Biogen Third Quarter 2015 Revenues Increase 11% to $2.8 Billion; Company Raises 2015 Full Year Guidance

October 21, 2015

Corporate restructuring to result in an 11% workforce reduction

First patient enrolled in aducanumab Phase 3 studies for Alzheimer's disease

Company announces agreement to license Mitsubishi Tanabe Pharma's Phase 3 ready molecule for autoimmune diseases

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Inc. (NASDAQ: BIIB) today reported third quarter 2015 results, including revenues of $2.8 billion, an 11% increase compared to the third quarter of 2014. Non-GAAP diluted earnings per share (EPS) for the third quarter of 2015 were $4.48, an increase of 18% over the third quarter of 2014. Non-GAAP net income attributable to Biogen for the third quarter of 2015 was $1.0 billion, an increase of 16% over the third quarter of 2014.

On a reported basis, GAAP diluted EPS for the third quarter of 2015 were $4.15, an increase of 15% over the third quarter of 2014. GAAP net income attributable to Biogen for the third quarter of 2015 was $966 million, an increase of 13% 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 also announced a corporate restructuring, which includes the termination of a number of pipeline programs and an 11% reduction in workforce. These changes are expected to reduce the current annual run rate of operating expenses by approximately $250 million. The Company plans to reinvest these savings to support key commercial initiatives, including increased sales and marketing activities behind TECFIDERA, and the advancement of high potential pipeline candidates in areas such as Alzheimer's disease, multiple sclerosis, and spinal muscular atrophy.

"We remain committed to maximizing the potential of our commercial portfolio, with a particular emphasis on TECFIDERA®," said Chief Executive Officer George A. Scangos, Ph.D. "We continue to see growth for our market leading portfolio of MS products, driven by the uptake of our oral therapy TECFIDERA in recently launched countries worldwide and the introduction of PLEGRIDY® to new markets."

"The decision to reduce the Company's workforce was extremely difficult, but we believe these actions are necessary to fulfill our mission of bringing important new medicines to patients. We have several high-quality programs that are now or soon will be in Phase 3, and the cost savings from the restructuring will be reinvested to carry out those programs aggressively and hopefully to bring them to patients as quickly as possible," Dr. Scangos continued. "We are grateful for the contributions of our talented and admired colleagues and we will do our best to treat everyone with fairness and dignity."

Corporate Restructuring

The Company plans to substantially complete the majority of the 11% reduction of its global workforce by the end of 2015. The Company is in the process of notifying employees affected by the restructuring, and has initiated the required consultation processes in European countries where employees may be impacted. Biogen has also discontinued several programs, including its Phase 3 program for TECFIDERA in secondary progressive MS, the development of anti-TWEAK in lupus nephritis, and certain activities in immunology and fibrosis research.

Implementing these changes is expected to reduce the current annual run rate of operating expenses by approximately $250 million. Biogen expects to incur a charge of approximately $85-$95 million, primarily in the fourth quarter of 2015.

Additionally, the Company plans to identify additional savings in non-labor expenses by the end of the year.

The restructuring is expected to yield savings for 2016 and beyond and provides additional financial flexibility to support marketed therapies and focus on a number of meaningful pipeline opportunities, including:

- Commercial initiatives aimed at increasing sales of TECFIDERA including new direct to consumer marketing programs;
- Aducanumab in Phase 3 for Alzheimer's disease;
- BAN2401 in Phase 2 for Alzheimer's disease;
- E2609 in Phase 2 for Alzheimer's disease;
- SMN-Rx in Phase 3 for spinal muscular atrophy;
- Anti-LINGO in Phase 2 for multiple sclerosis;
- Subject to deal closure, MT-1303, a Phase 3 ready asset for inflammatory bowel disease with potential further development in MS; and
- Raxatrigine (CNV1014802), a Phase 3 ready asset for trigeminal neuralgia and Phase 2b ready for lumbar radiculopathy.

Third Quarter 2015 Financial Highlights

- Total multiple sclerosis product sales were $2.2 billion compared to $2.1 billion in the same quarter last year.

- TECFIDERA revenues were $937 million compared to $787 million in the same quarter last year. These results consisted of $754 million in U.S. sales and $183 million in sales outside the U.S. compared to $638 million and $149 million, respectively, in the third quarter of 2014.
    - TECFIDERA revenues in the third quarter of 2015 increased 6% versus the second quarter of 2015. In the U.S., TECFIDERA revenues increased 5% versus the second quarter of 2015, partially due to an increase of inventory in the specialty pharmacy channel.

