

# Biogen Idec Third Quarter 2014 Revenues Increase 37% to \$2.5 Billion

October 22, 2014

PLEGRIDY<sup>TM</sup> Approved in the US and EU for Multiple Sclerosis

ELOCTATE<sup>TM</sup> Launched in the US for Hemophilia A

Rollout of TECFIDERA® Continues across the Globe

CAMBRIDGE, Mass.--(<u>BUSINESS WIRE</u>)--Biogen Idec Inc. (NASDAQ: BIIB) today reported third quarter 2014 results, including revenue of \$2.5 billion, a 37% increase compared to the third quarter of 2013. Third quarter 2014 non-GAAP diluted earnings per share (EPS) were \$3.80, an increase of 61% over the third quarter of 2013. Non-GAAP net income attributable to Biogen Idec for the third quarter was \$900 million, an increase of 60% over the third quarter of 2013.

On a reported basis, GAAP diluted EPS for the third quarter of 2014 were \$3.62, an increase of 77% over the third quarter of 2013. GAAP net income attributable to Biogen Idec for the third quarter of 2014 was \$857 million, an increase of 76% versus the same period in the prior year. A reconciliation of GAAP to Non-GAAP quarterly financial results and 2014 full year guidance can be found in Table 3 at the end of this release.

"The third quarter was a period of significant achievement as we continued to make progress against our corporate objectives," said Chief Executive Officer George A. Scangos, Ph.D. "We introduced innovative therapies for MS and hemophilia and began to launch them in markets worldwide. We also launched TECFIDERA in several European countries, furthering its position as a leading oral MS therapy.

"As we continued to extend our commercial business we remained focused on building our future, bringing to our team leading talent in technology, ALS research, neurology and gene therapy. I am also very proud of being recognized for our focus on corporate citizenship as again we were named the leading biotechnology company on the Dow Jones Sustainability Index," Dr. Scangos added.

## **Third Quarter 2014 Performance Highlights**

- TECFIDERA revenues were \$787 million, consisting of \$638 million in U.S. sales and \$149 million in sales outside the U.S.
- Interferon revenues, including AVONEX® and PLEGRIDY, were \$745 million, consisting of \$482 million in U.S. sales and \$263 million in sales outside the U.S.
- TYSABRI® revenues were \$501 million, consisting of \$275 million in U.S. sales and \$226 million in sales outside the U.S.
- Net revenues relating to RITUXAN® and GAZYVA® from our unconsolidated joint business arrangement were \$291 million.
- ALPROLIX® revenues were \$25 million, and ELOCTATE<sup>TM</sup> revenues were \$22 million.

#### Other Third Quarter 2014 Financial Results

- Revenues for FAMPYRA® and FUMADERM<sup>TM</sup> were \$37 million.
- Royalty revenues were \$67 million.
- Corporate partner revenues were \$36 million.
- As of September 30, 2014, Biogen Idec had cash, cash equivalents and marketable securities totaling approximately \$3.2 billion.
- During the quarter, the Internal Revenue Service issued final regulations related to the Branded Pharmaceutical Drug (BPD) Fee, which had the effect of changing the recognition of the fee for accounting purposes, from the period in which the fee was paid, to the period when the sale occurs. Our products that are subject to the BPD fee include PLEGRIDY, TECFIDERA, TYSABRI and RITUXAN. As a result of these final regulations, we recognized an incremental BPD fee which reduced our share of revenues from unconsolidated joint business by \$21.0 million and increased selling, general and administrative expense by \$18.5 million for the periods 2013 through the end of this quarter.

# 2014 Financial Guidance

Biogen Idec updated its full year 2014 financial guidance.

This updated guidance consists of the following components:

• Revenue growth is expected to be approximately 38% to 41% compared to 2013, unchanged from prior guidance.

- R&D expense is expected to be approximately 20% to 21% of total revenue.
  - For the balance of the year, full year guidance for R&D expense includes approximately \$50 million intended for new early and mid-stage business development opportunities. This amount is reduced from prior guidance due to revised business development expectations through the end of the year.
- SG&A expense is expected to be approximately 22% to 23% of total revenue, unchanged from prior guidance.
- GAAP diluted EPS is expected to be between \$12.00 and \$12.10.
- Non-GAAP diluted EPS is expected to be between \$13.45 and \$13.55, an increase over prior guidance primarily due to updated business development expectations.

Biogen Idec may incur charges, realize gains or experience other events in 2014 that could cause actual results to vary from this guidance.

