



## Biogen Idec Total Revenues Increased 32% to \$1.8 Billion in Third Quarter; Company Raises 2013 Financial Guidance

October 28, 2013

-- *TECFIDERA*<sup>®</sup> now the leading oral MS therapy in the United States --

WESTON, Mass.--([BUSINESS WIRE](#))--Biogen Idec Inc. (NASDAQ:BIIB) today reported third quarter 2013 total revenues of \$1.8 billion, an increase of 32% over the third quarter of 2012. Non-GAAP diluted EPS for the third quarter of 2013 were \$2.35, an increase of 23% over the third quarter of 2012. Non-GAAP net income attributable to Biogen Idec for the third quarter of 2013 was \$561 million, an increase of 23% versus the third quarter of 2012.

GAAP diluted EPS for the third quarter of 2013 were \$2.05, an increase of 23% over the third quarter of 2012. GAAP net income for the third quarter of 2013 was \$488 million, an increase of 22% over the third quarter of 2012. A reconciliation of our GAAP to Non-GAAP financial results can be found in Table 3 at the end of this release.

Revenue gains were driven by *TECFIDERA* (dimethyl fumarate) with *TECFIDERA* revenues totaling \$286 million during the third quarter of 2013. According to IMS, *TECFIDERA* is now the leading oral MS therapy in the United States after only six months on the market. *AVONEX*<sup>®</sup> (interferon beta-1a) revenues decreased slightly versus the third quarter of 2012 to \$733 million, while *TYSABRI*<sup>®</sup> (natalizumab) revenue increased by 46% as a result of Biogen Idec recording 100 percent of *TYSABRI* revenues following the Company's acquisition of full rights for the therapy from Elan in the second quarter of 2013. Global in-market sales for *TYSABRI* for the quarter were flat as compared to the third quarter of 2012.

"We believe the continued growth of *TECFIDERA* is a testament to its value to patients and physicians and we are pleased with how it has complemented our robust portfolio of MS therapies," said Chief Executive Officer George A. Scangos.

"Our continuing commitment to innovation also has resulted in exciting new data that show advances in many of our approved and investigational therapies as we continue to enhance options for MS patients now and in the future.

"Looking ahead, we believe we are entering an exciting period in our company's evolution as we anticipate bringing patients significant advances for the treatment of Hemophilia A and B, continue to take measures to strengthen our pipeline with new therapies to treat unmet medical needs, and further our efforts to transform our approach to early-stage research. I believe our organization is prepared to meet all of these new challenges and opportunities," Scangos added.

### **Performance of our Therapies in Detail**

- *TECFIDERA* revenues were \$286 million during the third quarter, consisting of \$284 million in U.S. sales and \$2 million in sales in Canada. The Company estimates that approximately \$12 million of U.S. *TECFIDERA* revenues in the third quarter represent incremental inventory in the channel. As a result, revenue generated in the U.S. from underlying patient demand was approximately \$272 million in the third quarter. As of the end of the third quarter, we estimate U.S. inventory in the channel was in the 4 to 5 week range or approximately \$92 million. *TECFIDERA* currently is approved in the United States, Canada and Australia. The Company continues to work to make *TECFIDERA* regulatory data protection clearer to all parties prior to approval from the European Medicines Agency (EMA).
- *AVONEX* third quarter revenues decreased slightly over the same period in the prior year to \$733 million. The total was comprised of \$457 million in U.S. sales and \$277 million in sales outside the U.S.
- *TYSABRI* revenues, adjusted for the impact of hedging, increased 46% year-over-year to \$401 million due to our recording 100 percent of *TYSABRI* revenues following our acquisition of full rights in *TYSABRI* from Elan in the second quarter of 2013. Global in-market sales of *TYSABRI* in the third quarter of 2013 totaled \$403 million, remaining flat when compared to *TYSABRI* global in-market sales in the third quarter of 2012. The total in-market sales were comprised of \$232 million in U.S. sales and \$171 million in sales outside the U.S.
- *RITUXAN*<sup>®</sup> (rituximab) revenues from our unconsolidated joint business arrangement were \$303 million for the quarter, an increase of 5% compared to the third quarter of 2012.

### **Other Financial Highlights**

- Revenues for *FAMPYRA*<sup>®</sup> and *FUMADERM*<sup>™</sup> totaled \$33 million in the third quarter of 2013, compared to \$28 million in the third quarter of 2012.
- Royalty revenues totaled \$54 million in the third quarter of 2013, compared to \$47 million in the third quarter of 2012.
- Corporate partner revenues totaled \$17 million in the third quarter of 2013, compared to \$12 million in the third quarter of 2012.
- As of September 30, 2013, Biogen Idec had cash, cash equivalents and marketable securities totaling approximately \$1.0

billion.

