BIOGEN IDEC INC.
Form DEFA14A
February 06, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
SCHEDULE 14A
PROXY STATEMENT PURSUANT TO SECTION 14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934

Filed by the Registrant þ
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Check the appropriate box:

o Preliminary Proxy Statement
o **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

o Definitive Proxy Statement

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BIOGEN IDEC INC.
(Name of Registrant as Specified In Its Charter)

N.A.
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(3) Filing Party:

(4) Date Filed:

Exhibit 99.1

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FOR IMMEDIATE RELEASE

Biogen Idec Reports Full Year and Fourth Quarter 2008 Results
2008 Revenues Grew 29% and Exceeded $4 Billion Goal

Cambridge, MA, February 6, 2009 Biogen Idec Inc. (NASDAQ: BIIB), a global biotechnology leader in the discovery, development, manufacturing, and commercialization of innovative therapies, today reported its full year and fourth quarter 2008 results.

Full Year 2008 Highlights:

Total revenues in 2008 were $4.1 billion, an increase of 29% from $3.2 billion in 2007. The increase was driven primarily by the continued growth of TYSABRI® (natalizumab) revenues, which were up 156% to $589 million for the year, RITUXAN® (rituximab) revenues from our unconsolidated joint business arrangement, which were up 22% to $1.1 billion, and AVONEX® (interferon beta-1a) sales, which increased 18% to $2.2 billion.

Global in-market net sales in 2008 of TYSABRI were $813 million, an increase of 137% over 2007, of which $422 million was in the U.S. and $391 million was in rest of world markets.

On a reported basis, calculated in accordance with accounting principles generally accepted in the U.S. (GAAP), full-year 2008 diluted earnings per share (EPS) were $2.65, an increase of 33% over $1.99 in 2007. GAAP net income for 2008 was $783 million, an increase of 23% over 2007 GAAP net income of $638 million.

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Non-GAAP diluted EPS for 2008 were $3.66, an increase of 34% over 2007. Non-GAAP net income for 2008 was $1.1 billion, an increase of 23% over 2007 non-GAAP net income of $879 million. A reconciliation of our GAAP to non-GAAP results is included on Table 3 within this press release.

A great company is built on outstanding products, pipeline and performance we re delivering all three for our shareholders, said Biogen Idec CEO James C. Mullen. In 2008, we grew revenues 29% to more than $4 billion and non-GAAP EPS 34% to $3.66. TYSABRI is well on its way to becoming a blockbuster. We ve transformed the pipeline over the past two years, with 22 programs in Phase 2 trials and beyond this year.

Fourth Quarter 2008 Highlights:

Fourth quarter revenues were $1.1 billion, an increase of 20% from $893 million in the prior year, driven primarily by the continued growth of TYSABRI revenue to $156 million in the quarter, AVONEX sales up 13% to $566 million, and RITUXAN revenues from our unconsolidated joint business arrangement up 20% to $303 million.

Global in-market net sales of TYSABRI in the fourth quarter of 2008 were $218 million, of which $115 million was in the U.S. and $103 million was in rest of world markets.

Fourth quarter 2008 GAAP diluted EPS were $0.70, an increase of 4% from $0.67 in the fourth quarter of 2007. GAAP net income for the quarter was $207 million, an increase of 3% from $201 million for the fourth quarter of 2007.

Fourth quarter 2008 non-GAAP diluted EPS were $0.93, an increase of 4% over non-GAAP diluted EPS of $0.89 in the fourth quarter 2007. Non-GAAP net income for the fourth quarter was $274 million, an increase of 3% over non-GAAP net income of $266 million in the fourth quarter of 2007. A reconciliation of our GAAP to non-GAAP results is included on Table 3 within this press release.

As of December 31, 2008 Biogen Idec had cash, cash equivalents and marketable securities of approximately $2.3 billion. In the fourth quarter, we recorded charges of $31 million, or $0.08 per share, in other income, net related to the impairment of marketable securities and strategic investments.

