



## Biogen Reports First Quarter 2015 Revenues of \$2.6 Billion

April 24, 2015

*Multiple sclerosis portfolio gains share globally with ongoing TECFIDERA® rollout in Europe and launch of PLEGRIDY®*

*Company advances research pipeline and development efforts in Alzheimer's disease, secondary progressive MS and neurological repair for MS*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Inc. (NASDAQ: BII) today reported first quarter 2015 results, including revenues of \$2.6 billion, a 20% increase compared to the first quarter of 2014. Non-GAAP diluted earnings per share (EPS) for the first quarter of 2015 were \$3.82, an increase of 55% over the first quarter of 2014. Non-GAAP net income attributable to Biogen for the first quarter of 2015 was \$900 million, an increase of 53% over the first quarter of 2014.

On a reported basis, GAAP diluted EPS for the first quarter of 2015 were \$3.49, an increase of 73% over the first quarter of 2014. GAAP net income attributable to Biogen for the first quarter of 2015 was \$823 million, an increase of 71% versus the same period in the prior year. (A reconciliation of GAAP to Non-GAAP quarterly financial results can be found in Table 3 at the end of this release).

"In the first quarter, we continued to gain share in the MS market and we believe that our MS product portfolio is well positioned to provide patients the breadth of choices that they need," said Chief Executive Officer George A. Scangos, Ph.D. "While we saw moderating patient growth of our oral MS therapy TECFIDERA in the U.S. and Germany, the launch of PLEGRIDY continued to go well, and we have seen continued strong performance from TYSABRI. We believe that our portfolio offers patients leading choices among oral, interferon, and high-efficacy therapies, and we look forward to continued growth in our global market share."

"Last month we presented compelling data for aducanumab (BIIB037), and we are planning to initiate Phase 3 studies later this year," Dr. Scangos continued. "In January we reported top line results of our phase 2 study of anti-LINGO in acute optic neuritis, which we believe demonstrate this compound's ability to remyelinate damaged neurons, and we presented detailed results of this study at AAN earlier this week. For the remainder of 2015, we look forward to continued pipeline progress, including a Phase 3 readout for TYSABRI in secondary progressive MS and Phase 2 data for both TYSABRI in acute ischemic stroke and Neublabin in neuropathic pain."

### **First Quarter 2015 Performance Highlights**

- Total multiple sclerosis product sales were \$2.1 billion compared to \$1.7 billion in the same quarter last year.
- TECFIDERA revenues were \$825 million compared to \$506 million in the same quarter last year. These results consisted of \$648 million in U.S. sales and \$177 million in sales outside the U.S. compared to \$460 million and \$46 million, respectively, in the first quarter of 2014.
  - TECFIDERA revenues in the first quarter of 2015 decreased 10% versus the fourth quarter of 2014. This decline was partially impacted by one fewer shipping week in the U.S. versus the prior quarter, increased discounts and allowances specific to the first quarter of 2015 and updated pricing assumptions in Germany.
- Interferon revenues, including AVONEX® and PLEGRIDY, were \$755 million compared to \$761 million in the same quarter last year. These results consisted of \$518 million in U.S. sales and \$236 million in sales outside the U.S. compared to \$476 million and \$285 million, respectively, in the first quarter of 2014.
- TYSABRI® revenues were \$463 million compared to \$441 million in the same quarter last year. These results consisted of \$273 million in U.S. sales and \$190 million in sales outside the U.S. compared to \$234 million and \$207 million, respectively, in the first quarter of 2014. TYSABRI U.S. sales include 13 shipping weeks in the first quarter of 2015 versus 12 in the first quarter of 2014.
- Net revenues relating to RITUXAN® and GAZYVA® from our unconsolidated joint business arrangement were \$331 million compared to \$297 million in the same quarter last year.
- ELOCTATE® revenues were \$54 million and ALPROLIX® revenues were \$43 million.

### **Other Financial Highlights**

- Revenues for FAMPYRA® and FUMADERM™ were \$34 million compared to \$35 million in the same quarter last year.
- Royalty revenues were \$20 million compared to \$38 million in the same quarter last year.
- Corporate partner revenues were \$32 million compared to \$52 million in the same quarter last year.
- Non-GAAP SG&A expense was \$560 million compared to \$509 million in the same quarter last year. GAAP SG&A expense was \$560 million compared to \$512 million in the same quarter last year.
- Non-GAAP R&D expense was \$461 million compared to \$527 million in the same quarter last year. GAAP R&D expense

was \$461 million compared to \$529 million in the same quarter last year.

- As of March 31, 2015, Biogen had cash, cash equivalents and marketable securities totaling approximately \$3.5 billion.