- Interferon revenues, including AVONEX® and PLEGRIDY, were $785 million compared to $745 million in the same quarter last year. These results consisted of $538 million in U.S. sales and $247 million in sales outside the U.S. compared to $482 million and $263 million, respectively, in the third quarter of 2014.
    - Interferon revenues in the third quarter of 2015 increased 14% versus the second quarter of 2015. In the U.S., interferon revenues increased 18% versus the second quarter of 2015, primarily due to a rebalancing of wholesaler inventory from the drawdown in the second quarter of 2015, which contributed approximately $40 million to the increase.

- TYSABRI® revenues were $480 million compared to $501 million in the same quarter last year. These results consisted of $284 million in U.S. sales and $196 million in sales outside the U.S. compared to $275 million and $226 million, respectively, in the third quarter of 2014.

- Net revenues relating to RITUXAN® and GAZYVA® from our unconsolidated joint business arrangement were $337 million compared to $291 million in the same quarter last year.

- ELOCTATE® revenues were $91 million and ALPROLIX® revenues were $66 million.

- Revenues for FAMPYRA® and FUMADERM™ were $34 million compared to $37 million in the same quarter last year.

- Royalty revenues were $9 million compared to $67 million in the same quarter last year.

- Corporate partner revenues were $40 million compared to $36 million in the same quarter last year.

- Foreign exchange, offset by hedging, weakened total revenues by approximately $63 million compared to the third quarter of 2014.

- Non-GAAP SG&A expense was $478 million compared to $569 million in the same quarter last year. GAAP SG&A expense was $478 million compared to $570 million in the same quarter last year.

- Non-GAAP R&D expense was $520 million compared to $416 million in the same quarter last year. GAAP R&D expense was $520 million compared to $417 million in the same quarter last year.

Capital Allocation Highlights

- As of September 30, 2015, Biogen purchased approximately 9.7 million shares of its common stock for a cost of approximately $3 billion in the open market under the Company's previously authorized $5.0 billion share repurchase program. Since the end of the quarter, the Company has purchased an additional 3.2 million shares for approximately $900 million.

- At the end of the third quarter of 2015, the Company's weighted average diluted shares were 233 million.

- In September 2015, Biogen issued senior unsecured notes in the aggregate principal amount of $6 billion.

- Through the end of the third quarter of 2015, Biogen had cash, cash equivalents and marketable securities totaling approximately $7.8 billion.

2015 Financial Guidance

In light of the restructuring, change in capital structure, and significant share repurchases, Biogen announced an update to its full year 2015 financial guidance. This guidance consists of the following components:

- Revenue growth is expected to be approximately 8% to 9% compared to 2014, a modest increase versus prior guidance. This guidance implies a sequential decrease in revenue in the fourth quarter of 2015 based on the assumption of stable US wholesaler inventory levels for the balance of the year in MS and a reduction in US wholesaler inventory for Rituxan.

- 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 19% to 20% of total revenue, a decrease from prior guidance.

- Non-GAAP diluted EPS is expected to be between $16.20 and $16.50, an increase from prior guidance.

- GAAP diluted EPS is expected to be between $14.65 and $14.95, an increase 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.

Business Development and Collaboration Highlights

- In July 2015, Biogen and the Parkinson's Institute and Clinical Center announced the formation of a strategic alliance focused on enhancing the understanding of the underlying biology of Parkinson's disease (PD).
- In August 2015, Biogen, the ALS Association and Columbia University Medical Center announced a new collaboration to better understand the differences and commonalities in the ALS (Amyotrophic Lateral Sclerosis) disease process and how genes influence the clinical features of the disease.
- In September 2015, Biogen announced an agreement with Mitsubishi Tanabe Pharma to exclusively license MT-1303, a Phase 3 ready experimental medicine with potential in multiple autoimmune indications, including inflammatory bowel disease and potentially multiple sclerosis. MT-1303 is a potentially best-in-class oral compound that targets the sphingosine 1-phosphate (S1P) receptor. This transaction is subject to customary closing conditions, including the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 in the United States, and is expected to close in the fourth quarter of 2015.

