. Scangos, Ph.D. “We are pleased with the recent European approval of BENEPALI<sup>®</sup> and positive CHMP opinion for FLIXABI<sup>®</sup>, both anti-TNF biosimilars. We are also encouraged by the recent positive CHMP opinion of ALPROLIX for hemophilia B in Europe.”

“The remainder of 2016 will be an exciting period as we look to advance a number of potential breakthrough therapies in the clinic,” Dr. Scangos continued. “We are executing Phase 3 clinical trials for aducanumab in early Alzheimer’s disease and, along with our collaboration partner Ionis, we are progressing nusinersen in spinal muscular atrophy. In the coming months, we expect opicinumab (anti-LINGO) Phase 2 data to provide us with a better understanding of its potential as a reparative therapy for multiple sclerosis.”

### Revenue Highlights

(In millions)	Q1 '16	Q4 '15	Q1 '15	Q1 '16 v. Q4 '15	Q1 '16 v. Q1 '15
<b>Multiple Sclerosis (MS):</b>					
TECFIDERA	\$ 946	\$ 993	\$ 825	(5%)	15%
Total Interferon	\$ 670	\$ 740	\$ 755	(9%)	(11%)
AVONEX	\$ 564	\$ 637	\$ 693	(11%)	(19%)
PLEGRIDY	\$ 106	\$ 103	\$ 62	4%	72%
TYSABRI	\$ 477	\$ 481	\$ 463	(1%)	3%
FAMPYRA	\$ 20	\$ 28	\$ 20	(27%)	1%
<b>Hemophilia:</b>					
ALPROLIX	\$ 75	\$ 71	\$ 43	5%	74%
ELOCTATE	\$ 108	\$ 101	\$ 54	6%	101%
<b>Other Product Revenues:</b>					
FUMADERM	\$ 11	\$ 13	\$ 14	(10%)	(16%)
BENEPALI	\$ 2	\$ —	\$ —	N/A	N/A
<b>Total Product Revenues:</b>	<b>\$ 2,309</b>	<b>\$ 2,426</b>	<b>\$ 2,172</b>	<b>(5%)</b>	<b>6%</b>
Anti-CD20 Revenues	\$ 329	\$ 334	\$ 331	(1%)	(0%)
Other Revenues	\$ 88	\$ 80	\$ 52	11%	69%
<b>Total Revenues</b>	<b>\$ 2,727</b>	<b>\$ 2,839</b>	<b>\$ 2,555</b>	<b>(4%)</b>	<b>7%</b>

Note: Numbers may not foot due to rounding.

### Expense Highlights

- R&D expense was \$437 million compared to \$542 million in the fourth quarter of 2015 and \$461 million in the first quarter of 2015.
  - R&D expense decreased 19% versus the fourth quarter of 2015, reflecting a \$60 million payment made to Mitsubishi Tanabe Pharma Corporation in the fourth quarter of 2015 along with the timing of clinical manufacturing runs and other R&D activities.
- SG&A expense was \$497 million compared to \$583 million in the fourth quarter of 2015 and \$560 million in the first quarter of 2015. The company remains focused on achieving additional savings in non-labor expenses, with the objective of reducing lower priority fees and services expenses.

## **Other Financial Highlights**

- For the first quarter of 2016, the Company's weighted average diluted shares were 219 million.
- At the end of the first quarter of 2016, Biogen had cash, cash equivalents and marketable securities totaling approximately \$6.8 billion, and \$6.5 billion in notes payable and other financing arrangements.