#### **Neurology Highlights**

- In January 2015, Biogen announced positive top-line results from the Phase 2 acute optic neuritis (AON) RENEW trial in which treatment with anti-LINGO-1 showed evidence of biological repair of the visual system. Anti-LINGO-1 also demonstrated an acceptable safety profile.
- In January 2015, Biogen and Google[x] Life Sciences began a partnership to explore drivers of multiple sclerosis disease progression through investigational technologies and methods, such as novel sensor platforms, advanced laboratory science, and bio-analytical tools.
- In February 2015, an international consortium that includes scientists and clinicians from Columbia University Medical Center (CUMC), Biogen and HudsonAlpha Institute for Biotechnology announced the identification of a new gene that is associated with sporadic amyotrophic lateral sclerosis, or Lou Gehrig's disease. The study was published in the online edition of *Science*.
- In March 2015, Biogen announced data from a pre-specified interim analysis of PRIME, the Phase 1b study of aducanumab (BIIB037), in which the compound demonstrated an acceptable safety profile and positive results on radiologic and clinical measurements in patients with prodromal or mild Alzheimer's disease.
- In March 2015, the European Medicines Agency (EMA) validated the Marketing Authorisation Application (MAA) for ZINBRYTA™ for the treatment of relapsing forms of multiple sclerosis. ZINBRYTA is being jointly developed by Biogen and AbbVie.
- In April 2015, Biogen initiated a Phase 3 study of TECFIDERA in secondary progressive multiple sclerosis.
- This week, Biogen is presenting new clinical data supporting the Company's marketed and investigational therapies for neurological diseases at the 67th American Academy of Neurology Annual Meeting. The 73 company-sponsored platform and poster presentations include subgroup efficacy data for TECFIDERA, long-term safety and efficacy data for PLEGRIDY, full results from the Phase 2 RENEW trial of anti-LINGO-1 in acute optic neuritis, subgroup data from the PRIME study of aducanumab in Alzheimer's disease, and data from the Phase 3 DECIDE study of ZINBRYTA in relapsing-remitting multiple sclerosis.

#### **Hemophilia Highlights**

- In January 2015, Biogen, Fondazione Telethon and Ospedale San Raffaele announced they entered into a worldwide collaboration to jointly develop gene therapies for the treatment of both hemophilia A and B. The agreement will combine San Raffaele - Telethon Institute for Gene Therapy's extensive expertise in creating new gene therapy strategies and developing them from the bench to bedside with Biogen's deep understanding of hematology to potentially treat the underlying causes of hemophilia A and B.
- In February 2015, Biogen and Swedish Orphan Biovitrum AB announced positive top-line results of the Kids B-LONG Phase 3 clinical study that evaluated the safety, efficacy and pharmacokinetics of ALPROLIX in children under age 12 with severe hemophilia B.
- In March 2015, ELOCTATE was launched in Japan, becoming the first available recombinant hemophilia A therapy in Japan that has prolonged circulation in the body.

#### **Immunology Highlights**

- In February 2015, Biogen's collaboration partner UCB announced that dapirolizumab pegol (Anti-CD40 Ligand) was well tolerated in a Phase 1b trial in systemic lupus erythematosus. The compound is expected to progress to Phase 2 in 2016.

#### **Other Events**

- In January 2015, Biogen and Columbia University Medical Center formed a \$30 million strategic alliance to conduct genetics discovery research on the underlying causes of disease and to identify new treatment approaches.
- In January 2015, Samsung Bioepis, a joint venture (JV) between Samsung Biologics and Biogen, received EMA acceptance and validation of its MAA for its etanercept biosimilar candidate. In March 2015, the EMA also accepted and validated the MAA for the JV's infliximab biosimilar candidate.
- In February 2015, Biogen completed its acquisition of U.K.-based Convergence Pharmaceuticals. Convergence is a clinical-stage biopharmaceutical company with an innovative portfolio of ion channel-modulating product candidates for neuropathic pain including CNV1014802, a product candidate being developed for trigeminal neuralgia, a chronic orphan disease.

#### **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. EDT on April 24, 2015, 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 the world's oldest independent biotechnology company 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 about the prospects of our product portfolio, the potential and progress of our pipeline and business development activities, and anticipated clinical trials and data readouts. 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; failure to protect and enforce our data, intellectual property and other proprietary rights and the risks and uncertainties relating to intellectual property claims; difficulties in obtaining adequate coverage or changes in pricing or the availability of reimbursement for our products; the occurrence of adverse safety events, restrictions on use with our products or product liability claims; uncertainty of success in developing, licensing or acquiring other product candidates or additional indications for existing products, including the risk that unexpected concerns 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; results 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; 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; problems with our manufacturing processes or capacity; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including exchange rate fluctuations; charges and other costs relating to our properties; currency fluctuations; fluctuations in our effective tax rate; the market, interest and credit risks associated with our portfolio of marketable securities; environmental risks; 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.

