



## Biogen 2015 Revenues Increase 11% to \$10.8 Billion

January 27, 2016

2015 Non-GAAP Diluted EPS Rise 23%, GAAP Diluted EPS Rise 24%

*Company advances leading neuroscience portfolio including programs in Alzheimer's disease, spinal muscular atrophy, and a repair & regeneration therapy for multiple sclerosis*

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--Biogen Inc. (NASDAQ: BII) today reported full year and fourth quarter 2015 results, including full year revenues of \$10.8 billion, an 11% increase versus 2014. Full year 2015 Non-GAAP diluted earnings per share (EPS) were \$17.01, an increase of 23% versus 2014. Non-GAAP net income attributable to Biogen Inc. for the year was \$3.9 billion, an increase of 20% versus the prior year.

On a reported basis, GAAP diluted EPS for 2015 were \$15.34, an increase of 24% versus 2014. GAAP net income attributable to Biogen Inc. for 2015 was \$3.5 billion, an increase of 21% versus 2014. (A reconciliation of GAAP to Non-GAAP full year and quarterly financial results can be found in Table 3 at the end of this release).

"We saw solid performance in our industry leading multiple sclerosis portfolio and strong adoption of our hemophilia therapies," said Chief Executive Officer George A. Scangos, Ph.D. "We continue to make investments in important and promising programs that we believe have the potential to help people suffering from devastating diseases, and we are also excited about the potential to launch three new products this year: BENEPALI<sup>®</sup>, ZINBRYTA<sup>™</sup>, and an infliximab biosimilar."

"The year ahead will be very exciting for our pipeline, as we look to advance several potential breakthrough programs," Dr. Scangos continued. "We are executing two Phase 3 clinical trials for aducanumab in Alzheimer's disease, and are awaiting new data from two other Alzheimer's candidates. We are encouraged by open label Phase 2 data for nusinersen for spinal muscular atrophy, the leading genetic cause of infant mortality, and are advancing two Phase 3 studies in infants and children with our collaboration partner Ionis. We expect to see Phase 2 data for anti-LINGO in multiple sclerosis in the middle of the year, allowing us to better understand its potential to reverse or repair damage caused by the disease. We are also focused on expanding our leadership in neurology by continuing to attract top talent and using new technology, novel science and a better understanding of disease biology to pursue early stage programs in areas such as Parkinson's disease and ALS."

### **Full Year 2015 Financial Highlights**

- TECFIDERA<sup>®</sup> revenues were \$3.6 billion compared to \$2.9 billion in 2014. These results consisted of \$2.9 billion in U.S. sales and \$730 million in sales outside the U.S. compared to \$2.4 billion and \$483 million, respectively, in 2014.
- Interferon revenues, including AVONEX<sup>®</sup> and PLEGRIDY<sup>®</sup>, were \$3.0 billion compared to \$3.1 billion in 2014. These results consisted of \$2.0 billion in U.S. sales and \$951 million in sales outside the U.S. compared to \$2.0 billion and \$1.1 billion, respectively, in 2014.
- TYSABRI<sup>®</sup> revenues were \$1.9 billion compared to \$2.0 billion in 2014. These results consisted of \$1.1 billion in U.S. sales and \$783 million in sales outside the U.S. compared to \$1.0 billion and \$934 million, respectively, in 2014.
- Net revenues relating to RITUXAN<sup>®</sup> and GAZYVA<sup>®</sup> from our unconsolidated joint business arrangement were \$1.3 billion compared to \$1.2 billion in 2014.
- ELOCTATE<sup>®</sup> revenues were \$320 million compared to \$58 million in 2014.
- ALPROLIX<sup>®</sup> revenues were \$234 million compared to \$76 million in 2014.
- Revenues for FAMPYRA<sup>™</sup> and FUMADERM<sup>™</sup> were \$141 million compared to \$143 million in 2014.
- Royalty revenues were \$48 million compared to \$177 million in 2014.
- Corporate partner revenues were \$189 million compared to \$128 million in 2014.
- Foreign exchange, offset by \$166 million in net hedging gains, weakened total revenues by approximately \$227 million compared to 2014.
- Non-GAAP and GAAP SG&A expense was \$2.1 billion compared to \$2.2 billion in 2014.
- Non-GAAP and GAAP R&D expense was \$2.0 billion compared to \$1.9 billion in 2014.

### **Fourth Quarter 2015 Financial Highlights**

- TECFIDERA revenues were \$993 million compared to \$916 million in the same quarter last year. These results consisted of \$785 million in U.S. sales and \$208 million in sales outside the U.S. compared to \$743 million and \$173 million,

respectively, in the fourth quarter of 2014. TECFIDERA U.S. sales included 13 shipping weeks in the fourth quarter of 2015 versus 14 in the fourth quarter of 2014.

