



Biogen Idec Increases Revenue 6 percent to \$1.4 Billion in the Third Quarter

October 25, 2012

-- Non-GAAP Diluted EPS Rises 19%; GAAP Diluted EPS Up 17% --

-- Long-lasting Factor IX Hemophilia Candidate Reaches Primary Safety and Efficacy Endpoints in Phase 3 Trial --

-- Focus Remains on Commercial Execution, Investing in Future Success, Preparing for Upcoming Milestones --

WESTON, Mass.--([BUSINESS WIRE](#))--Biogen Idec Inc. (NASDAQ: BIIB) today announced third quarter 2012 financial results, delivering revenue growth of 6 percent to \$1.4 billion and non-GAAP diluted Earnings Per Share (EPS) growth of 19 percent.

Third Quarter 2012 Highlights:

- AVONEX[®] (interferon beta-1a) revenues increased 8 percent year-over-year to \$736 million. TYSABRI[®] (natalizumab) revenues were \$275 million, a decrease of 1 percent, compared to the third quarter of 2011. RITUXAN[®] (rituximab) revenues from our unconsolidated joint business arrangement were \$288 million for the quarter, an increase of 8 percent year-over-year.
- Global in-market sales of TYSABRI in the third quarter of 2012 were \$404 million, an increase of 3 percent over the third quarter of 2011. The total was comprised of \$230 million in United States sales and \$173 million in sales outside the U.S.
- During the third quarter, Biogen Idec recognized a gain of \$32 million in relation to the sale of our royalty and other rights related to BENLYSTA[®] (belimumab) to a DRI Capital managed fund (DRI). Under the terms of the agreement, Biogen Idec will receive a multiple on certain royalties payable to DRI for the period covering October 2011 through September 2014. The initial amount recognized covers the royalty period from October 1, 2011 through June 30, 2012.
- Third quarter 2012 GAAP diluted EPS was \$1.67, an increase of 17 percent as compared to the third quarter of 2011. GAAP net income attributable to Biogen Idec for the quarter was \$398 million, an increase of 13 percent as compared to the third quarter of 2011.
- Non-GAAP diluted EPS for the third quarter of 2012 was \$1.91, an increase of 19 percent as compared to the third quarter of 2011. Non-GAAP net income attributable to Biogen Idec for the third quarter of 2012 was \$455 million, an increase of 15 percent as compared to the third quarter of 2011. A reconciliation of our GAAP to non-GAAP results is included in Table 3 within this press release.

As of September 30, 2012, Biogen Idec had cash, cash equivalents and marketable securities of approximately \$3.3 billion.

"Through the first three quarters of 2012, Biogen Idec is on track to accomplish what we set out to do at the beginning of the year," said George A. Scangos, Ph.D., chief executive officer. "We have enhanced our leadership position in the multiple sclerosis market with strong results from AVONEX and TYSABRI; we have advanced our late-stage pipeline, with positive results from the registrational study for factor IX in hemophilia B; and we continue preparations for the potential launch of BG-12 next year. We look forward to data readouts for factor VIII in hemophilia A soon, followed by dextrampixole in ALS and PEGylated interferon in relapsing MS in the coming months. Our hard work is reflected in this quarter's results."

TYSABRI Patient Growth

Based upon data available to us through the TOUCH[®] prescribing program and other third party sources, as of the end of September 2012, we estimate that approximately 71,100 patients are on commercial and clinical TYSABRI therapy worldwide, and that cumulatively, approximately 108,300 patients have been treated with TYSABRI in the post-marketing setting.

Other Products and Royalty Revenues

Revenues from other products in the third quarter of 2012 were \$28 million, compared to \$17 million in the third quarter of 2011.

Table 4 provides individual product revenues.

Royalty revenues were \$47 million in the third quarter of 2012, compared to \$52 million in the third quarter of 2011.

For the third quarter of 2012, corporate partner revenues were \$12 million, compared to \$16 million in the third quarter of 2011.

Updated 2012 Financial Guidance

Biogen Idec also updated its full year 2012 financial guidance. This guidance consists of the following components:

- Revenue growth is expected to be in the mid to high-single digits versus 2011.
- Cost of Sales is expected to be approximately 9 percent to 10 percent of total revenue.