TABLE 1

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

	For the Three Months Ended March 31,	
	2015	2014
Revenues:		
Product, net	\$2,172,322	\$1,742,765
Unconsolidated joint business	330,611	296,885
Royalty	19,814	37,856
Corporate partner	32,216	52,245
Total revenues	<u>2,554,963</u>	<u>2,129,751</u>
Cost and expenses:		
Cost of sales, excluding amortization of acquired intangible assets	312,431	279,245
Research and development	460,549	528,884
Selling, general and administrative	560,361	511,674
Amortization of acquired intangible assets	95,903	143,258
(Gain) loss on fair value remeasurement of contingent consideration	7,844	(799)
Total cost and expenses	<u>1,437,088</u>	<u>1,462,262</u>
Gain on sale of rights	-	3,859
Income from operations	1,117,875	671,348
Other income (expense), net	(14,986)	(5,601)
Income before income tax expense and equity in loss of investee, net of tax	1,102,889	665,747
Income tax expense	281,881	178,414
Equity in loss of investee, net of tax	834	7,605
Net income	820,174	479,728
Net income (loss) attributable to noncontrolling interests, net of tax	(2,367)	(228)
Net income attributable to Biogen Inc.	<u>\$ 822,541</u>	<u>\$ 479,956</u>

Net income per share:

Basic earnings per share attributable to Biogen Inc.	<u>\$ 3.50</u>	<u>\$ 2.03</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 3.49</u>	<u>\$ 2.02</u>
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Inc.	<u>234,995</u>	<u>236,786</u>
Diluted earnings per share attributable to Biogen Inc.	<u>235,630</u>	<u>237,849</u>

TABLE 2

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

	As of <u>March 31, 2015</u>	As of <u>December 31, 2014</u>
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 2,151,997	\$ 1,845,384
Accounts receivable, net	1,389,995	1,292,445
Inventory	825,349	804,022
Other current assets	<u>891,555</u>	<u>730,822</u>
Total current assets	5,258,896	4,672,673
Marketable securities	1,377,325	1,470,652
Property, plant and equipment, net	1,739,628	1,765,683
Intangible assets, net	4,353,123	4,028,507
Goodwill	1,849,852	1,760,249
Investments and other assets	<u>640,630</u>	<u>618,795</u>
<b>TOTAL ASSETS</b>	<u>\$ 15,219,454</u>	<u>\$ 14,316,559</u>
<b>LIABILITIES AND EQUITY</b>		
Current portion of notes payable	\$ 3,254	\$ 3,136
Other current liabilities	1,942,977	2,216,570
Notes payable	580,672	582,061
Long-term deferred tax liability	130,564	50,656
Other long-term liabilities	892,529	650,096
Equity	<u>11,669,458</u>	<u>10,814,040</u>
<b>TOTAL LIABILITIES AND EQUITY</b>	<u>\$ 15,219,454</u>	<u>\$ 14,316,559</u>

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 March 31,	
	<u>2015</u>	<u>2014</u>
GAAP earnings per share - Diluted	\$ 3.49	\$ 2.02
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.33	0.45
Non-GAAP earnings per share - Diluted	<u>\$ 3.82</u>	<u>\$ 2.47</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 March 31,	
	2015	2014
GAAP net income attributable to Biogen Inc.	\$ 822.5	\$ 480.0
Adjustments:		
Amortization of acquired intangible assets	92.5	139.8
(Gain) loss on fair value remeasurement of contingent consideration	7.8	(0.8)
SG&A: Stock option expense	-	2.6
R&D: Stock option expense	-	2.3
Income tax effect related to reconciling items	(22.6)	(37.0)
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 900.2</u>	<u>\$ 586.9</u>

#### 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 diluted earnings per share:

#### 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 March 31,	
	2015	2014
PRODUCT REVENUES		
Multiple Sclerosis (MS):		
TECFIDERA	\$ 824.9	\$ 505.7
AVONEX	692.7	761.5
PLEGRIDY	61.8	-
TYSABRI	462.6	441.0
FAMPYRA	20.0	19.0
Hemophilia:		
ALPROLIX	43.1	-
ELOCTATE	53.6	-
Other product revenues:		
FUMADERM	13.6	15.6
Total product revenues, net	<u>\$ 2,172.3</u>	<u>\$ 1,742.8</u>



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