Revenue Performance

Revenues from AVONEX, the worldwide leading therapy for patients with relapsing forms of MS, increased 13% in the fourth quarter to $566 million. Full-year AVONEX sales increased 18% to $2.2 billion. In 2008, U.S. sales of AVONEX increased 18% to $1.3 billion and international sales increased 18% to $926 million.

Revenues for the fourth quarter and full-year 2008 included $303 million and $1.1 billion, respectively, from Biogen Idec s joint business arrangement related to

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RITUXAN, a treatment for certain B-cell non-Hodgkin s lymphomas (NHL) and rheumatoid arthritis (RA) that Biogen Idec co-promotes in the U.S. with Genentech, Inc. All U.S. sales of RITUXAN are recognized by Genentech, and Biogen Idec records its share of the pretax co-promotion profits. U.S. net sales of RITUXAN were $677 million in the fourth quarter (Q4 2007: $596 million) and $2.6 billion for the full year (2007: $2.3 billion), as reported by Genentech.

During the fourth quarter of 2008, Biogen Idec recognized revenue of $156 million related to TYSABRI. This amount is comprised of:

$53 million related to product sold through Elan in the U.S.; and,

$103 million related to product sold in rest of world markets.

As of the end of December 2008, approximately 37,600 patients were on commercial and clinical TYSABRI therapy worldwide. To date, the safety data continues to support a favorable benefit-risk profile for TYSABRI. According to data available as of the end of December 2008:

In the U.S., approximately 20,200 patients were on TYSABRI therapy commercially;

Outside the U.S., approximately 16,900 patients were on TYSABRI therapy commercially; and,

In global clinical trials, approximately 600 patients were on TYSABRI therapy.

Cumulatively, in the post-marketing setting**:**

Approximately 48,300 patients have been treated with TYSABRI; and,

Of those patients, approximately 20,000 have received at least one year of TYSABRI therapy, approximately 10,700 patients have received at least 18 months of TYSABRI therapy, and 4,300 patients have received at least 24 months of TYSABRI therapy.

Revenues from other products in the fourth quarter of 2008 were $10 million (Q4 2007: $12 million).

Table 4 provides individual product revenues.

Royalties were $29 million in the fourth quarter compared to $33 million in the fourth quarter of 2007. Royalties for the full year 2008 were $116 million as compared to $102 million in 2007.

Development Pipeline Progress

Biogen Idec made significant progress in the development of the pipeline. There are five ongoing registrational programs with novel molecules, and the Company expects this number to grow to eight by year end 2009. In total, there are 22 programs in Phase 2 or beyond in the clinical pipeline. During 2008, the Company accomplished 11 data readouts that enabled clinical development decisions and initiated three proof of concept studies. In addition, five programs started first in human trials and six programs were transitioned from research to development in 2008.

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Financial Guidance

Following its strong performance in 2008, Biogen Idec outlined its 2009 financial guidance, consistent with achieving the company s 2010 financial goals:

Revenue growth is expected to be in the high single digits.

- This includes the expected decline in the RITUXAN rest of world revenues, and the recent strengthening of the U.S. dollar.

Operating Expenses, excluding collaboration profit share, is expected to be between $2.0 to $2.1 billion.

R&D is expected to be approximately 26-28% of total revenue.

SG&A is expected to be approximately 19-20% of total revenue.

Non-GAAP tax rate is expected to be between 28-30%. GAAP tax rate is expected to be between 32%-34%. The difference between the GAAP and non-GAAP tax rate is the result of the full year effects of the reconciling items detailed in Table 3 within this press release.

Non-GAAP diluted EPS is expected to be above $4.00. GAAP diluted EPS is expected to be above $2.80.

Capital Expenditures in the range of $210-$250 million.

We may incur charges or realize gains in 2009 that could cause actual results to vary from this guidance.

