



Biogen Idec Reports Third Quarter 2011 Results

October 28, 2011

-- Revenue Increases 11% to \$1.3 Billion, Non-GAAP Diluted EPS Rises 19% and GAAP Diluted EPS Up 36% --

-- Expect to file for BG-12 approval in first half of 2012 based on strong Phase III data --

-- Worldwide collaboration agreement for Syk inhibitor program strengthens early-stage pipeline and immunology focus --

WESTON, Mass.--([BUSINESS WIRE](#))--Biogen Idec Inc. (NASDAQ: BIIB), a global biotechnology leader in the discovery, development, manufacturing and commercialization of innovative therapies, today announced its third quarter 2011 results.

Third Quarter 2011 Highlights:

- Third quarter revenues increased 11% to \$1.3 billion, compared to the third quarter of 2010. TYSABRI® (natalizumab) revenues increased 26% year-over-year to \$277 million while AVONEX® (interferon beta-1a) revenues increased 6% year-over-year to \$682 million. RITUXAN® (rituximab) revenues from our unconsolidated joint business arrangement were \$266 million for the quarter, an increase of 3% versus prior year.
- Global in-market sales of TYSABRI in the third quarter of 2011 were \$393 million, an increase of 28% over the third quarter of 2010. The total was comprised of \$197 million in U.S. sales and \$195 million in sales outside the U.S.
- On a reported basis, calculated in accordance with accounting principles generally accepted in the U.S. (GAAP), third quarter 2011 GAAP diluted EPS were \$1.43, an increase of 36% over the third quarter of 2010. GAAP net income attributable to Biogen Idec for the quarter was \$352 million, an increase of 38% from the third quarter of 2010.
- Non-GAAP diluted EPS for the third quarter of 2011 were \$1.61, an increase of 19% over the third quarter of 2010. Non-GAAP net income attributable to Biogen Idec for the third quarter of 2011 was \$395 million, an increase of approximately 20% from the third quarter of 2010. A reconciliation of our GAAP to non-GAAP results is included on Table 3 within this press release.

As of September 30, 2011, Biogen Idec had cash, cash equivalents and marketable securities of approximately \$2.9 billion.

"This has been a quarter of tremendous accomplishments for Biogen Idec," said George A. Scangos, Ph.D., the company's chief executive officer. "We continued to deliver strong product and financial performance driven by the growth of TYSABRI. The recent positive data readout from the CONFIRM trial of BG-12 is a truly meaningful development for our company and for multiple sclerosis patients, and we are thrilled by it. We now have strong results for BG-12 in two large and robust clinical trials and we anticipate filing for approval in the first half of next year with the intent of bringing this potentially major new therapy to MS patients as soon as possible. We continue to improve the quality of our pipeline by concentrating on cutting-edge science with the greatest potential to help patients and drive growth, and we are focused on excellence in execution as we prepare for the potential of multiple product launches in coming years."

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 2011, we estimate that approximately 63,500 patients were on commercial and clinical TYSABRI therapy worldwide, and that cumulatively approximately 92,200 patients have ever been treated with TYSABRI in the post-marketing setting.

Other Products and Royalties

Revenues from other products in the third quarter of 2011 were \$17 million, compared to \$12 million in the third quarter of 2010.

Table 4 provides individual product revenues.

Royalties were \$52 million in the third quarter of 2011, an increase of 43% compared to the third quarter of 2010.

Corporate partner revenues in the third quarter of 2011 were \$16 million, compared to \$5 million in the third quarter of 2010.

Revised Financial Guidance

Biogen Idec also revised its full year 2011 financial guidance. This guidance consists of the following components:

- Revenue growth is expected to be in the mid-single digits versus 2010.
- Cost of Sales is expected to be approximately 9% to 10% of total revenue.
- R&D is expected to be at the high end of 22% to 24% of total revenue.
- SG&A is expected to be at the high end of 20% to 21% of total revenue.

- Tax rate is expected to be approximately 26% to 28% of pretax income.
- GAAP diluted EPS is expected to be above \$4.91.
- Non-GAAP diluted EPS is expected to be above \$5.70.
- Capital expenditures are expected to be in the range of \$200 to \$220 million.

Biogen Idec may incur charges, realize gains or experience other events in 2011 that could cause actual results to vary from this guidance.