Neurology Highlights

- In September 2015, Biogen announced that the first patient has been enrolled in the Phase 3 studies, ENGAGE and EMERGE, for its investigational treatment aducanumab for early Alzheimer's disease.
- In October 2015, Biogen presented new clinical data for its portfolio of MS therapies at the 31st meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Barcelona, Spain. Presentations included results providing evidence for the strong and sustained efficacy of TECFIDERA in relapsing-remitting multiple sclerosis (RRMS) patients who were newly diagnosed or who were early in the course of disease, disability and cognitive outcomes data for ZINBRYTA™ versus intramuscular interferon beta-1a, and additional Phase 2 results for anti-LINGO-1 in acute optic neuritis.
- In October 2015, Biogen announced the top-line results from the Phase 3 ASCEND study evaluating natalizumab (TYSABRI) in secondary progressive multiple sclerosis. The study did not achieve its primary and secondary endpoints. Detailed results from the ASCEND study will be presented at a future medical meeting.
- During the quarter, Roche announced positive results from two Phase 3 studies evaluating ocrelizumab compared with interferon beta-1a in RRMS as well as a Phase 3 study evaluating ocrelizumab versus placebo in primary progressive MS (PPMS). If approved for commercial sale by the FDA, Biogen will receive tiered royalties ranging between 13.5-24% of US net sales.
- Biogen has ceased development of anti-TWEAK in lupus nephritis after a Phase 2 futility analysis. Biogen will provide more information on the anti-TWEAK program in future scientific presentations.

Hemophilia Highlights

- In August 2015, Biogen presented interim results from the Phase 3 B-YOND open label extension study of ALPROLIX in hemophilia B at 67th Annual Meeting for the National Hemophilia Foundation. These interim data showed that participants in the study maintained low bleeding rates with one to two week prophylaxis regimens. Safety results were typical of the hemophilia B populations studied.
- In August 2015, interim results from the ASPIRE extension study of ELOCTATE in hemophilia A were published in *Haemophilia*. These data demonstrated that people on extended-interval prophylaxis regimens with ELOCTATE experienced low bleeding rates. Safety results were consistent with the general hemophilia A population.
- In September 2015, Biogen and Swedish Orphan Biovitrum AB (Sobi) announced a positive recommendation from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the marketing authorization of ELOCTA™ (rFVIIIFc). If approved, Sobi would lead commercialization in Europe.
- In October 2015, Biogen, Sobi, and the World Federation of Hemophilia (WFH) announced that the first shipments of much-needed hemophilia therapy have started to arrive at treatment centers across the developing world. This initiative is the first phase of Biogen and Sobi's ten-year commitment to produce up to 1 billion International Units (IUs) of hemophilia therapy for humanitarian use.

Other Highlights

- In September 2015, Biogen announced that it was named the biotechnology industry leader on the Dow Jones Sustainability World Index for the second year in a row. The company was also named to the Dow Jones Sustainability Index North America for the sixth consecutive year, one of only three biotech companies included.
- In October, Biogen announced that Tony Kingsley, executive vice president, Global Commercial Operations, will leave the company and a search has been initiated for a permanent replacement. In the interim, his responsibilities will be assumed by John G. Cox, executive vice president, Pharmaceutical Operations & Technology.

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 21, 2015, and will be

accessible through the Investors section of Biogen's homepage, 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.

Safe Harbor

This press release contains forward-looking statements, including statements relating to: commercial product and pipeline potential and progress; anticipated benefits, cost savings, and charges related to our corporate restructuring initiatives; anticipated benefits and potential of investments, collaborations and business development activities; and updated 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; 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; the occurrence of adverse safety events, restrictions on use with our products or product liability claims; difficulties in obtaining adequate coverage or changes in pricing or the availability of reimbursement for our products; 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; problems with our manufacturing processes; failure to manage our growth and execute our growth initiatives; failure to achieve the anticipated benefits and savings from our corporate restructuring efforts; failure to comply with legal and regulatory requirements; risks relating to technology failures or breaches; risks related to indebtedness; 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; risks relating to investment in and expansion of manufacturing capacity for future clinical and commercial requirements; 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; risks relating to access to capital and credit markets; environmental risks; risks relating to the sale and distribution by third parties of counterfeit versions of our products; risks relating to the use of social media for our business; change in control provisions in certain of our collaboration agreements; 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 September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product, net	$2,391,717	$2,117,366	$6,762,605	$5,916,423
Unconsolidated joint business	337,181	290,678	1,005,302	890,859
Royalty	8,989	67,148	37,386	145,348
Corporate partner	39,972	36,254	119,171	110,019
Total revenues	2,777,859	2,511,446	7,924,464	7,062,649
Cost and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	310,028	302,639	908,579	873,771
Research and development	519,863	417,174	1,471,140	1,393,331
Selling, general and administrative	477,827	570,436	1,530,083	1,658,732
Amortization of acquired intangible assets	98,065	122,431	285,972	382,515
(Gain) loss on fair value remeasurement of contingent consideration	244	(49,433)	5,887	(46,213)
Total cost and expenses	1,406,027	1,363,247	4,201,661	4,262,136
Gain on sale of rights	-	4,379	-	12,138
Income from operations	1,371,832	1,152,578	3,722,803	2,812,651
Other income (expense), net	(15,413)	(16,290)	(41,288)	(17,030)
Income before income tax expense and equity in loss of investee, net of tax	1,356,419	1,136,288	3,681,515	2,795,621
Income tax expense	330,093	274,774	904,475	721,709
Equity in loss of investee, net of tax	6,833	5,394	12,548	14,932
Net income	1,019,493	856,120	2,764,492	2,058,980