Recent Events

On January 13, 2009, Biogen Idec presented at the JP Morgan Healthcare Conference and provided a number of pipeline updates. Namely, the company plans to begin a Phase 3 program of pegylated interferon beta 1a in 2009; plans to start multiple Phase 2 trials this year of the Hsp90 inhibitor in various tumor types based on positive interim data from the GIST trial; and discussed positive data from Phase 2a trials of BIIB14 in Parkinson s and the decision to advance to the next clinical step of development.

On December 18, 2008, Biogen Idec and Genentech announced that a Phase 3 clinical study of RITUXAN (rituximab) in patients with early rheumatoid arthritis (RA) who have not previously been treated with methotrexate (MTX) met its primary endpoint. In this study, known as IMAGE, patients received two infusions of either 500 mg or 1000 mg of RITUXAN or placebo for up to two treatment courses in combination with a stable dose of MTX. At week 52, only patients in the 1000 mg treatment group met the primary endpoint and showed

significantly less progression of joint damage compared to patients who received placebo in combination with MTX.

On December 6, 2008, Biogen Idec and Genentech announced that two global Phase 3 studies in chronic lymphocytic leukemia (CLL), CLL8 and REACH, showed RITUXAN (rituximab) plus chemotherapy significantly increased the time patients lived without their disease advancing, as defined by the primary endpoint of progression-free survival (PFS), when compared to chemotherapy alone. Results from both studies were featured during a press briefing at the 50th Annual Meeting of the American Society of Hematology (ASH) in San Francisco.

On October 30, 2008, Biogen Idec announced that it elected to participate with Genentech in the development and commercialization of GA101 in the United States. Genentech recently acquired development and U.S. commercialization rights to GA101 from Glycart, a company owned by Roche, and Roche. GA101 is a novel humanized anti-CD20 monoclonal antibody engineered to increase both direct- and immune-mediated target cell death for the potential treatment of hematologic malignancies.

On October 23, 2008, Biogen Idec announced the publication of Phase 2b data showing that a 240 mg three-times-daily dose of the company s novel oral compound, BG-12 (BG00012, dimethyl fumarate), reduced the number of new gadolinium enhancing (Gd+) lesions by 69 percent in patients with relapsing-remitting multiple sclerosis (MS) when compared to treatment with placebo ($p<0.0001$). These results have been published in the October 25th issue of *The Lancet*.

Conference Call and Webcast

The company s earnings conference call for the fourth quarter will be broadcast via the internet at 8:30 a.m. ET on February 6, 2009, and will be accessible through the investor relations section of Biogen Idec s homepage, 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 earnings conference call and will be available on our web site subsequently through March 15, 2009.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec s significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. 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. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from that which we expect, including our continued dependence on our two principal products, AVONEX and RITUXAN, the uncertainty of success in commercializing other products including TYSABRI, the occurrence of adverse safety events with our products, competitive pressures, changes in the availability of reimbursement for our products, our dependence on collaborations over which we may not always have full control, failure to execute our growth initiatives, possible adverse impact of government regulation, problems with our manufacturing processes and our reliance on third parties, the impact of the global credit crisis, the market, interest and credit risks associated with our portfolio of marketable securities, our significant investment in a new manufacturing facility in Denmark, our ability to attract and retain qualified personnel, the risks of doing business internationally, the actions of activist shareholders, fluctuations in our operating results, our ability to protect our intellectual property rights and the cost of doing so, product liability claims, fluctuations in our effective tax rate, our level of indebtedness, environmental risks, aspects of our corporate governance and collaborations and the other risks and uncertainties that are described in Item 1.A. Risk Factors in our annual report on Form 10-K and in other reports we file with the SEC. These forward-looking statements speak only as of the date of this press release, and we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Important Information

Biogen Idec and its directors, executive officers and other members of its management and employees may be deemed to be participants in the solicitation of proxies from the stockholders of Biogen Idec in connection with the Company s 2009 annual meeting of stockholders. Information concerning the interests of participants in the solicitation of proxies will be included in any proxy statement filed by Biogen Idec in connection with the Company s 2009 annual meeting of stockholders.