- TECFIDERA revenues in the fourth quarter of 2015 increased 6% versus the third quarter of 2015, including a 4% increase in U.S. revenues, which benefited by approximately \$30 million due to an increase of inventory in the wholesale channel.
- Interferon revenues, including AVONEX and PLEGRIDY, were \$740 million compared to \$777 million in the same quarter last year. These results consisted of \$506 million in U.S. sales and \$233 million in sales outside the U.S. compared to \$528 million and \$249 million, respectively, in the fourth quarter of 2014. AVONEX U.S. sales included 13 shipping weeks in the fourth quarter of 2015 versus 14 in the fourth quarter of 2014.
- TYSABRI revenues were \$481 million compared to \$484 million in the same quarter last year. These results consisted of \$278 million in U.S. sales and \$203 million in sales outside the U.S. compared to \$266 million and \$218 million, respectively, in the fourth quarter of 2014.
- Net revenues relating to RITUXAN and GAZYVA from our unconsolidated joint business arrangement were \$334 million compared to \$305 million in the same quarter last year.
- ELOCTATE revenues were \$101 million compared to \$37 million in the same quarter last year.
- ALPROLIX revenues were \$71 million compared to \$40 million in the same quarter last year.
- Revenues for FAMPYRA and FUMADERM were \$40 million compared to \$33 million in the same quarter last year.
- Royalty revenues were \$10 million compared to \$31 million in the same quarter last year.
- Corporate partner revenues were \$69 million compared to \$18 million in the same quarter last year.
  - Corporate partner revenues in the fourth quarter of 2015 increased 74% versus the third quarter of 2015 related to contract manufacturing for Samsung Bioepis and another strategic partner.
- Foreign exchange, offset by \$40 million in net hedging gains, weakened total revenues by approximately \$35 million compared to the same quarter last year.
- Non-GAAP SG&A expense was \$583 million compared to \$573 million in the same quarter last year. GAAP SG&A expense was \$583 million compared to \$574 million in the same quarter last year.
- Non-GAAP R&D expense was \$542 million compared to \$499 million in the same quarter last year. GAAP R&D expense was \$542 million compared to \$500 million in the same quarter last year.
- GAAP diluted EPS were \$3.77, an increase of 1% versus the fourth quarter of 2014. GAAP net income attributable to Biogen for the quarter was \$832 million, a decrease of 6% versus the fourth quarter of 2014. GAAP results in 2015 include the impact of a \$93 million pretax restructuring charge for employee severance and R&D program termination costs in connection with the cost reduction initiative announced in October 2015.
- Non-GAAP diluted EPS were \$4.50, an increase of 10% versus the fourth quarter of 2014. Non-GAAP net income attributable to Biogen for the quarter was \$995 million, an increase of 3% from the fourth quarter of 2014.

#### **Capital Allocation Highlights**

- In 2015, Biogen purchased approximately 16.8 million shares of its common stock, completing its previously authorized \$5.0 billion share repurchase program.
- For 2015, the Company's full year weighted average diluted shares were 231 million. For the fourth quarter of 2015, the Company's weighted average diluted shares were 221 million. The Company ended the year with approximately 219 million basic shares outstanding.
- At the end of 2015, Biogen had cash, cash equivalents and marketable securities totaling approximately \$6.2 billion, and \$6.5 billion in notes payable and other financing arrangements.

#### **2016 Financial Guidance**

Biogen also announced its full year 2016 financial guidance. This guidance consists of the following components:

- Revenue is expected to be approximately \$11.1 to \$11.3 billion.
- R&D expense is expected to be approximately 19% to 20% of total revenue.
  - The Company plans to continue to invest in a number of R&D programs across its emerging mid- and late-stage pipeline, including aducanumab for Alzheimer's disease, nusinersen for spinal muscular atrophy, raxatrigine for trigeminal neuralgia and amiselimod for inflammatory bowel disease.
- SG&A expense is expected to be approximately 17% to 18% of total revenue.
  - The Company anticipates an approximately 200 basis point improvement over 2015 driven by the headcount reduction announced in October 2015 as well as a reduction in fees and services expenses.

- Non-GAAP diluted EPS is expected to be between \$18.30 and \$18.60.
- GAAP diluted EPS is expected to be between \$16.85 and \$17.15.

Biogen may incur charges, realize gains or experience other events in 2016 that could cause actual results to vary from this guidance.

