



## Biogen Second Quarter 2015 Revenues Increase 7% to \$2.6 Billion

July 24, 2015

*TECFIDERA® now the most prescribed oral MS therapy globally*

*Sites initiated for aducanumab Phase 3 studies for Alzheimer's disease*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Inc. (NASDAQ: BIIB) today reported second quarter 2015 results, including revenues of \$2.6 billion, a 7% increase compared to the second quarter of 2014. Non-GAAP diluted earnings per share (EPS) for the second quarter of 2015 were \$4.22, an increase of 21% over the second quarter of 2014. Non-GAAP net income attributable to Biogen for the second quarter of 2015 was \$995 million, an increase of 20% over the second quarter of 2014.

On a reported basis, GAAP diluted EPS for the second quarter of 2015 were \$3.93, an increase of 31% over the second quarter of 2014. GAAP net income attributable to Biogen for the second quarter of 2015 was \$927 million, an increase of 30% 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).

"Biogen remains focused on improving the lives of people living with complex diseases," said Chief Executive Officer George A. Scangos, Ph.D. "TECFIDERA, which is now the most prescribed oral MS therapy globally, is experiencing moderated patient growth following rapid initial uptake. The launch of PLEGRIDY® is expanding into new markets, and TYSABRI® continues to add new patients requiring higher efficacy. Additionally, our hemophilia products are being adopted by an increasing number of patients, and we are working toward the anticipated launches of our first two biosimilar candidates in Europe next year."

"The Company also continues to invest in the science that is core to our future," Dr. Scangos continued, "and we are continuing to advance our pipeline in areas where patients have limited or no treatment options. We are excited to report we are now actively recruiting for two global Phase 3 studies of aducanumab in patients with early Alzheimer's disease. We see aducanumab as a potentially transformational opportunity for Biogen, and for patients with this devastating disease."

### **Second Quarter 2015 Financial Highlights**

- Total multiple sclerosis product sales were \$2.1 billion compared to \$2.0 billion in the same quarter last year.
- TECFIDERA revenues were \$883 million compared to \$700 million in the same quarter last year. These results consisted of \$721 million in U.S. sales and \$163 million in sales outside the U.S. compared to \$585 million and \$115 million, respectively, in the second quarter of 2014.
  - TECFIDERA revenues in the second quarter of 2015 increased 7% from \$825 million in the first quarter of 2015. In the U.S., TECFIDERA revenues increased 11%, which was partially offset by an 8% decrease outside the U.S. The decrease outside the U.S. was primarily due to lower pricing in Germany, as unit volume increased 14%.
- Interferon revenues, including AVONEX® and PLEGRIDY, were \$690 million compared to \$774 million in the same quarter last year. These results consisted of \$455 million in U.S. sales and \$235 million in sales outside the U.S. compared to \$498 million and \$276 million, respectively, in the second quarter of 2014.
  - Interferon revenues in the second quarter of 2015 decreased 9% from \$755 million in the first quarter of 2015. Interferon revenues decreased 12% in the U.S. and 1% outside the U.S. versus the first quarter of 2015. The Company believes the majority of the U.S. decrease is due to an inventory reduction in the wholesale channel.
- TYSABRI revenues were \$463 million compared to \$533 million in the same quarter last year. These results consisted of \$269 million in U.S. sales and \$195 million in sales outside the U.S. compared to \$250 million and \$284 million, respectively, in the second quarter of 2014. TYSABRI revenues outside the U.S. decreased 31% versus the second quarter of 2014, due primarily to the recognition of \$54 million of previously deferred revenues in Italy in the second quarter of 2014 following a pricing agreement with AIFA.
- Net revenues relating to RITUXAN® and GAZYVA® from our unconsolidated joint business arrangement were \$338 million compared to \$303 million in the same quarter last year.
- ELOCTATE® revenues were \$74 million and ALPROLIX® revenues were \$54 million.
- Revenues for FAMPYRA® and FUMADERM™ were \$34 million compared to \$38 million in the same quarter last year.
- Royalty revenues were \$9 million compared to \$40 million in the same quarter last year. The decrease is primarily due to the cessation of ANGIOMAX® royalty payments following the expiration of applicable U.S. patent rights in December 2014.
- Corporate partner revenues were \$47 million compared to \$22 million in the same quarter last year.
- Foreign exchange, offset by hedging, weakened total revenues by approximately \$79 million compared to the second

quarter of 2014.