#### Multiple Sclerosis (MS) Events

- In July 2014, Biogen Idec received marketing authorization from the European Commission for PLEGRIDY, a pegylated interferon administered subcutaneously once every two weeks for adults with relapsing-remitting multiple sclerosis.
- In August 2014, the U.S. Food and Drug Administration approved PLEGRIDY as a new treatment for people with relapsing forms of multiple sclerosis.
- In September 2014, Biogen Idec presented extensive new data from its multiple sclerosis portfolio at the sixth Triennial Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Research and Treatment in Multiple Sclerosis in Boston.
- TECFIDERA was recently launched in Denmark, the Netherlands, Switzerland, and Hungary.

#### **Hemophilia Events**

- In July 2014, Biogen Idec launched ELOCTATE in the U.S. for the treatment of adults and children with hemophilia A.
- In October 2014, Biogen Idec submitted a Marketing Authorisation Application (MAA) for ELOCTA to the European Medicines Agency (EMA). ELOCTA is the approved trade name in Europe for ELOCTATE. The MAA submission is subject to validation by the EMA.

#### **Other Events**

- During the third quarter of 2014, Biogen Idec announced the hiring of several key leaders including:
  - Adriana Karaboutis, Executive Vice President, Technology and Business Solutions, to lead Biogen Idec's information technology (IT) operations and advance the Company's use of technology and data to enhance overall engagement with patients and healthcare providers.
  - Donald R. Johns, M.D., Vice President, to lead Biogen Idec's amyotrophic lateral sclerosis (ALS) Innovation Hub
    (ALS iHub), a dedicated unit focused on accelerating the discovery and development of novel therapies for ALS by
    integrating research with clinical development.
  - Olivier Danos, Ph.D., Senior Vice President, Gene Therapy, to lead the Company's gene therapy research group, a team dedicated to identifying and developing new technologies for gene transfer and genome engineering.
- In September 2014, Biogen Idec announced that it was named the biotechnology industry leader on the Dow Jones Sustainability World Index. The Company was also named to the Dow Jones Sustainability Index North America for the fifth consecutive year, one of only two biotech companies included.

# **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. EDT on October 22, 2014, and will be accessible through the Investors section of Biogen Idec's homepage, <a href="www.biogenidec.com">www.biogenidec.com</a>. 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 Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec 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 <a href="www.biogenidec.com">www.biogenidec.com</a>.

# Safe Harbor

This press release contains forward-looking statements, including statements about our business strategy and 2014 financial guidance. 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; uncertainty of success in execution of our commercialization of new products; 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; difficulties in obtaining or changes in the availability of reimbursement for our products; uncertainty of success in developing other product candidates, including our ability to obtain product approvals in a timely manner or at all for new or current products; the occurrence of adverse safety events with our products; failure to compete effectively due to significant product competition in the markets for our products; dependence on collaborators and other third parties for the development and commercialization of products; problems with our manufacturing processes; failure to manage our growth and execute our growth initiatives; failure to comply with legal and regulatory requirements; the risks of doing business internationally; charges and other costs relating to our properties; risks and uncertainties relating to the timing, outcome and impact of legal, administrative and other proceedings and disputes; 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)

	For the Thi Ended Sep		For the Nine Months Ended September 30,		
	2014	2013	2014	2013	
Revenues:					
Product, net	\$2,117,366	\$1,453,554	\$5,916,423	\$3,935,251	
Unconsolidated joint business	290,678	303,210	890,859	856,601	
Royalty	67,148	54,144	145,348	125,076	
Corporate partner	36,254	16,872	110,019	49,421	
Total revenues	2,511,446	1,827,780	7,062,649	4,966,349	
Cost and expenses:					
Cost of sales, excluding amortization of acquired intangible assets	302,639	234,696	873,771	599,173	
Research and development	417,174	410,017	1,393,331	1,021,820	
Selling, general and administrative	570,436	405,584	1,658,732	1,189,194	
Amortization of acquired intangible assets	122,431	99,998	382,515	233,524	
Collaboration profit sharing	-	-	-	85,357	
(Gain) loss on fair value remeasurement of contingent consideration	(49,433)	(97)	(46,213)	(2,983)	
Total cost and expenses	1,363,247	1,150,198	4,262,136	3,126,085	
Gain on sale of rights	4,379	6,949	12,138	17,319	
Income from operations	1,152,578	684,531	2,812,651	1,857,583	
Other income (expense), net	(16,290)	(4,640)	(17,030)	(29,525)	
Income before income tax expense and equity in loss of investee, net of tax	1,136,288	679,891	2,795,621	1,828,058	
Income tax expense	274,774	186,105	721,709	410,753	
Equity in loss of investee, net of tax		6,170	14,932	12,270	
Net income	856,120	487,616	2,058,980	1,405,035	
Net income (loss) attributable to noncontrolling interests, net of tax	(738)		7,660		