- During the third quarter of 2013, Biogen Idec repurchased 1.7 million shares of stock at a total cost of approximately \$360 million.

### **2013 Financial Guidance**

Biogen Idec increased its full year 2013 financial guidance. This guidance consists of the following components:

- Revenue growth is expected to be approximately 23% to 25%.
- Cost of Sales is expected to be approximately 12% to 14% of total revenue.
- R&D expense is expected to be approximately 21% to 23% of total revenue.
- SG&A expense is expected to be approximately 24% to 26% of total revenue.
- Tax expense is expected to be approximately 24% to 25% of pretax income.
- Non-GAAP diluted EPS is expected to be between \$8.65 and \$8.85.
- GAAP diluted EPS is expected to be between \$7.50 and \$7.70.
- Capital expenditures are expected to be in the range of \$250 to \$270 million.

Biogen Idec may incur charges, realize gains or experience other events in 2013 that could cause actual results to vary from this guidance.

### **New Data and Analyses Across Biogen Idec's MS Franchise**

Earlier this month, Biogen Idec presented extensive new data from its multiple sclerosis portfolio at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Congress in Copenhagen, Denmark. More than 55 company-sponsored presentations were showcased. Highlights included:

- Interim analyses from the ENDORSE long-term extension study showing that TECFIDERA continues to offer consistent and strong efficacy combined with a favorable safety profile in a broad range of patients with relapsing-remitting multiple sclerosis in patients who had received TECFIDERA for up to six and a half years.
- New data on TYSABRI that reaffirmed the therapy's efficacy in reducing multiple sclerosis disease activity. This effect was particularly significant in people with relapsing MS who initiated treatment when they had lower Expanded Disability Status Scale (EDSS) scores as well as in those who have been treated for more than two years.
- New clinical and MRI data from year one of the two-year, pivotal, Phase 3 ADVANCE study of PLEGRIDY™ (peginterferon beta-1a), which demonstrated a reduction in relapses, disability progression and the number of MS lesions when compared to placebo, and further supported the clinical efficacy profile of PLEGRIDY as a potential new treatment option for people with multiple sclerosis.

### **Additional Highlights**

- On September 9, 2013, [Biogen Idec](#) announced a broad, multi-year collaboration with Isis Pharmaceuticals to leverage antisense technology to advance the treatment of neurological diseases. The agreement combines Biogen Idec's expertise in neurology with Isis' leadership in antisense technology to develop novel therapies to treat neurological disorders. Through this collaboration, Biogen Idec gains exclusive rights to the use of Isis' antisense technology to develop therapies for a broad range of neurological targets. Targets discovered in this collaboration can be developed by Biogen Idec as biologic, small molecule, or antisense drugs. The agreement also provides Biogen Idec with the option to license ongoing antisense development programs against neurological targets.
- This month, Biogen Idec, along with other partners including the National Hemophilia Foundation (NHF), announced the national rollout of *My Life, Our Future: Genotyping for Progress in Hemophilia*, which offers genetic testing to people with hemophilia. Through genotyping, it is possible to identify the specific DNA mutation(s), or change(s), responsible for a person's hemophilia and provide potentially useful information about bleeding severity or risk for inhibitors. The program will also work to create a central repository to enhance research to drive a better scientific understanding of the disorder.
- On September 24, 2013, [Biogen Idec](#) announced that it has been added to the prestigious [Dow Jones Sustainability World Index](#) (DJSI World) – becoming the first and only U.S. based biotech sector firm to make the list. The Company was also named to the Dow Jones Sustainability Index (DJSI) North America for the fourth consecutive year, one of only three biotech companies included.

### **Conference Call and Webcast**

The Company's earnings conference call for the third quarter will be broadcast via the internet at 9:00 a.m. EDT on October 28, 2013, and will be accessible through the Investors section of Biogen Idec's homepage, [www.biogenidec.com](http://www.biogenidec.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 one month.

### **About Biogen Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the Company generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the Company, please visit [www.biogenidec.com](http://www.biogenidec.com).