- Non-GAAP SG&A expense was \$492 million compared to \$540 million in the same quarter last year. GAAP SG&A expense was \$492 million compared to \$577 million in the same quarter last year.
- Non-GAAP R&D expense was \$491 million compared to \$446 million in the same quarter last year. GAAP R&D expense was \$491 million compared to \$447 million in the same quarter last year.
- As of June 30, 2015, Biogen had cash, cash equivalents and marketable securities totaling approximately \$4.5 billion.
- In May 2015, Biogen announced that its Board of Directors authorized a program to repurchase up to \$5 billion of the Company's common stock. Biogen currently expects that purchases will be executed within a period of up to five years.

### **2015 Financial Guidance**

As previously announced, the Company plans to provide annual financial guidance and one update per year. Biogen's mid-year update to its full year 2015 financial guidance consists of the following components:

- Revenue growth is expected to be approximately 6% to 8% compared to 2014, a decrease from prior guidance based largely on revised expectations for the growth of TECFIDERA.
- R&D expense is expected to be approximately 19% to 20% of total revenue, unchanged from prior guidance.
- SG&A expense is expected to be approximately 20% to 21% of total revenue, unchanged from prior guidance.
- GAAP diluted EPS is expected to be between \$14.25 and \$14.70, a decrease from prior guidance.
- Non-GAAP diluted EPS is expected to be between \$15.50 and \$15.95, a decrease from prior guidance.

Biogen may incur charges, realize gains or experience other events in 2015 that could cause actual results to vary from this guidance.

### **Neurology Highlights**

- In April 2015, the U.S. Food and Drug Administration accepted for review the Biologics License Application for ZINBRYTA™ for the treatment of relapsing forms of multiple sclerosis. ZINBRYTA is being jointly developed by Biogen and AbbVie.
- In June 2015, Biogen's collaboration partner Isis Pharmaceuticals announced additional data from two Phase 2 studies of ISIS-SMN<sub>Rx</sub> for the treatment of spinal muscular atrophy in infants and children. Available data to date continues to support further development, and two Phase 3 studies are active and currently enrolling patients.
- In July 2015, Biogen and Applied Genetic Technologies Corporation (AGTC) announced a broad collaboration and license agreement to develop gene therapies for multiple ophthalmic diseases. The collaboration will focus on the development of a portfolio of AGTC's therapeutic programs, including both a clinical stage candidate and a pre-clinical candidate for orphan diseases of the retina that can lead to blindness in children and adults.
- In July 2015, Biogen presented new data from the Phase 1b PRIME study of aducanumab at the Alzheimer's Association International Conference®. Consistent with previously reported results, the one-year data from the 6 mg/kg arm demonstrated a statistically significant reduction of beta amyloid in the brain. In exploratory analyses, the 6 mg/kg dose showed an improvement in the slowing of clinical decline, as measured by the Mini Mental State Examination (MMSE) and Clinical Dementia Rating sum of boxes (CDR-SB) scales, which was not statistically significant. In a pre-specified analysis across placebo and all doses of aducanumab, the slowing of clinical decline was shown to be dose-dependent, and this dose-dependence achieved statistical significance for both scales. In this analysis, aducanumab demonstrated acceptable safety and tolerability.
- Biogen recently initiated clinical sites for two global Phase 3 studies, EMERGE and ENGAGE, for aducanumab in Alzheimer's disease. EMERGE and ENGAGE are each planned to enroll 1,350 patients with early Alzheimer's disease.
- Plans are underway to continue the development of TYSABRI (natalizumab) for acute ischemic stroke following the Company's Phase 2 study. While the Phase 2 results did not demonstrate an impact on change in infarct volume, the primary endpoint, secondary and exploratory clinical endpoints suggest that TYSABRI did have a beneficial impact on patient functional deficits.
- Biogen has ceased development of Neublabin in moderate to severe sciatica after Phase 2 study results failed to meet the Company's targeted product profile.