- R&D expense is expected to be approximately 24 percent to 25 percent of total revenue. R&D expense is inclusive of approximately \$20 to \$30 million of a potential upfront payment in the fourth quarter earmarked for a discovery collaboration which we are in the process of negotiating.
- SG&A expense is expected to be approximately 22 percent to 23 percent of total revenue.
- Tax expense is expected to be approximately 23 percent to 25 percent of pretax income.
- Non-GAAP diluted EPS is expected to be between \$6.40 and \$6.50.
- GAAP diluted EPS is expected to be between \$5.63 and \$5.73.
- Capital expenditures are expected to be in the range of \$230 to \$250 million.

Biogen Idec may incur charges, realize gains or experience other events in 2012 that could cause actual results to vary from this guidance.

Recent Events

- On October 18, Biogen Idec announced the U.S. Food and Drug Administration (FDA) has extended the initial PDUFA date for its review of the New Drug Application (NDA) for the marketing approval of BG-12 (dimethyl fumarate), the company's oral therapeutic candidate for the treatment of multiple sclerosis (MS). The three month extension is a standard extension period. The FDA has indicated that the extension of the PDUFA date is needed to allow additional time for review of the application. The agency did not ask for additional studies.
- On October 10, Biogen Idec presented extensive data from the company's leading MS franchise during the 28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Lyon, France. Fifty-three poster and platform presentations further showcased Biogen Idec's commitment to advancing the treatment of MS and improving the lives of people living with the disease around the world. Approved and investigational therapies in Biogen Idec's MS franchise presented at the conference included BG-12, daclizumab-HYP, anti-LINGO, TYSABRI, AVONEX and FAMPYRA[®] (prolonged-release fampridine tablets).

Third Quarter Events

- On September 26, [Biogen Idec](http://www.biogenidec.com) and Swedish Orphan Biovitrum (Sobi) announced positive top-line results from a Phase 3 study investigating long-lasting recombinant Factor IX Fc fusion protein (rFIXFc) in hemophilia B. The primary efficacy and safety objectives were met and Biogen Idec plans to submit a Biologics License Application to the FDA by the first quarter of 2013.
- On September 19, Biogen Idec announced that the September 20, 2012 issue of the *New England Journal of Medicine* (NEJM) published detailed results from two pivotal clinical trials that evaluated oral BG-12 for the treatment of MS. Results of the Phase 3 DEFINE and CONFIRM studies support BG-12's potential as a new oral option for MS treatment.

Conference Call and Webcast

The company's earnings conference call for the third quarter will be broadcast via the internet at 8:00 a.m. ET on October 25, 2012, and will be accessible through the Investors section of Biogen Idec's homepage, 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.

About AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. AVONEX is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS.

Symptoms of depression, suicidal ideation, or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Severe hepatic injury, including cases of hepatic failure has been reported rarely in patients. Rare cases of anaphylaxis have been reported. While beta interferons do not have any known direct cardiac toxicity, cases of congestive heart failure, cardiomyopathy, and cardiomyopathy with congestive heart failure have been reported in patients without known predisposition. Decreased peripheral blood counts have been reported from postmarketing experience. Seizures have been reported in patients using AVONEX, including patients with no prior history of seizure. Autoimmune disorders of multiple target organs have been reported. Routine periodic blood chemistry, hematology, liver function, and thyroid function tests are recommended. There are no adequate and well-controlled studies in pregnant women. AVONEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The most common side effects associated with AVONEX treatment are flu-like symptoms, including chills, fever, myalgia, and asthenia.

For additional important safety information, and the complete United States full prescribing information, please visit www.AVONEX.com.

About TYSABRI

TYSABRI is approved in more than 65 countries. TYSABRI is approved in the United States as a monotherapy for relapsing forms of MS, generally for

patients who have had an inadequate response to, or are unable to tolerate, an alternative MS therapy. In the European Union, it is approved for highly active relapsing-remitting MS (RRMS) in adult patients who have failed to respond to beta interferon or have rapidly evolving, severe RRMS.

TYSABRI has advanced the treatment of MS patients with its established efficacy. Data from the Phase 3 AFFIRM trial, which was published in the New England Journal of Medicine, showed that after two years, TYSABRI treatment led to a 68 percent relative reduction ($p < 0.001$) in the annualized relapse rate when compared with placebo and reduced the relative risk of disability progression by 42-54 percent ($p < 0.001$).