In 2016, the Company plans to provide one update to its annual financial guidance, which is expected to be provided in connection with its second quarter earnings release. This approach is intended to synchronize guidance with internal business planning processes and to ensure a continued focus on long-term value creation.

### **Recent Company Events**

- In November 2015, Biogen and Swedish Orphan Biovitrum AB (Sobi) announced that the European Commission approved ELOCTA<sup>®</sup> (rFVIIIIFc) for the treatment of hemophilia A in all 28 European Union (EU) member states, as well as Iceland, Liechtenstein and Norway. ELOCTA, the trade name for ELOCTATE in Sobi's territory, is the first hemophilia A treatment in the EU to offer prolonged protection against bleeding episodes with prophylactic injections every three to five days. Sobi will lead commercialization in Europe.
- In December 2015, Biogen presented new data demonstrating that ELOCTATE and ALPROLIX may effectively manage target joint bleeding and maintain low annualized bleeding rates in people with severe hemophilia A and B. The data were presented by Biogen and Sobi at the 57<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition.
- In December 2015, Biogen initiated a Phase 1/2 clinical study of IONIS-SOD1<sub>Rx</sub> (BIIB067) in patients with amyotrophic lateral sclerosis (ALS), including patients with a mutation in superoxide dismutase 1 (SOD1), which accounts for approximately 2% of ALS patients. IONIS-SOD1<sub>Rx</sub> is an antisense oligonucleotide designed to reduce the production of SOD1 and is being developed in collaboration with Ionis Pharmaceuticals.
- In January 2016, Samsung Bioepis, the joint venture between Biogen and Samsung Biologics, received approval from the European Commission for BENEPAI, the first etanercept biosimilar referencing Enbrel<sup>®</sup> to be approved in the EU. BENEPAI will be manufactured and commercialized in the EU by Biogen and is the first product from its biosimilar pipeline to be approved.

### **Conference Call and Webcast**

The Company's earnings conference call for the fourth quarter will be broadcast via the internet at 8:30 a.m. EST on January 27, 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 to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. 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 product labeling, press releases and additional information about the Company, please visit [www.biogen.com](http://www.biogen.com).

### **Safe Harbor**

This press release contains forward-looking statements, including statements relating to: Biogen's commercial business and prospects; investments in, and potential of, pipeline and collaboration programs; anticipated timing of data readouts; potential product approvals and timing of launches; 2016 full year guidance 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 and commercialization of products and other aspects of our business, which are outside of our control; failure to manage our growth and execute our growth initiatives; failure to achieve the anticipated benefits and savings from our corporate restructuring efforts; 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; the market, interest and credit risks associated with our portfolio of marketable securities; risks relating to our ability to repurchase stock, including at favorable prices; 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.

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

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2015	2014	2015	2014
<b>Revenues:</b>				
Product, net	\$ 2,425.9	\$ 2,287.0	\$ 9,188.5	\$ 8,203.4
Unconsolidated joint business	333.9	304.5	1,339.2	1,195.4
Royalty	10.1	31.4	47.5	176.7
Corporate partner	69.4	17.8	188.6	127.8
Total revenues	<u>2,839.3</u>	<u>2,640.7</u>	<u>10,763.8</u>	<u>9,703.3</u>
<b>Cost and expenses:</b>				
Cost of sales, excluding amortization of acquired intangible assets	331.8	297.3	1,240.4	1,171.0
Research and development	541.7	500.1	2,012.8	1,893.4
Selling, general and administrative	583.0	573.6	2,113.1	2,232.3
Amortization of acquired intangible assets	96.6	107.2	382.6	489.8
Restructuring charges	93.4	-	93.4	-
(Gain) loss on fair value remeasurement of contingent consideration	24.6	7.3	30.5	(38.9)
Total cost and expenses	<u>1,671.1</u>	<u>1,485.5</u>	<u>5,872.8</u>	<u>5,747.7</u>
Gain on sale of rights	-	4.6	-	16.8
Income from operations	1,168.2	1,159.8	4,891.0	3,972.4
Other income (expense), net	(82.4)	(8.8)	(123.7)	(25.8)
Income before income tax expense and equity in loss of investee, net of tax	1,085.8	1,151.0	4,767.3	3,946.6
Income tax expense	257.1	268.2	1,161.6	989.9
Equity in loss of investee, net of tax	-	0.2	12.5	15.1
Net income	828.7	882.6	3,593.2	2,941.6
Net income (loss) attributable to noncontrolling interests, net of tax	(2.9)	(0.9)	46.2	6.8
Net income attributable to Biogen Inc.	<u>\$ 831.6</u>	<u>\$ 883.5</u>	<u>\$ 3,547.0</u>	<u>\$ 2,934.8</u>
<b>Net income per share:</b>				
Basic earnings per share attributable to Biogen Inc.	<u>\$ 3.77</u>	<u>\$ 3.75</u>	<u>\$ 15.38</u>	<u>\$ 12.42</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 3.77</u>	<u>\$ 3.74</u>	<u>\$ 15.34</u>	<u>\$ 12.37</u>
<b>Weighted-average shares used in calculating:</b>				
Basic earnings per share attributable to Biogen Inc.	<u>220.4</u>	<u>235.5</u>	<u>230.7</u>	<u>236.4</u>
Diluted earnings per share attributable to Biogen Inc.	<u>220.8</u>	<u>236.3</u>	<u>231.2</u>	<u>237.2</u>