Net income (loss) attributable to noncontrolling interests, net of tax	53,871	(738)	49,053	7,660
Net income attributable to Biogen Inc.	$ 965,622	$ 856,858	$2,715,439	$2,051,320
Net income per share:				
Basic earnings per share attributable to Biogen Inc.	$ 4.16	$ 3.63	$ 11.60	$ 8.67
Diluted earnings per share attributable to Biogen Inc.	$ 4.15	$ 3.62	$ 11.57	$ 8.64
Weighted-average shares used in calculating:				
Basic earnings per share attributable to Biogen Inc.	232,191	236,217	234,134	236,641
Diluted earnings per share attributable to Biogen Inc.	232,612	236,972	234,659	237,449

TABLE 2

BIOGEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	As of September 30, 2015	As of December 31, 2014
ASSETS		
Cash, cash equivalents and marketable securities	$ 5,842,502	$ 1,845,384
Accounts receivable, net	1,327,780	1,292,445
Inventory	918,921	804,022
Other current assets	1,181,670	730,303
Total current assets	9,270,873	4,672,154
Marketable securities	1,947,354	1,470,652
Property, plant and equipment, net	2,027,821	1,765,683
Intangible assets, net	4,181,245	4,028,507
Goodwill	2,408,854	1,760,249
Investments and other assets	892,221	617,536
TOTAL ASSETS	$ 20,728,368	$ 14,314,781
LIABILITIES AND EQUITY		
Current portion of notes payable and other financing arrangements	$ 5,171	$ 3,136
Other current liabilities	2,628,797	2,216,570
Notes payable and other financing arrangements	6,529,275	580,283
Long-term deferred tax liability	136,761	50,656
Other long-term liabilities	861,421	650,096
Equity	10,566,943	10,814,040
TOTAL LIABILITIES AND EQUITY	$ 20,728,368	$ 14,314,781

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 September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
GAAP earnings per share - Diluted	$ 4.15	$ 3.62	$ 11.57	$ 8.64
Adjustments to GAAP net income attributable to Biogen Inc. (as detailed below)	0.33	0.18	0.95	1.11
Non-GAAP earnings per share - Diluted	$ 4.48	$ 3.80	$ 12.52	$ 9.75

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 September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
GAAP net income attributable to Biogen Inc.	$ 965.6	$ 856.9	$ 2,715.4	$ 2,051.3
Adjustments:				
Amortization of acquired intangible assets	94.0	118.7	273.3	371.5
(Gain) loss on fair value remeasurement of contingent consideration	0.2	(49.4)	5.9	(46.2)
SG&A: Stock option expense	-	1.4	-	5.4
R&D: Stock option expense	-	1.2	-	4.8
Donation to Biogen Foundation	-	-	-	35.0
Income tax effect related to reconciling items	(17.7)	(29.2)	(57.4)	(106.2)
Non-GAAP net income attributable to Biogen Inc.	$ 1,042.2	$ 899.6	$ 2,937.2	$ 2,315.6

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.	$ 3,422.0	231.2	$ 14.80
Adjustments:			
Amortization of acquired intangible assets	364.0		
2015 Restructuring initiatives	85.0		
(Gain) loss on fair value remeasurement of contingent consideration	9.0		
Income tax effect related to reconciling items	(100.0)		
Projected Non-GAAP net income attributable to Biogen Inc.	$ 3,780.0	231.2	$ 16.35

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 Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
PRODUCT REVENUES				
Multiple Sclerosis (MS):				
TECFIDERA	$ 937.4	$ 787.1	$ 2,645.6	$ 1,993.2
AVONEX	685.1	741.8	1,993.0	2,277.1
PLEGRIDY	99.7	3.4	236.0	3.4
TYSABRI	479.7	501.2	1,405.4	1,475.6
FAMPYRA	21.0	20.4	62.1	61.7
Hemophilia:				
ALPROLIX	65.7	25.3	163.2	35.7
ELOCTATE	90.6	21.6	218.5	21.6
Other product revenues:				
FUMADERM	12.5	16.5	38.8	48.1
Total product revenues, net	$ 2,391.7	$ 2,117.3	$ 6,762.6	$ 5,916.4

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