Recent Events

Showcasing world-class R&D

- On October 26, 2011, Biogen Idec announced positive topline results for CONFIRM, the second of two pivotal Phase III clinical trials designed to evaluate the investigational oral compound BG-12 (dimethyl fumarate) in people with relapsing-remitting multiple sclerosis (RRMS). Results showed that 240 mg of BG-12, administered either twice a day (BID) or three times a day (TID), demonstrated significant efficacy and favorable safety and tolerability profiles. Further analyses of the CONFIRM study are ongoing, and the company anticipates presenting detailed data at a future medical meeting.
- On October 21, 2011, Biogen Idec announced positive data from the Phase III DEFINE clinical trial of oral BG-12 in people with RRMS. Results showed that 240 mg of BG-12, administered either twice a day or three times a day, significantly reduced the proportion of patients who relapsed by 49 percent and 50 percent, respectively, at two years compared with placebo. Detailed data from DEFINE was presented at the 5th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS) in Amsterdam, the Netherlands, including a platform presentation.
- On October 19, 2011, Biogen Idec and Elan Corporation announced 28 company-supported TYSABRI presentations at ECTRIMS and ACTRIMS, held in Amsterdam, the Netherlands. Key data indicated patients on TYSABRI experienced reduced annualized relapse rates, particularly in those treated with TYSABRI early in the course of their disease. Data from AFFIRM, a long-term outcomes study, showed ARR and EDSS benefits were seen with earlier treatment of TYSABRI over delayed treatment. Data from a separate study showed TYSABRI-treated patients experienced improved incontinence-related quality of life. Additional data sets were presented further supporting Biogen Idec's and Elan's efforts to stratify the risk of PML in TYSABRI-treated patients.
- On October 12, 2011, Biogen Idec announced a robust selection of data from the company's multiple sclerosis (MS) franchise were presented in 48 posters and five platform presentations during ECTRIMS and ACTRIMS in Amsterdam, the Netherlands, October 19 through the 22. Therapies in Biogen Idec's MS franchise presented at the conference included TYSABRI, BG-12, FAMPYRA® (prolonged-release fampridine tablets), AVONEX, and daclizumab high-yield process (DAC HYP).
- On August 9, 2011, Biogen Idec and [Abbott](#) announced positive top-line results from SELECT, a global, registrational Phase 2b clinical trial designed to evaluate the investigational compound DAC HYP in people with RRMS over one year.

Advancing corporate strategy

- On October 27, 2011, Biogen Idec and Portola Pharmaceuticals, Inc. announced that they entered into an exclusive, worldwide collaboration and license agreement under which both companies will develop and commercialize highly selective, novel oral Syk inhibitors for the treatment of various autoimmune and inflammatory diseases, including rheumatoid arthritis and systemic lupus erythematosus. The collaboration's lead molecule, PRT062607, has been shown to be a highly potent and specific oral inhibitor of Syk in a broad panel of in vitro kinase and cellular assays and is currently in Phase 1 studies. Results of the studies to date suggest the compound is well tolerated and has a profile suitable for once-daily dosing.
- On October 20, 2011, Biogen Idec and Elan Corporation announced that the U.S. Food and Drug Administration extended the initial PDUFA date for its review of the supplemental Biologics License Application (sBLA) for TYSABRI. The sBLA was submitted in December 2010 to update the Prescribing Information for TYSABRI to include anti-JC virus antibody status as a factor to help stratify the risk of PML in the TYSABRI-treated population. The three month extension is a standard extension period.
- On September 29, 2011, Biogen Idec announced Tony Kingsley will assume the role of Executive Vice President of Global Commercial Operations with the promotion being effective on November 7, 2011. Mr. Kingsley will oversee development and execution of Biogen Idec's global commercial business strategies, reporting directly to Chief Executive Officer George A. Scangos, Ph.D.
- On September 6, 2011, Biogen Idec acquired 100% of the remaining Dompé shares in its joint ventures in both Italy and Switzerland. This integration is part of Biogen Idec's and Dompé Group's broader strategy to focus on each company's respective core business. Under the terms of the agreement, the joint ventures will become 100%-owned affiliates of Biogen Idec, giving the company a direct commercial presence in 29 countries.
- On August 15, 2011, Biogen Idec completed an agreement with Quest Diagnostics, Inc. that allows for commercial testing

of patients in the United States for the JC Virus antibody. The JC Virus Antibody Test was developed and analytically validated by Focus Diagnostics, Inc., the infectious disease diagnostics business of Quest Diagnostics.