### **Hemophilia Highlights**

- In June 2015, Biogen presented 23 Company-sponsored platform and poster presentations at the International Society on Thrombosis and Haemostasis 2015 Congress. The data presented included full results from the Kids B-LONG study of ALPROLIX in children with hemophilia B as well as interim results on the long-term safety and efficacy of ELOCTATE in hemophilia A from the ASPIRE extension study.

- In June 2015, Biogen and Swedish Orphan Biovitrum AB (Sobi) announced that the European Medicines Agency accepted the Marketing Authorization Application of ALPROLIX for the treatment of hemophilia B. In July 2015, Sobi exercised its opt-in right to assume final development and commercialization responsibilities for ALPROLIX for the territory composed of Europe, North Africa, Russia and certain Middle Eastern markets.

#### **Other Events**

- In June 2015, Biogen and Samsung Bioepis Co., Ltd presented results from their anti-TNF biosimilar portfolio at the European League Against Rheumatism Annual Congress (EULAR 2015).
- In June 2015, Biogen announced that it has achieved carbon neutrality, a milestone reached through a multi-year initiative to reduce its own emissions and by investing in environmental projects to offset the remaining carbon associated with its business.
- In June 2015, Biogen announced that it intends to build a new, next generation manufacturing facility in Solothurn, Switzerland to support its emerging pipeline. Biogen also recently entered into a definitive agreement with Eisai Co., Ltd. to transfer ownership of Eisai's Research Triangle Park manufacturing campus to Biogen.
- In July 2015, Biogen announced that Douglas Williams, Ph.D., Executive Vice President of Research & Development, will leave the Company at the end of July to become chief executive officer of a start-up biotechnology company.

#### **Conference Call and Webcast**

The Company's earnings conference call for the second quarter will be broadcast via the internet at 8:30 a.m. EDT on July 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 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: product growth prospects; pipeline potential and progress; planned enrollment of clinical trials; anticipated benefits and potential of investments, collaborations and business development activities; timing and execution of stock repurchases; and 2015 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; 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 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; 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; risks relating to investment in and expansion of manufacturing capacity for future clinical and commercial requirements; failure to comply with legal and regulatory requirements; 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; 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; 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 June 30,		For the Six Months Ended June 30,	
		2015	2014	2015	2014
Revenues:					

Product, net	\$2,198,566	\$2,056,292	\$4,370,888	\$3,799,057
Unconsolidated joint business	337,510	303,296	668,121	600,181
Royalty	8,583	40,344	28,397	78,200
Corporate partner	46,983	21,520	79,199	73,765
Total revenues	<u>2,591,642</u>	<u>2,421,452</u>	<u>5,146,605</u>	<u>4,551,203</u>
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	286,120	291,887	598,551	571,132
Research and development	490,728	447,273	951,277	976,157
Selling, general and administrative	491,895	576,622	1,052,256	1,088,296
Amortization of acquired intangible assets	92,004	116,826	187,907	260,084
(Gain) loss on fair value remeasurement of contingent consideration	(2,201)	4,019	5,643	3,220
Total cost and expenses	<u>1,358,546</u>	<u>1,436,627</u>	<u>2,795,634</u>	<u>2,898,889</u>
Gain on sale of rights	-	3,900	-	7,759
Income from operations	1,233,096	988,725	2,350,971	1,660,073
Other income (expense), net	(10,889)	4,861	(25,875)	(740)
Income before income tax expense and equity in loss of investee, net of tax	1,222,207	993,586	2,325,096	1,659,333
Income tax expense	292,501	268,521	574,382	446,935
Equity in loss of investee, net of tax	4,881	1,933	5,715	9,538
Net income	924,825	723,132	1,744,999	1,202,860
Net income (loss) attributable to noncontrolling interests, net of tax	(2,451)	8,626	(4,818)	8,398
Net income attributable to Biogen Inc.	<u>\$ 927,276</u>	<u>\$ 714,506</u>	<u>\$1,749,817</u>	<u>\$1,194,462</u>
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	<u>\$ 3.94</u>	<u>\$ 3.02</u>	<u>\$ 7.44</u>	<u>\$ 5.05</u>
Diluted earnings per share attributable to Biogen Inc.	<u>\$ 3.93</u>	<u>\$ 3.01</u>	<u>\$ 7.42</u>	<u>\$ 5.03</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	<u>235,286</u>	<u>236,661</u>	<u>235,122</u>	<u>236,729</u>
Diluted earnings per share attributable to Biogen Inc.	<u>235,718</u>	<u>237,401</u>	<u>235,671</u>	<u>237,634</u>