Net income attributable to Biogen Idec Inc.	\$ 856,858         \$ 487,616         \$2,051,320         \$1,405,035	
Net income per share:		
Basic earnings per share attributable to Biogen Idec Inc.	<b>\$</b> 3.63 <b>\$</b> 2.06 <b>\$</b> 8.67 <b>\$</b> 5.93	
Diluted earnings per share attributable to Biogen Idec Inc.	\$ 3.62 \$ 2.05 \$ 8.64 \$ 5.89	
Weighted-average shares used in calculating:		
Basic earnings per share attributable to Biogen Idec Inc.	236,217 237,070 236,641 237,131	
Diluted earnings per share attributable to Biogen Idec Inc.	236,972 238,349 237,449 238,508	

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

	As of September 30, 2014		As of December 31, 2013			
ASSETS						
Cash, cash equivalents and marketable securities	\$	1,861,346	\$	1,222,729		
Accounts receivable, net		1,091,232		824,406		
Inventory		753,063		659,003		
Other current assets		666,470		478,796		
Total current assets		4,372,111		3,184,934		
Marketable securities		1,371,431		625,772		
Property, plant and equipment, net		1,724,129		1,750,710		
Intangible assets, net		4,129,754		4,474,653		
Goodwill		1,541,204		1,232,916		
Investments and other assets	_	565,513		594,350		
TOTAL ASSETS	\$	13,704,142	\$	11,863,335		
LIABILITIES AND EQUITY						
Current portion of notes payable	\$	3,220	\$	3,494		
Other current liabilities		1,937,427		1,754,785		
Notes payable		583,977		592,433		
Long-term deferred tax liability		90,357		232,554		
Other long-term liabilities		658,276		659,231		
Equity		10,430,885		8,620,838		
TOTAL LIABILITIES AND EQUITY	\$	13,704,142	\$	11,863,335		

#### 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)

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,				
EARNINGS PER SHARE		2014 2013		2014			2013	
GAAP earnings per share - Diluted	\$	3.62	\$	2.05	\$	8.64	\$	5.89
Adjustments to net income attributable to Biogen Idec Inc. (as detailed below)		0.18		0.31		1.11		0.73
Non-GAAP earnings per share - Diluted	\$	3.80	\$	2.35	\$	9.75	\$	6.62
An itemized reconciliation between net income attributable to Biogen Idec Inc. on a GA GAAP net income attributable to Biogen Idec Inc.	AP bas \$	is and on a 856.9	a non \$	-GAAP ba 487.6	isis is \$	as follows: 2,051.3	\$	1.405.0
Adjustments:	*	000.0	Ψ		*	_,000	*	.,
Amortization of acquired intangible assets		118.7		97.1		371.5		225.2
(Gain) loss on fair value remeasurement of contingent consideration		(49.4)		(0.1)		(46.2)		(3.0)
SG&A: Stock option expense		1.4		1.3		5.4		4.2
R&D: Stock option expense		1.2		1.2		4.8		3.6
Donation to Biogen Idec Foundation		-		-		35.0		-
Income tax effect related to reconciling items		(29.2)		(26.0)		(106.2)		(55.7)
Non-GAAP net income attributable to Biogen Idec Inc.	\$	899.6	\$	561.1	\$	2,315.6	\$	1,579.3

#### 2014 Full Year Guidance: GAAP to Non-GAAP Reconciliation

An itemized reconciliation between projected net income attributable to Biogen Idec 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 Idec Inc.	2,860	237	\$	12.05	
Adjustments:					
Amortization of acquired intangible assets	470				
(Gain) loss on fair value remeasurement of contingent consideration	(44)				
Stock option expense	13				
Donation to Biogen Idec Foundation	35				
Income tax effect related to reconciling items	(130)				
Projected Non-GAAP net income attributable to Biogen Idec Inc.	3,204	237	\$	13.50	

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 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 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 remeasurements 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)

			ee Months ember 30,	For the Nine Months Ended September 30			
	20	14	2013	2014	2013		
PRODUCT REVENUES							
Multiple Sclerosis (MS):							
AVONEX	\$ 74	1,848	\$ 733,449	\$2,277,094	\$2,253,963		
PLEGRIDY	3	3,382	-	3,382	-		
TECFIDERA	787	7,122	286,366	1,993,212	478,500		
TYSABRI	501	1,237	400,995	1,475,722	1,099,906		
Hemophilia:							
ALPROLIX	25	5,305	-	35,702	-		
ELOCTATE	2	1,560	-	21,560	-		
Other product revenues:							
FAMPYRA	20	),384	16,691	61,660	56,705		
FUMADERM	16	5,528	16,053	48,091	46,177		
Total product revenues, net	\$2,117	7,366	\$1,453,554	\$5,916,423	\$3,935,251		

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