Conference Call and Webcast

The company's earnings conference call for the third quarter will be broadcast via the internet at 8:30 a.m. ET on October 28, 2011, 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 earnings conference call and will be available there subsequently for one month.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. 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 \$4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the anticipated development of BG-12, potential product launches and financial guidance. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "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, RITUXAN and TYSABRI, the importance of TYSABRI's sales growth, product competition, uncertainty of success in commercializing other products, 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, failure to execute our growth initiatives, failure to comply with government regulation and possible adverse impact of changes in such regulation, our ability to protect our intellectual property rights and the cost of doing so, problems with our manufacturing processes and our reliance on third parties, charges and other costs relating to our properties, fluctuations in our effective tax rate, our ability to attract and retain qualified personnel, the risks of doing business internationally, product liability claims, fluctuations in our operating results, the market, interest and credit risks associated with our portfolio of marketable securities, our level of indebtedness, environmental risks, change of control provisions in our collaborations, representation of activist shareholders on our board of directors, 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.
September 30, 2011
Consolidated Statements of Income
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
REVENUES				
Product	\$ 975,757	\$ 876,850	\$2,839,562	\$2,560,305
Unconsolidated joint business	266,471	257,981	739,054	819,281
Royalties	51,585	35,952	105,811	92,072
Corporate partner	16,121	5,006	37,497	25,693
Total revenues	<u>1,309,934</u>	<u>1,175,789</u>	<u>3,721,924</u>	<u>3,497,351</u>
COST AND EXPENSES				
Cost of sales, excluding amortization of acquired intangible assets	123,527	95,918	327,143	299,958
Research and development	301,391	319,054	880,668	957,759
Selling, general and administrative	261,398	244,160	772,217	755,147
Collaboration profit sharing	81,475	63,991	244,319	190,240
Amortization of acquired intangible assets	49,347	53,531	157,699	155,568
Restructuring charges	1,803	-	18,390	-

Fair value adjustment of contingent consideration	2,500	-	5,900	-
Acquired in-process research and development	<u>-</u>	<u>205,000</u>	<u>-</u>	<u>244,976</u>
Total cost and expenses	<u>821,441</u>	<u>981,654</u>	<u>2,406,336</u>	<u>2,603,648</u>
Income from operations	488,493	194,135	1,315,588	893,703
Other income (expense), net	<u>(7,727)</u>	<u>(6,945)</u>	<u>(9,504)</u>	<u>(14,318)</u>
INCOME BEFORE INCOME TAX EXPENSE	480,766	187,190	1,306,084	879,385
Income tax expense	<u>127,104</u>	<u>75,011</u>	<u>339,608</u>	<u>252,564</u>
NET INCOME	<u>\$ 353,662</u>	<u>\$ 112,179</u>	<u>\$ 966,476</u>	<u>\$ 626,821</u>
Net income attributable to noncontrolling interest, net of tax	<u>1,836</u>	<u>(141,936)</u>	<u>32,286</u>	<u>(138,174)</u>
NET INCOME ATTRIBUTABLE TO BIOGEN IDEC INC.	<u>\$ 351,826</u>	<u>\$ 254,115</u>	<u>\$ 934,190</u>	<u>\$ 764,995</u>
BASIC EARNINGS PER SHARE	<u>\$ 1.45</u>	<u>\$ 1.06</u>	<u>\$ 3.85</u>	<u>\$ 2.98</u>
DILUTED EARNINGS PER SHARE	<u>\$ 1.43</u>	<u>\$ 1.05</u>	<u>\$ 3.81</u>	<u>\$ 2.95</u>
WEIGHTED-AVERAGE SHARES USED IN CALCULATING: BASIC EARNINGS PER SHARE	242,883	239,864	242,266	256,586
DILUTED EARNINGS PER SHARE	<u>245,366</u>	<u>242,313</u>	<u>245,140</u>	<u>258,906</u>

TABLE 2
Biogen Idec Inc.
September 30, 2011
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>September 30, 2011</u>	<u>December 31, 2010</u>
ASSETS		
Cash, cash equivalents and marketable securities	\$ 1,519,521	\$ 1,207,744
Accounts receivable, net	581,052	605,329
Inventory	310,934	289,066
Other current assets	<u>425,781</u>	<u>438,281</u>
Total current assets	<u>2,837,288</u>	<u>2,540,420</u>
Marketable securities	1,349,359	743,101
Property, plant and equipment, net	1,572,259	1,641,634
Intangible assets, net	1,659,114	1,772,826
Goodwill	1,146,314	1,146,314
Investments and other assets	<u>237,870</u>	<u>248,198</u>
TOTAL ASSETS	<u>\$ 8,802,204</u>	<u>\$ 8,092,493</u>

LIABILITIES AND SHAREHOLDERS' EQUITY

Current portion of notes payable and other financing arrangements	\$ 3,422	\$ 137,153
Other current liabilities	881,924	912,969
Long-term deferred tax liability	238,175	200,950
Notes payable and line of credit	1,060,639	1,066,379
Other long-term liabilities	384,450	325,599
Shareholders' equity	<u>6,233,594</u>	<u>5,449,443</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 8,802,204</u>	<u>\$ 8,092,493</u>

TABLE 3
Biogen Idec Inc.
September 30, 2011
Condensed Consolidated Statements of Income - Non-GAAP
(in millions, except per share amounts)
(unaudited)