In addition, Biogen Idec files annual, quarterly and special reports with the Securities and Exchange Commission (the SEC). The proxy statements and other reports, when available, can be obtained free of charge at the SEC s web site at www.sec.gov or from Biogen Idec at www.biogenidec.com. Biogen Idec stockholders are advised to read carefully any proxy statement filed in connection with the Company s 2009 annual meeting of stockholders when it becomes available before making any voting or investment decision. The Company s proxy statement will also be available for free by writing to Biogen Idec Inc., 14 Cambridge Center, Cambridge, MA 02142. In addition, copies of the proxy materials may be requested from our proxy solicitor, Innisfree M&A Incorporated, by toll-free telephone at (877) 750-5836 or by e-mail at info@innisfreema.com.

TABLE 1
Biogen Idec Inc.
December 31, 2008
Consolidated Statements of Income
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	**2007**	**2008**	**2007**
REVENUES				
Product	$ 731,836	$ 604,227	$ 2,839,651	$ 2,136,821
Unconsolidated joint business	303,213	253,707	1,128,238	926,098
Royalties	28,966	32,969	116,224	102,141
Corporate partner	4,898	2,397	13,394	6,557
Total revenues	1,068,913	893,300	4,097,507	3,171,617
COST AND EXPENSES				
Cost of sales	101,161	87,566	401,989	335,192
Research and development	292,767	229,292	1,072,058	925,164
Selling, general and administrative	230,963	193,730	925,305	776,103
Amortization of acquired intangible assets	90,631	70,925	332,745	257,495
Collaboration profit sharing	37,673	13,909	136,041	14,079
In-process research and development		35,808	25,000	84,172
Gain on sale of long lived assets	(9,242)	(360)	(9,242)	(360)
Total cost and expenses	743,953	630,870	2,883,896	2,391,845
Income from operations	324,960	262,430	1,213,611	779,772
Other income (expense), net	(34,851)	32,631	(64,668)	130,823
INCOME BEFORE INCOME TAXES	290,109	295,061	1,148,943	910,595
Income taxes	83,456	93,911	365,776	272,423
NET INCOME	$ 206,653	$ 201,150	$ 783,167	$ 638,172
BASIC EARNINGS PER SHARE	$ 0.71	$ 0.68	$ 2.67	$ 2.02
DILUTED EARNINGS PER SHARE	$ 0.70	$ 0.67	$ 2.65	$ 1.99
WEIGHTED-AVERAGE SHARES USED IN CALCULATING:				
BASIC EARNINGS PER SHARE	291,532	294,561	292,332	315,836
DILUTED EARNINGS PER SHARE	293,777	299,665	294,984	320,171

TABLE 2
Biogen Idec Inc.
December 31, 2008
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2008	December 31, 2007
ASSETS		
Cash, cash equivalents and marketable securities	$ 1,341,971	$ 979,070
Collateral received for loaned securities	29,991	208,209
Accounts receivable, net	446,665	392,646
Loaned securities	29,446	204,433
Inventory	263,602	233,987
Other current assets	346,325	350,062
Total current assets	2,458,000	2,368,407
Marketable securities	891,406	932,271
Property, plant and equipment, net	1,594,754	1,497,383
Intangible assets, net	2,161,058	2,492,354
Goodwill	1,138,621	1,137,372
Investments and other assets	235,152	201,028
TOTAL ASSETS	$ 8,478,991	$ 8,628,815
LIABILITIES AND SHAREHOLDERS EQUITY		
Collateral payable on loaned securities	$ 29,991	$ 208,209
Current portion of notes payable	27,667	1,511,135
Other current liabilities	865,564	469,831
Long-term deferred tax liability	356,017	521,525
Notes payable	1,085,431	51,843
Other long-term liabilities	308,238	331,977
Shareholders equity	5,806,083	5,534,295
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 8,478,991	$ 8,628,815

