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

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#### **BIOGEN IDEC INC.**

(Name of Registrant as Specified In Its Charter)

#### N.A.

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#### PROXY COMMUNICATION STATEMENT:

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, and 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.

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**PRESENTATION** 

#### **Operator**

Good morning. My name is Dennis and I will be your conference operator today. At this time I was like to welcome everyone to the Biogen Idec fourth-quarter earnings call. All lines have been placed on mute to prevent any background noise. After the speakers remarks there will be a question-and-answer session. (Operator Instructions) I will now turn the call over to Miss Elizabeth Woo, Vice President, Investor Relations. Please go ahead, ma am.

#### Elizabeth Woo - Biogen Idec Inc. VP, Investor Relations

Thank you, Dennis. Welcome, everyone, to Biogen Idec s earnings conference call for the fourth quarter and full year 2008. Before we begin I would encourage everyone to go to the Investor Relations section of our website, biogenidec.com, to print out the press release and related financial tables. These will be particularly useful when our CFO, Paul Clancy, reviews the financial results and reconciliation to non-GAAP financial measures discussed today. We have also posted slides on our website that outline the topics discussed on today s call.

Let me start with the Safe Harbor statement. Comments made in this conference call include forward-looking statements about the Company s expectations regarding future financial results, including our 2009 financial guidance, our longer-term operational and financial goals, the sales potential of TYSABRI and other products, the availability of external growth opportunities, and pipeline advancements.

Such statements are subject to risks and uncertainties which could cause actual results to differ materially from expectations. In particular, careful consideration should be given to the risks and uncertainties that are described in our earnings release and in Item 1a of the Company s reports on Form 10-K and 10-Q and in other reports Biogen Idec files with the SEC. The Company does not undertake any obligation to publicly update any forward-looking statements.

Information concerning the solicitation of proxies will be included in our 2009 proxy statement which we will file with the SEC and which will be available free of charge at the SEC s website or the Company s website. Today on the call I am joined by Jim Mullen, CEO of Biogen Idec; Bill Sibold, Senior Vice President, US Commercial; Dr. Cecil Pickett, President, R&D; and Paul Clancy, CFO and Executive Vice President, Finance. I will now turn the call over to Jim.

# Jim Mullen - Biogen Idec Inc. President & CEO

Thank you, Elizabeth. Good morning, everyone. Thanks for joining us. Value is created with outstanding products, pipeline performance, and we have been delivering on all three for our shareholders. In 2008 we grew revenues 29% to more than \$4 billion and non-GAAP EPS by 34%. TYSABRI is well on its way to becoming a blockbuster and we have transformed the pipeline over the past two years with 22 programs in Phase II trials and beyond.

As we complete 2008 and look forward to 2009, let me update you on our progress toward our stated 2010 goals, and you can find that on the sixth chart that we have on the website. Our marketed products posted extremely strong business performance in 2008. Total revenues grew 29% year-over-year, the highest growth rates since the 2003 merger, and grew to over \$4.1 billion.

The growth was driven by AVONEX; 18% year-over-year growth to \$2.2 billion. This market-leading success for AVONEX as a \$2 billion brand is due to its long-term safety and efficacy profile.

TYSABRI global revenue more than doubled to over \$800 million with Biogen Idec realizing \$589 million. The number of patients on TYSABRI continues to grow. Approximately 2,300 patients were added in fourth quarter for a net total of 37,600 patients on therapy at year-end.

At the end of the year in the post marketing setting, TYSABRI had over 10,000 patients with at least 18 months, and 4,300 with at least two years, of therapy. These numbers are the same numbers I presented at the JPMorgan conference in January.

As we proceed throughout the year the long-term experience with TYSABRI will continue to grow and provide the medical community with greater clarity on the safety and efficacy profile of TYSABRI over longer periods of time. Our marketing efforts will continue to focus on the efficacy story, education on PML, and placing PML management in the context of the overall product.

Almost 18 months ago, I set a goal of 100,000 patients on therapy by the end of 2010. We remain highly focused on achieving the 100,000 patient goal, but at this point it looks as if it will be quite difficult to reach the number by that date. We continue to believe 20% market share is a relevant target for the most efficacious MS therapy on the market and Bill Sibold, our Senior Vice President, US Commercial, will take you through an update of the MS franchise in a few moments.

Revenue from RITUXAN unconsolidated joint business grew 22% to over \$1.1 billion and RITUXAN is on track to achieve two additional indications. The first is in rheumatoid arthritis, DMARD inadequate responders. This file will be submitted has been submitted and the PDUFA date is later this summer. The IMAGE data announced in Q4 showed strength in a competitive profile for RITUXAN in rheumatoid arthritis. Additionally, we and our partners plan to expand the label in CLL by filing the CLL8 and REACH data in both US and Europe later this year.

Strategically, our pipeline is focused on first-in-class or best-in-class specialty products in diseases with high unmet need and global applications. Finding a good drug is obviously the most difficult step and by comparison building a specialty marketing infrastructure is relatively easy. We have a good mix of first-in-class and best-in-class molecules throughout the pipeline and the biology of many of our programs have clinical applications across a variety of therapeutic areas.

Under Cecil Pickett s leadership, the pipeline has been substantially strengthened over the past two years. This progress is due to additions from disciplined business development as well as clinical progress. We currently have five programs in late-stage development, expect to have six shortly with the initiation of the PEG interferon Phase III trials mid-year. We now have 22 programs in Phase II or beyond, more than 60 clinical trials ongoing in more than 15 indications, and more than 35 preclinical and discovery research programs.