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain, which usually leads to death or severe disability. Infection by the JC virus (JCV) is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. Factors that increase the risk of PML are presence of anti-JCV antibodies, prior immunosuppressant use, and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. Other serious adverse events that have occurred in TYSABRI-treated patients include hypersensitivity reactions (e.g., anaphylaxis) and infections, including opportunistic and other atypical infections. Clinically significant liver injury has also been reported in the post-marketing setting. A list of adverse events can be found in the full TYSABRI product labeling for each country where it is approved.

TYSABRI is marketed and distributed by Biogen Idec Inc. and Elan Corporation, plc. For full prescribing information, including boxed warning and important safety information, and more information about TYSABRI, please visit www.biogenidec.com or www.elan.com.

Safe Harbor

This press release contains forward-looking statements, including statements about potential product launches, 2012 financial guidance, clinical trial readouts and regulatory submissions. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “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 our three principal products, AVONEX, TYSABRI and RITUXAN, the importance of TYSABRI's sales growth, uncertainty of success in commercializing other products, product competition, the occurrence of adverse safety events with our products, changes in the availability of reimbursement for our products, adverse market and economic conditions, our dependence on collaborations and other third parties over which we may not always have full control, problems with our manufacturing processes and our reliance on third parties, failure to comply with government regulation, our ability to protect our intellectual property rights and have sufficient rights to market our products together with the cost of doing so, the risks of doing business internationally, failure to 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, product liability claims, fluctuations in our operating results, the market, interest and credit risks associated with our portfolio of marketable securities, environmental risks, change of control provisions in our collaborations 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)

	<u>For the Three Months</u>		<u>For the Nine Months</u>	
	<u>Ended September 30,</u>	<u>2011</u>	<u>Ended September 30,</u>	<u>2011</u>
	<u>2012</u>		<u>2012</u>	<u>2011</u>
Revenues:				
Product	\$1,039,110	\$ 975,757	\$3,091,398	\$2,839,562
Unconsolidated joint business	287,792	266,471	856,975	739,054
Royalty	46,625	51,585	112,509	105,811
Corporate partner	<u>12,027</u>	<u>16,121</u>	<u>37,638</u>	<u>37,497</u>
Total revenues	<u>1,385,554</u>	<u>1,309,934</u>	<u>4,098,520</u>	<u>3,721,924</u>
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	139,358	123,527	411,666	327,143
Research and development	304,217	301,391	989,738	880,668
Selling, general and administrative	299,631	261,398	901,488	772,217
Collaboration profit sharing	75,545	81,475	239,951	244,319
Amortization of acquired intangible assets	53,013	49,347	151,256	157,699
Fair value adjustment of contingent consideration	9,456	2,500	23,573	5,900

Restructuring charge	803	1,803	2,225	18,390
Total cost and expenses	882,023	821,441	2,719,897	2,406,336
Gain on sale of rights	31,719	-	31,719	-
Income from operations	535,250	488,493	1,410,342	1,315,588
Other income (expense), net	(4,548)	(7,727)	13,546	(9,504)
Income before income tax expense and equity in loss of investee, net of tax	530,702	480,766	1,423,888	1,306,084
Income tax expense	131,044	127,104	334,213	339,608
Equity in loss of investee, net of tax	1,258	-	1,769	-
Net income	398,400	353,662	1,087,906	966,476
Net income attributable to non-controlling interests, net of tax	-	1,836	-	32,286
Net income attributable to Biogen Idec Inc.	<u>\$ 398,400</u>	<u>\$ 351,826</u>	<u>\$ 1,087,906</u>	<u>\$ 934,190</u>
Net income per share:				
Basic earnings per share attributable to Biogen Idec Inc.	<u>\$ 1.68</u>	<u>\$ 1.45</u>	<u>\$ 4.56</u>	<u>\$ 3.85</u>
Diluted earnings per share attributable to Biogen Idec Inc.	<u>\$ 1.67</u>	<u>\$ 1.43</u>	<u>\$ 4.53</u>	<u>\$ 3.81</u>
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Idec Inc.	<u>236,474</u>	<u>242,883</u>	<u>238,331</u>	<u>242,266</u>
Diluted earnings per share attributable to Biogen Idec Inc.	<u>238,125</u>	<u>245,366</u>	<u>240,137</u>	<u>245,140</u>