TABLE 3
Biogen Idec Inc.
December 31, 2008
Condensed Consolidated Statements of Income Non-GAAP
(in millions, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
EARNINGS PER SHARE	**2008**	**2007**	**2008**	**2007**
GAAP earnings per share Diluted	$ 0.70	$ 0.67	$ 2.65	$ 1.99
Adjustments to net income (as detailed below)	0.23	0.22	1.01	0.75
Non-GAAP earnings per share Diluted	$ 0.93	$ 0.89	$ 3.66	$ 2.74

An itemized reconciliation between net income on a GAAP basis and net income on a non-GAAP basis is as follows:

GAAP net income	$ 206.7	$ 201.2	$ 783.2	$ 638.2
Adjustments:				
COGS: Stock Option Expense				0.1
R&D: Restructuring	1.1		1.2	1.2
R&D: Stock option expense	2.0	3.5	8.5	12.9
R&D: Expenses paid by Cardiokine	1.2		5.2	
SG&A: Restructuring	0.9		3.8	0.6
SG&A: Stock option expense	5.5	5.3	17.7	22.6
Amortization of acquired intangible assets	90.6	70.9	332.7	257.5
In-process research and development related to the contingent consideration payment in 2008 associated with the 2006 Conforma acquisition, and the 2007 acquisition of Syntonix and consolidation of Cardiokine and Neurimmune		35.8	25.0	84.2
Gain on sale of long lived assets	(9.2)	(0.4)	(9.2)	(0.4)
Other income (expense), net: Expenses paid by Cardiokine in 2008, consolidation of Cardiokine and Neurimmune in 2007	(1.2)	(34.3)	(5.2)	(72.3)
Income taxes: Income tax effect of above reconciling items	(23.3)	(16.0)	(81.9)	(65.5)
Non-GAAP net income	$ 274.3	$ 266.0	$ 1,081.0	$ 879.1

2009 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	**$ 820.6**	**292.6**	**$ 2.80**
Adjustments:			
In-process research and development	40.0		

Stock option expense	29.3		
Amortization of acquired intangible assets	357.1		
Other items	4.0		
Income taxes: Income tax effect of reconciling items	(81.7)		
Projected Non-GAAP net income	**$ 1,169.3**	**292.6**	**$ 4.00**

Use of Non-GAAP Financial Measures

Our non-GAAP net income and non-GAAP diluted EPS financial measures exclude the following items from GAAP net income 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 and Syntonix Pharmaceuticals, and the consolidation of Cardiokine and Neurimmune. These include charges for in-process research and development and the incremental charges related to the 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 SFAS 123R.

We believe that excluding the impact of expensing stock options better reflects the recurring economic characteristics of our business. We also exclude stock option expense from our non-GAAP R&D expenses and SG&A expenses, but include P&L impact of restricted stock awards and cash incentives in our non-GAAP results.

3. Unusual or non-recurring 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 and diluted EPS should not be viewed in isolation or as a substitute for reported, or GAAP, net income and diluted EPS.

TABLE 4
Biogen Idec Inc.
December 31, 2008
Product Revenues
(in thousands)
(unaudited)

	Three Months Ended December 31,	
	2008	**2007**
PRODUCT REVENUES		
Avonex®	$ 565,779	$ 502,525
Tysabri®	155,593	89,642
Fumaderm®	10,631	9,019
Other	(167)	3,041
Total product revenues	$ 731,836	$ 604,227

	Twelve Months Ended December 31,	
	2008	**2007**
PRODUCT REVENUES		
Avonex®	$ 2,202,533	$ 1,867,842
Tysabri®	588,598	229,844
Fumaderm®	43,422	21,547
Other	5,098	17,588
Total product revenues	$ 2,839,651	$ 2,136,821