## **Recent Events**

- This week, Biogen is presenting new data supporting the Company's marketed and pipeline MS therapies at the 68<sup>th</sup> American Academy of Neurology (AAN) Annual Meeting. Presentations include efficacy data for TECFIDERA in newly diagnosed patients; data highlighting efficacy on key cognitive outcomes and the reversibility of the targeted mechanism of action of ZINBRYTA<sup>TM</sup>; 10 year real-world evidence of the proven long-term efficacy of TYSABRI<sup>®</sup> in patients with high disease activity; and analyses showing that PLEGRIDY<sup>®</sup> reduces conversion of MRI lesions to T1 black holes.
- At this week's AAN Meeting, Biogen's collaboration partner Ionis Pharmaceuticals also presented an update from its ongoing open-label Phase 2 study of nusinersen in infants with spinal muscular atrophy.
- In April 2016, Samsung Bioepis, the joint venture between Biogen and Samsung BioLogics, received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommending that marketing authorisation be granted for FLIXABI, an infliximab biosimilar candidate referencing Remicade<sup>®</sup>. If approved, FLIXABI will be the second anti-TNF biosimilar manufactured and commercialized by Biogen in the European Union (EU).
- In March 2016, Biogen announced the appointment of Michel Vounatsos as Executive Vice President and Chief Commercial Officer effective April 18, 2016. Mr. Vounatsos joins Biogen following a distinguished 20 year career at Merck.
- In February 2016, Swedish Orphan Biovitrum AB (publ) (Sobi) and Biogen received a positive opinion from the CHMP recommending that marketing authorisation be granted for ALPROLIX, a recombinant factor IX Fc fusion protein therapy for the treatment of hemophilia B.
- In February 2016, the Roche Group announced that the US Food and Drug Administration approved Gazyva<sup>®</sup> plus bendamustine chemotherapy followed by Gazyva alone as a new treatment for people with follicular lymphoma who did not respond to a Rituxan<sup>®</sup>-containing regimen, or had their follicular lymphoma return after such treatment. Follicular lymphoma is the most common type of indolent (slow-growing) non-Hodgkin lymphoma (NHL) and accounts for approximately one in five cases of NHL. In the U.S., Biogen shares operating profits and losses relating to GAZYVA with Genentech, a Roche Group company.
- In February 2016, Biogen announced that it joined the Centre for Therapeutic Target Validation (CTTV), the pioneering public-private collaboration to improve the success rate for discovering new medicines. The CTTV fosters deep, ongoing interactions between academic and industry members for the purpose of developing open, transformative approaches to selecting and validating novel targets in drug development.

- In January 2016, following approval from the European Commission, Biogen launched BENEPAI, the first etanercept biosimilar referencing Enbrel<sup>®</sup> to be approved in the EU. BENEPAI is now available in the UK, Germany, Denmark, Norway, Sweden, and the Netherlands.

### **Conference Call and Webcast**

The Company's earnings conference call for the first quarter will be broadcast via the internet at 8:30 a.m. EDT on April 21, 2016, and will be accessible through the Investors section of Biogen's homepage, [www.biogen.com](http://www.biogen.com). Supplemental information in the form of a slide presentation will also be accessible at the same location on the internet at the time of the conference call and will be subsequently available on the website for at least one month.

### **About Biogen**

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune, and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit [www.biogen.com](http://www.biogen.com). Follow us on [Twitter](#).

### **Safe Harbor**

This press release contains forward-looking statements, including statements relating to: Biogen's commercial business; pipeline and collaboration programs; anticipated data readouts; and other financial matters. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements.

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 principal products; failure to compete effectively due to significant product competition in the markets for our products; difficulties in obtaining and maintaining adequate coverage, pricing and reimbursement for our products; risks associated with current and potential future healthcare reforms; the occurrence of adverse safety events, restrictions on use with our products or product liability claims; 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; 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 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; problems with our manufacturing processes; our dependence on collaborators and other third parties for the development, regulatory approval and commercialization of products and other aspects of our business, which are outside of our control; failure to achieve the anticipated benefits and savings from our corporate restructuring efforts; failure to manage our growth and execute our growth initiatives; risks relating to technology failures or breaches; failure to comply with legal and regulatory requirements; risks related to indebtedness; the risks of doing business internationally, including currency exchange rate fluctuations; charges and other costs relating to our properties; fluctuations in our effective tax rate; risks relating to investment in and expansion of manufacturing capacity for future clinical and commercial requirements; risks related to commercialization of biosimilars; risks related to investment in properties; the market, interest and credit



risks associated with our portfolio of marketable securities; risks relating to stock repurchase programs; risks relating to access to capital and credit markets; environmental risks; risks relating to the sale and distribution by third parties of counterfeit 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 SEC.

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

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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 March 31,	
	2016	2015
<b>Revenues:</b>		
Product, net	\$ 2,309.4	\$ 2,172.3
Revenues from anti-CD20 therapeutic programs	329.5	330.6
Other	87.9	52.0
Total revenues	<u>2,726.8</u>	<u>2,555.0</u>
<b>Cost and expenses:</b>		
Cost of sales, excluding amortization of acquired intangible assets	313.0	312.4
Research and development	437.3	460.5
Selling, general and administrative	497.3	560.4
Amortization of acquired intangible assets	88.8	95.9
Restructuring Charges	9.7	—
(Gain) loss on fair value remeasurement of contingent consideration	2.3	7.8
Total cost and expenses	<u>1,348.4</u>	<u>1,437.1</u>
<b>Income from operations</b>	<u>1,378.4</u>	<u>1,117.9</u>
Other income (expense), net	(52.8)	(15.0)
<b>Income before income tax expense and equity in loss of investee, net of tax</b>	<u>1,325.6</u>	<u>1,102.9</u>
Income tax expense	356.4	281.9
Equity in loss of investee, net of tax	—	0.8
<b>Net income</b>	<u>969.2</u>	<u>820.2</u>
<b>Net income (loss) attributable to noncontrolling interests, net of tax</b>	<u>(1.7)</u>	<u>(2.4)</u>
<b>Net income attributable to Biogen Inc.</b>	<u>\$ 970.9</u>	<u>\$ 822.5</u>
<b>Net income per share:</b>		
Basic earnings per share attributable to Biogen Inc.	<u>\$ 4.44</u>	<u>\$ 3.50</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 4.43</u>	<u>\$ 3.49</u>
<b>Weighted-average shares used in calculating:</b>		
Basic earnings per share attributable to Biogen Inc.	<u>218.9</u>	<u>235.0</u>
Diluted earnings per share attributable to Biogen Inc.	<u>219.3</u>	<u>235.6</u>