TABLE 2  
BIOPEN INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(unaudited, in thousands)

	As of June 30, 2015	As of December 31, 2014
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 2,368,673	\$ 1,845,384
Accounts receivable, net	1,310,821	1,292,445
Inventory	865,738	804,022
Other current assets	<u>1,073,753</u>	<u>730,822</u>
Total current assets	5,618,985	4,672,673
Marketable securities	2,101,796	1,470,652
Property, plant and equipment, net	1,837,670	1,765,683
Intangible assets, net	4,294,791	4,028,507
Goodwill	2,154,341	1,760,249
Investments and other assets	751,588	618,795
<b>TOTAL ASSETS</b>	<u>\$ 16,759,171</u>	<u>\$ 14,316,559</u>
<b>LIABILITIES AND EQUITY</b>		
Current portion of notes payable	\$ 3,262	\$ 3,136
Other current liabilities	2,552,570	2,216,570
Notes payable	576,207	582,061
Long-term deferred tax liability	138,403	50,656
Other long-term liabilities	915,731	650,096
Equity	<u>12,572,998</u>	<u>10,814,040</u>
<b>TOTAL LIABILITIES AND EQUITY</b>	<u>\$ 16,759,171</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 June 30,		For the Six Months Ended June 30,	
	2015	2014	2015	2014
GAAP earnings per share - Diluted	\$ 3.93	\$ 3.01	\$ 7.42	\$ 5.03
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.29	0.48	0.62	0.93
Non-GAAP earnings per share - Diluted	<u>\$ 4.22</u>	<u>\$ 3.49</u>	<u>\$ 8.04</u>	<u>\$ 5.96</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 June 30,		For the Six Months Ended June 30,	
	2015	2014	2015	2014
GAAP net income attributable to Biogen Inc.	\$ 927.3	\$ 714.5	\$ 1,749.8	\$ 1,194.5
Adjustments:				
Amortization of acquired intangible assets	86.8	113.0	179.3	252.8
(Gain) loss on fair value remeasurement of contingent consideration	(2.2)	4.0	5.6	3.2
SG&A: Stock option expense	-	1.5	-	4.0
R&D: Stock option expense	-	1.2	-	3.5
Donation to Biogen Foundation	-	35.0	-	35.0
Income tax effect related to reconciling items	(17.1)	(40.1)	(39.7)	(77.1)
Non-GAAP net income attributable to Biogen Inc.	<u>\$ 994.8</u>	<u>\$ 829.1</u>	<u>\$ 1,895.0</u>	<u>\$ 1,415.9</u>

#### 2015 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.	\$ 3,411.6	235.7	\$ 14.48
Adjustments:			
Amortization of acquired intangible assets	358.8		
(Gain) loss on fair value remeasurement of contingent consideration	15.8		
Income tax effect related to reconciling items	(80.5)		
Projected Non-GAAP net income attributable to Biogen Inc.	<u>\$ 3,705.7</u>	235.7	\$ 15.73

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		For the Six Months	
	Ended June 30,		Ended June 30,	
	2015	2014	2015	2014
PRODUCT REVENUES				
Multiple Sclerosis (MS):				
TECFIDERA	\$ 883.3	\$ 700.4	\$1,708.2	\$1,206.1
AVONEX	615.2	773.8	1,307.9	1,535.3
PLEGRIDY	74.5	-	136.3	-
TYSABRI	463.1	533.4	925.7	974.4
FAMPYRA	21.1	22.3	41.1	41.3
Hemophilia:				
ALPROLIX	54.4	10.4	97.5	10.4
ELOCTATE	74.3	-	127.9	-
Other product revenues:				
FUMADERM	12.7	16.0	26.3	31.6
Total product revenues, net	<u>\$ 2,198.6</u>	<u>\$ 2,056.3</u>	<u>\$4,370.9</u>	<u>\$3,799.1</u>



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