### Safe Harbor

This press release contains forward-looking statements, including statements about 2013 financial guidance, the growth of TECFIDERA, potential product launches and timing thereof, possible advances and impact of potential treatments, and efforts to transform the Company's approach to early-stage research. 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 four principal products, AVONEX, TECFIDERA, TYSABRI and RITUXAN; failure to protect and enforce our data, intellectual property and other proprietary rights and the diminution of our ability to derive anticipated benefits from our products; uncertainty of success in executing our commercial launch of TECFIDERA; uncertainty of success in commercializing and developing other products, including our ability to obtain product approvals in a timely manner or at all for new or current products; failure to compete effectively due to significant product competition in the markets for our products; the occurrence of adverse safety events with our products; changes in the availability of reimbursement for our products; adverse market and economic conditions, which may cause continued pressure on product pricing or otherwise impact the extent of reimbursement for our products or the timing of payments to us; problems with our manufacturing processes, limitation in our capacity and our reliance on third parties; failure to comply with government regulation; the risks of doing business internationally; failure to manage our growth and execute our growth initiatives; charges and other costs relating to our properties; fluctuations in our effective tax rate; our ability to attract and retain qualified personnel; uncertainty and potential liabilities relating to product liability and intellectual property claims; 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 Idec Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Income**  
**(unaudited, in thousands, except per share amounts)**

	<b>For the Three Months</b>		<b>For the Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
<b>Revenues:</b>				
Product, net	\$1,453,554	\$1,039,110	\$3,935,251	\$3,091,398
Unconsolidated joint business	303,210	287,792	856,601	856,975
Royalty	54,144	46,625	125,076	112,509
Corporate partner	<u>16,872</u>	<u>12,027</u>	<u>49,421</u>	<u>37,638</u>
Total revenues	<u>1,827,780</u>	<u>1,385,554</u>	<u>4,966,349</u>	<u>4,098,520</u>
<b>Cost and expenses:</b>				
Cost of sales, excluding amortization of acquired intangible assets	234,696	139,358	599,173	411,666
Research and development	410,017	304,217	1,021,820	989,738
Selling, general and administrative	405,584	299,631	1,189,194	901,488
Amortization of acquired intangible assets	99,998	53,013	233,524	151,256
Collaboration profit sharing	-	75,545	85,357	239,951
(Gain) loss on fair value remeasurement of contingent consideration	(97)	9,456	(2,983)	23,573
Restructuring charge	<u>-</u>	<u>803</u>	<u>-</u>	<u>2,225</u>
Total cost and expenses	<u>1,150,198</u>	<u>882,023</u>	<u>3,126,085</u>	<u>2,719,897</u>
Gain on sale of rights	<u>6,949</u>	<u>31,719</u>	<u>17,319</u>	<u>31,719</u>

<b>Income from operations</b>	684,531	535,250	1,857,583	1,410,342
Other income (expense), net	<u>(4,640)</u>	<u>(4,548)</u>	<u>(29,525)</u>	<u>13,546</u>
<b>Income before income tax expense and equity in loss of investee, net of tax</b>	679,891	530,702	1,828,058	1,423,888
Income tax expense	186,105	131,044	410,753	334,213
Equity in loss of investee, net of tax	<u>6,170</u>	<u>1,258</u>	<u>12,270</u>	<u>1,769</u>
<b>Net income</b>	487,616	398,400	1,405,035	1,087,906
<b>Net income attributable to non-controlling interests, net of tax</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
<b>Net income attributable to Biogen Idec Inc.</b>	<u>\$ 487,616</u>	<u>\$ 398,400</u>	<u>\$1,405,035</u>	<u>\$1,087,906</u>
<b>Net income per share:</b>				
Basic earnings per share attributable to Biogen Idec Inc.	<u>\$ 2.06</u>	<u>\$ 1.68</u>	<u>\$ 5.93</u>	<u>\$ 4.56</u>
Diluted earnings per share attributable to Biogen Idec Inc.	<u>\$ 2.05</u>	<u>\$ 1.67</u>	<u>\$ 5.89</u>	<u>\$ 4.53</u>
<b>Weighted-average shares used in calculating:</b>				
Basic earnings per share attributable to Biogen Idec Inc.	<u>237,070</u>	<u>236,474</u>	<u>237,131</u>	<u>238,331</u>
Diluted earnings per share attributable to Biogen Idec Inc.	<u>238,349</u>	<u>238,125</u>	<u>238,508</u>	<u>240,137</u>

**TABLE 2**  
**Biogen Idec Inc. and Subsidiaries**  
**Condensed Consolidated Balance Sheets**  
(unaudited, in thousands)

	<u>As of September 30, 2013</u>	<u>As of December 31, 2012</u>
<b>ASSETS</b>		
Cash, cash equivalents and marketable securities	\$ 668,693	\$ 1,705,710
Accounts receivable, net	891,396	686,848
Inventory	614,483	447,373
Other current assets	<u>469,100</u>	<u>404,406</u>
Total current assets	2,643,672	3,244,337
Marketable securities	373,558	2,036,658
Property, plant and equipment, net	1,806,074	1,742,226
Intangible assets, net	4,580,199	1,631,547
Goodwill	1,210,718	1,201,296
Investments and other assets	<u>636,028</u>	<u>274,054</u>
<b>TOTAL ASSETS</b>	<u>\$ 11,250,249</u>	<u>\$ 10,130,118</u>
<b>LIABILITIES AND EQUITY</b>		
Current portion of notes payable and line of credit	\$ 3,385	\$ 453,379