TABLE 2

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

	As of March 31, 2016	As of December 31, 2015
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 3,585.4	\$ 3,428.5
Accounts receivable, net	1,395.1	1,227.0
Inventory	964.6	893.4
Other current assets	1,256.2	1,151.4
Total current assets	7,201.3	6,700.3
Marketable securities	3,189.8	2,760.4
Property, plant and equipment, net	2,258.9	2,187.6
Intangible assets, net	4,012.2	4,085.1
Goodwill	2,917.9	2,663.8
Investments and other assets	1,094.6	1,107.6
<b>TOTAL ASSETS</b>	<b>\$ 20,674.7</b>	<b>\$ 19,504.8</b>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities	\$ 2,776.6	\$ 2,577.7
Long-term notes payable and other financing arrangements	6,535.6	6,521.5
Other long-term liabilities	1,034.4	1,030.7
Equity	10,328.1	9,374.9
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 20,674.7</b>	<b>\$ 19,504.8</b>

**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, 2016	December 31, 2015	March 31, 2015
GAAP earnings per share - Diluted	\$ 4.43	\$ 3.77	\$ 3.49
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.36	0.74	0.33
Non-GAAP earnings per share - Diluted	\$ 4.79	\$ 4.50	\$ 3.82

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, 2016	December 31, 2015	March 31, 2015
GAAP net income attributable to Biogen Inc.	\$ 970.9	\$ 831.6	\$ 822.5
Adjustments:			
Amortization of acquired intangible assets	85.7	92.0	92.5
(Gain) loss on fair value remeasurement of contingent consideration	2.3	24.6	7.8
Restructuring charges	9.7	93.4	—
Income tax effect related to reconciling items	(19.2)	(46.9)	(22.6)
Non-GAAP net income attributable to Biogen Inc.	\$ 1,049.4	\$ 994.7	\$ 900.2

**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 forms 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. Purchase accounting and merger-related adjustments.

We exclude certain purchase accounting related items associated with the acquisition of businesses, assets and amounts in relation to the consolidation of variable interest entities for which we are the primary beneficiary. These adjustments include charges for in-process research and development, the amortization of certain acquired intangible assets and fair value remeasurement of our contingent consideration obligations.

2. Other items.

We evaluate other items 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.

TABLE 4

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

(In millions)	For the Three Months Ended								
	March 31, 2016			December 31, 2015			March 31, 2015		
	United States	Rest of World	Total	United States	Rest of World	Total	United States	Rest of World	Total
Multiple Sclerosis (MS):									
TECFIDERA	\$ 744.3	\$ 201.6	\$ 945.9	\$ 785.1	\$ 207.7	\$ 992.8	\$ 648.3	\$ 176.6	\$ 824.9
Interferon*	467.5	202.9	670.4	506.3	233.4	739.7	518.2	236.3	754.5
TYSABRI	288.2	188.8	477.0	277.8	202.9	480.7	272.9	189.7	462.6
FAMPYRA	—	20.2	20.2	—	27.6	27.6	—	20.0	20.0
Hemophilia:									
ELOCTATE	98.7	9.0	107.7	95.9	5.2	101.2	53.2	0.4	53.6
ALPROLIX	64.6	10.4	75.0	60.0	11.3	71.3	41.1	2.0	43.1
Other product revenues:									
FUMADERM	—	11.4	11.4	—	12.6	12.6	—	13.6	13.6
BENEPALI	—	1.8	1.8	—	—	—	—	—	—
Total product revenues	<u>\$ 1,663.3</u>	<u>\$ 646.1</u>	<u>\$ 2,309.4</u>	<u>\$ 1,725.1</u>	<u>\$ 700.7</u>	<u>\$ 2,425.9</u>	<u>\$ 1,533.7</u>	<u>\$ 638.6</u>	<u>\$ 2,172.3</u>

\*Interferon includes AVONEX and PLEGRIDY