EARNINGS PER SHARE	Three Months Ended		Nine Months Ended	
	September 30, 2011	2010	September 30, 2011	2010
GAAP earnings per share - Diluted	\$ 1.43	\$ 1.05	\$ 3.81	\$ 2.95
Adjustments to net income attributable to Biogen Idec Inc. (as detailed below)	<u>0.18</u>	<u>0.30</u>	<u>0.58</u>	<u>0.78</u>
Non-GAAP earnings per share - Diluted	<u>\$ 1.61</u>	<u>\$ 1.35</u>	<u>\$ 4.39</u>	<u>\$ 3.73</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.	\$ 351.8	\$ 254.1	\$ 934.2	\$ 765.0
Adjustments:				
R&D: Restructuring and severance	-	-	-	1.2
R&D: Stock option expense	1.8	2.4	3.5	4.9
R&D: Expenses paid by Cardiokine	-	1.1	-	4.9
SG&A: Restructuring and severance	-	-	-	5.7
SG&A: Stock option expense	2.9	3.5	5.5	23.0
Amortization of acquired intangible assets	48.6	53.5	156.9	155.6
Restructuring charges	1.8	-	18.4	-
Fair value adjustment of contingent consideration associated with the 2010 Panima acquisition	2.5	-	5.9	-
Acquired in-process research and development related to the initial consolidation of Knopp and the contingent consideration payment associated with the 2007 Syntonix acquisition	-	205.0	-	245.0
Income tax expense: Income tax effect related to reconciling items	(14.9)	(45.4)	(48.4)	(87.7)
Noncontrolling interest: Initial Consolidation of Knopp and expenses paid by Cardiokine	-	(146.1)	-	(149.9)
Non-GAAP net income attributable to Biogen Idec Inc.	<u>\$ 394.5</u>	<u>\$ 328.1</u>	<u>\$1,076.0</u>	<u>\$ 967.7</u>

2011 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:

	\$ Millions	Shares	Diluted EPS
Projected GAAP net income attributable to Biogen Idec Inc.	<u>\$ 1,203.0</u>	<u>245</u>	<u>\$ 4.91</u>
Adjustments:			
Stock option expense	10.5		
Amortization of acquired intangible assets	205.7		
Restructuring charges	21.7		

Contingent consideration	7.1		
Income taxes	(51.5)		
Projected Non-GAAP net income attributable to Biogen Idec Inc.	\$ 1,396.5	245	\$ 5.70

Use of Non-GAAP Financial Measures

Our “non-GAAP net income attributable to Biogen Idec Inc.” and “non-GAAP diluted EPS” financial measures exclude the following items from GAAP net income attributable to Biogen Idec Inc. and diluted EPS:

1. Purchase accounting and merger-related adjustments.

We exclude certain purchase accounting impacts, such as those related to the 2003 merger between Biogen, Inc. and Idec Pharmaceuticals, Inc., the acquisitions of Fumapharm AG, Conforma Therapeutics, Syntonix Pharmaceuticals, and Panima Pharmaceuticals AG and the consolidation of Knopp and Cardiokine. These include charges for in-process research and development and amortization of the acquired intangible assets. Excluding these charges provides management and investors with a supplemental measure of performance in which the Company’s acquired intellectual property is treated in a comparable manner to its internally developed intellectual property.

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. We exclude stock option expense from our non-GAAP R&D expenses and SG&A expenses, but include the impact of all other share-based awards and cash incentives in our non-GAAP results.

3. Other items.

We evaluate these 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 believe it is important to share these non-GAAP financial measures with shareholders as they better represent the ongoing economics of the business, reflect how we manage the business internally and set operational goals, and form the basis of our management incentive programs. Non-GAAP net income attributable to Biogen Idec Inc. and diluted EPS should not be viewed in isolation or as a substitute for reported, or GAAP, net income attributable to Biogen Idec Inc. and diluted EPS.

TABLE 4
Biogen Idec Inc.
September 30, 2011
Product Revenues
(in thousands)
(unaudited)

PRODUCT REVENUES	Three Months Ended September 30,	
	2011	2010
Avonex®	\$ 681,687	\$ 643,623
Tysabri®	277,322	220,739
Fumaderm®	13,612	12,365
Fampyra®	3,136	-
Other	-	123
Total product revenues	<u>\$ 975,757</u>	<u>\$ 876,850</u>

PRODUCT REVENUES	Nine Months Ended September 30,	
	2011	2010
Avonex®	\$1,983,398	\$1,864,284
Tysabri®	810,098	658,621
Fumaderm®	41,182	37,255
Fampyra®	3,136	-

Other	1,748	145
Total product revenues	<u>\$2,839,562</u>	<u>\$2,560,305</u>

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