TABLE 2  
BIOGEN INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(unaudited, in millions)

	As of December 31, 2015	As of December 31, 2014
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 3,428.5	\$ 1,845.4
Accounts receivable, net	1,227.0	1,292.4
Inventory	893.4	804.0
Other current assets	1,151.4	593.2
Total current assets	<u>6,700.3</u>	<u>4,535.0</u>
Marketable securities	2,760.4	1,470.7
Property, plant and equipment, net	2,187.6	1,765.7
Intangible assets, net	4,085.1	4,028.5
Goodwill	2,663.8	1,760.2
Investments and other assets	1,107.6	754.6
TOTAL ASSETS	<u>\$ 19,504.8</u>	<u>\$ 14,314.7</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities	\$ 2,577.7	\$ 2,218.1

Notes payable and other financing arrangements	6,521.5	580.3
Other long-term liabilities	1,030.7	702.3
Equity	9,374.9	10,814.0
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>\$ 19,504.8</b>	<b>\$ 14,314.7</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 basis and on a Non-GAAP basis is as follows:

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2015	2014	2015	2014
GAAP earnings per share - Diluted	\$ 3.77	\$ 3.74	\$ 15.34	\$ 12.37
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.74	0.35	1.67	1.46
Non-GAAP earnings per share - Diluted	<u>\$ 4.50</u>	<u>\$ 4.09</u>	<u>\$ 17.01</u>	<u>\$ 13.83</u>

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

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2015	2014	2015	2014
GAAP net income attributable to Biogen Inc.	\$ 831.6	\$ 883.5	\$ 3,547.0	\$ 2,934.8
Adjustments:				
Amortization of acquired intangible assets	92.0	101.4	365.3	472.9
(Gain) loss on fair value remeasurement of contingent consideration	24.6	7.3	30.5	(38.9)
Restructuring charges	93.4	-	93.4	-
SG&A: Stock option expense	-	1.1	-	6.4
R&D: Stock option expense	-	1.0	-	5.8
Donation to Biogen Foundation	-	-	-	35.0
Income tax effect related to reconciling items	(46.9)	(28.7)	(104.3)	(134.9)
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 994.7</u>	<u>\$ 965.6</u>	<u>\$ 3,931.9</u>	<u>\$ 3,281.1</u>

2016 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 basis and on a Non-GAAP basis is as follows:

	\$	Shares	Diluted EPS
Projected GAAP net income attributable to Biogen Inc.	\$ 3,722.0	218.8	\$ 17.01
Adjustments:			
Amortization of acquired intangible assets	350.0		
(Gain) loss on fair value remeasurement of contingent consideration	20.0		
Restructuring charges	10.0		
Income tax effect related to reconciling items	(65.0)		
Projected Non-GAAP net income attributable to Biogen Inc.	<u>\$ 4,037.0</u>	218.8	\$ 18.45

Numbers may not foot due to rounding.

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. Stock option expense recorded in accordance with the accounting standard for share-based payments.

3. 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)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2015	2014	2015	2014
PRODUCT REVENUES				
Multiple Sclerosis (MS):				
TECFIDERA	\$ 992.8	\$ 916.0	\$ 3,638.4	\$ 2,909.2
AVONEX	637.2	736.0	2,630.2	3,013.1
PLEGRIDY	102.5	41.1	338.5	44.5
TYSABRI	480.7	483.9	1,886.1	1,959.5
FAMPYRA	27.6	18.5	89.7	80.2
Hemophilia:				
ALPROLIX	71.3	40.3	234.5	76.0
ELOCTATE	101.2	36.8	319.7	58.4
Other product revenues:				
FUMADERM	12.6	14.4	51.4	62.5
Total product revenues, net	<u>\$ 2,425.9</u>	<u>\$ 2,287.0</u>	<u>\$ 9,188.5</u>	<u>\$ 8,203.4</u>

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