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

	<u>As of September 30, 2012</u>	<u>As of December 31, 2011</u>
ASSETS		
Cash, cash equivalents and marketable securities	\$ 1,605,794	\$ 1,690,657
Accounts receivable, net	661,519	584,603
Inventory	392,936	326,843
Other current assets	<u>395,139</u>	<u>373,324</u>
Total current assets	3,055,388	2,975,427
Marketable securities	1,741,534	1,416,737
Property, plant and equipment, net	1,676,583	1,571,387
Intangible assets, net	1,681,232	1,608,191
Goodwill	1,204,740	1,146,314
Investments and other assets	<u>271,144</u>	<u>331,548</u>
TOTAL ASSETS	<u>\$ 9,630,621</u>	<u>\$ 9,049,604</u>

LIABILITIES AND EQUITY

Current portion of notes payable and line of credit	\$ 453,209	\$ 3,292
Other current liabilities	1,067,884	909,597
Long-term deferred tax liability	249,577	248,644
Notes payable, line of credit and other financing arrangements	658,442	1,060,808
Other long-term liabilities	539,569	400,276
Equity	<u>6,661,940</u>	<u>6,426,987</u>
TOTAL LIABILITIES AND EQUITY	<u>\$ 9,630,621</u>	<u>\$ 9,049,604</u>

TABLE 3
Biogen Idec Inc. and Subsidiaries
Condensed Consolidated Statements of Income - Non-GAAP
(unaudited, in millions, except per share amounts)

EARNINGS PER SHARE	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
GAAP earnings per share - Diluted	\$ 1.67	\$ 1.43	\$ 4.53	\$ 3.81
Adjustments to net income attributable to Biogen Idec Inc. (as detailed below)	0.24	0.18	0.60	0.58
Non-GAAP earnings per share - Diluted	<u>\$ 1.91</u>	<u>\$ 1.61</u>	<u>\$ 5.13</u>	<u>\$ 4.39</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.	\$ 398.4	\$ 351.8	\$ 1,087.9	\$ 934.2
Adjustments:				
R&D: Restructuring and other	7.5	-	8.6	-
R&D: Stock option expense	1.0	1.8	2.6	3.5
SG&A: Stock option expense	1.4	2.9	2.8	5.5
Amortization of acquired intangible assets	50.9	48.6	145.2	156.9
2010 Restructuring initiatives	0.8	1.8	2.2	18.4
Fair value adjustment of contingent consideration	9.5	2.5	23.6	5.9
Income tax effect related to reconciling items	(14.8)	(14.9)	(40.9)	(48.4)
Non-GAAP net income attributable to Biogen Idec Inc.	<u>\$ 454.7</u>	<u>\$ 394.5</u>	<u>\$ 1,232.0</u>	<u>\$ 1,076.0</u>

2012 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:

	\$	Shares	Diluted EPS
Projected GAAP net income attributable to Biogen Idec Inc.*	\$ 1,362	240	\$ 5.68
Adjustments:			
Stock option expense	7		
Restructuring and other	11		
Amortization of acquired intangible assets	194		
Fair value adjustment of contingent consideration	25		
Income tax expense: Income tax effect related to reconciling items	(52)		
Projected Non-GAAP net income attributable to Biogen Idec Inc.	<u>\$ 1,547</u>	<u>240</u>	<u>\$ 6.45</u>

* Includes approximately \$20 million to \$30 million of R&D expense related to a potential upfront payment for a discovery collaboration currently under negotiation.

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.

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

PRODUCT REVENUES	For the Three Months	
	Ended September 30,	
	2012	2011
AVONEX	\$ 736,208	\$ 681,687
TYSABRI	274,769	277,322
FAMPYRA	12,168	3,136
FUMADERM	15,965	13,612
Other	-	-
Total product revenues	<u>\$1,039,110</u>	<u>\$ 975,757</u>

PRODUCT REVENUES	For the Nine Months	
	Ended September 30,	
	2012	2011
AVONEX	\$2,159,893	\$1,983,398
TYSABRI	840,725	810,098
FAMPYRA	46,889	3,136
FUMADERM	43,891	41,182
Other	-	1,748
Total product revenues	<u>\$3,091,398</u>	<u>\$2,839,562</u>

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