Other current liabilities	1,515,326	1,204,010
Notes payable and other financing arrangements	694,894	687,396
Long-term deferred tax liability	302,483	217,272
Other long-term liabilities	608,473	604,266
Equity	<u>8,125,688</u>	<u>6,963,795</u>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b><u>\$ 11,250,249</u></b>	<b><u>\$ 10,130,118</u></b>

**TABLE 3**  
**Biogen Idec Inc. and Subsidiaries**  
**GAAP to Non-GAAP Reconciliation: Net Income and Net Income Per Share**  
**(unaudited, in millions, except per share amounts)**

<b>EARNINGS PER SHARE</b>	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
GAAP earnings per share - Diluted	\$ 2.05	\$ 1.67	\$ 5.89	\$ 4.53
Adjustments to net income attributable to Biogen Idec Inc. (as detailed below)	0.31	0.24	0.73	0.60
Non-GAAP earnings per share - Diluted	<u>\$ 2.35</u>	<u>\$ 1.91</u>	<u>\$ 6.62</u>	<u>\$ 5.13</u>

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

GAAP net income attributable to Biogen Idec Inc.	\$ 487.6	\$ 398.4	\$ 1,405.0	\$ 1,087.9
Adjustments:				
Amortization of acquired intangible assets	97.1	50.9	225.2	145.2
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration	(0.1)	9.5	(3.0)	23.6
SG&A: Stock option expense	1.3	1.4	4.2	2.8
R&D: Stock option expense	1.2	1.0	3.6	2.6
R&D: Restructuring and other	-	7.5	-	8.6
2010 Restructuring initiatives	-	0.8	-	2.2
Income tax effect related to reconciling items	(26.0)	(14.8)	(55.7)	(40.9)
Non-GAAP net income attributable to Biogen Idec Inc.	<u>\$ 561.1</u>	<u>\$ 454.7</u>	<u>\$ 1,579.3</u>	<u>\$ 1,232.0</u>

#### **2013 Full Year Guidance: GAAP to Non-GAAP Adjustments**

An itemized reconciliation between projected EPS on a GAAP basis and on a non-GAAP basis is as follows:

	<b>\$</b>	<b>Shares</b>	<b>Diluted EPS</b>
Projected GAAP net income attributable to Biogen Idec Inc.	1,810	238	\$ 7.60
Adjustments:			
Stock option expense	9		
Loss on exit of Weston facility	25		
Amortization of acquired intangible assets	330		
Fair value adjustment of contingent consideration	1		
Income tax expense: Income tax effect related to reconciling items	(90)		
Projected Non-GAAP net income attributable to Biogen Idec Inc.	<u>2,085</u>	<u>238</u>	<u>\$ 8.75</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 Idec Inc. and diluted earnings per share.

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

1. Purchase accounting and merger-related adjustments.

We exclude certain charges related to the 2003 merger between Biogen Inc. and Idec Pharmaceuticals, Inc., certain acquisition-related items, and certain 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 adjustments to the fair value of our contingent consideration obligations. The exclusion of these charges provides management and investors with a supplemental measure of performance which the Company believes better reflects the underlying economics of the business.

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

We believe that excluding the impact of expensing stock options better reflects the recurring economic characteristics of our business.

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 Idec Inc.

Numbers may not foot due to rounding.

**TABLE 4**  
**Biogen Idec Inc. and Subsidiaries**  
**Product Revenues**  
**(unaudited, in thousands)**

	<b>For the Three Months</b>	
	<b>Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>PRODUCT REVENUES</b>		
AVONEX®	\$ 733,449	\$ 736,208
TYSABRI®	400,995	274,769
TECFIDERA®	286,366	-
FAMPYRA®	16,691	12,168
FUMADERM™	16,053	15,965
Total product revenues	<u>\$1,453,554</u>	<u>\$1,039,110</u>

	<b>For the Nine Months</b>	
	<b>Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>PRODUCT REVENUES</b>		
AVONEX®	\$2,253,963	\$2,159,893
TYSABRI®	1,099,906	840,725
TECFIDERA®	478,500	-
FAMPYRA®	56,705	46,889
FUMADERM™	46,177	43,891
Total product revenues	<u>\$3,935,251</u>	<u>\$3,091,398</u>

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