In 2008, three proof-of-concept studies were initiated and five programs went into the clinic and started first-in-human trials. Cecil will review the 2008 pipeline progress in his comments.

Finally, with respect to performance, our goal from 2007 to 2010 is to deliver 15 and 20 top and bottom line compounded annual growth rates similar to what we achieved in the 2003 to 2007 timeframe. Out of the gates in year one we posted a very strong start with 29% top-line and 34% bottom-line growth while simultaneously driving the pipeline forward. As you will hear in greater detail from Paul Clancy, our CFO, we expect 2009 non-GAAP earnings per share to be above \$4 per share.

Two variables that will have the most impact on the 2009 P&L are, on the top line, pace and timing of TYSABRI growth and, in the expense lines, the speed of advancement of late-stage clinical trials.

In conclusion, we have strong franchises, strong cash flows, and a strong balance sheet ending the year with approximately \$2.3 billion in cash and marketable securities. We continue to focus on products pipeline performance as drivers of long-term shareholder value creation.

As you have seen from our second press release this morning, we have received a notice from Icahn Entities proposing a slate of directors for election to our Board at the 2009 annual meeting and several other proposals. This notice just came in last night; the Board has not reviewed the proposals.

I will now turn the call over to Bill Sibold, the Head of our US commercial business, Bill?

#### Bill Sibold - Biogen Idec Inc. SVP, US Commercial

Thanks, Jim. I am pleased to report that Q4 was another strong quarter that capped a great 2008. In 2008 our global neurology business reached approximately \$2.8 billion in revenue with about \$721 million of that coming in the fourth quarter. This is up 33% for the full year versus 2007 and up 22% for the quarter versus the prior year. This was driven by strong results for both AVONEX and TYSABRI. AVONEX s \$566 million in global revenue in Q4 was up 13% year-over-year. In Q4 revenue was up 22% year-over-year in the US and 1% year-over-year internationally. For the full year AVONEX s revenue grew 18% to \$2.2 billion. These results reflect the strength of AVONEX s market-leading positions with over 135,000 patients on therapy worldwide.

TYSABRI had in-market revenue of \$218 million in the fourth quarter, an over 69% increase compared to the prior year. For the full year, TYSABRI s market revenue more than doubled to \$813 million. As we announced in January, we continue to increase the number of patients on TYSABRI in the US and internationally. As you can see from the numbers in the press release, we are approaching 40,000 patients on therapy and have significant increases in the number of patients on therapy for one year, 18 months, and two years.

These strong results help position us for continued success with both brands in 2009. We will be leveraging AVONEX s proven efficacy in early MS as well as its clear long-term benefit. Specifically, we now have available the ASSURANCE data that was released at ECTRIMS which shows that patients who remained on AVONEX for up to 15 years since the original pivotal trial had reduced disability progression, greater quality of life, and significantly greater sense of independence in self-care versus those patients who had either switched to another therapy or discontinued therapy.

Additionally, we are looking forward to the release of the results from the 10-year CHAMPION extension trial at AAN in May. This is the first trial looking at the long-term impacts of treatment in early MS patients. The combination of AVONEX s proven efficacy and best-in-class compliance is why it is the number one MS therapy in the world. AVONEX disrupts the disease, not patients lives, and has demonstrated that it has the power to work early and keep patients active longer.

Turning to TYSABRI. As you know, there remains significant unmet need in the MS market. There are over 450,000 patients on therapy worldwide and we estimate that about 20% of ABCR patients are switching therapies every year. Market research indicates that over 90% of physicians consider TYSABRI to be the most effective MS therapy. Therefore, we are looking forward to the time to when TYSABRI will be the leading product prescribed for MS patients.

While we recognize that there are hurdles to be overcome, it is difficult to find examples where a product with a commanding efficacy benefit for a serious disease like MS should not also become the most broadly administered therapy. To achieve this goal, we have three key objectives for 2009.

First, refocus communication on TYSABRI s unprecedented efficacy for both physicians and patients. Second, help physicians increase their comfort diagnosing and managing PML. Third, translate resulting improvements in TYSABRI s benefit risk perception into increased and sustained use.

We continue to closely monitor touch data to understand trends in US TYSABRI prescribing patterns. As you are aware, the moderation in patient growth that occurred in Q3 was driven by both the slowdown in the rate of new patient adds as well as an increase in discontinuation. That trend appears to have generally stabilized in Q4. The slowdown in new patient adds is largely driven by perceptions of benefit risk, which has been impacted by recent events. However, the type of patients coming to TYSABRI appears to be unchanged based on both their time since diagnosis with MS and their prior therapy. COPAXONE is still the largest source of switchers and, additionally, we continue to see about 4% to 5% of TYSABRI patients naive to therapy.

We are launching a number of programs in 2009 that directly address physicians and patients perception of TYSABRI s benefit risk profile. This is to build on the progress we made at the end of 2008. The percent of physicians who believe that the benefits of TYSABRI outweigh the risks rebounded in December from a low in August and is approaching pre-July 31 levels. We are increasing the level of education about PML and clinical vigilance to increase prescribers awareness and comfort.

Additionally, many of you are aware of the data presented at ECTRIMS showing that TYSABRI reverses disability in some patients. As we move forward into 2009 we will be enhancing our focus on communicating this powerful and unmatched efficacy data. MS is a very serious disease and not treating it with an appropriate sense of urgency almost certainly leads to inferior outcomes for patients.

We are also closely watching patient discontinuations. While anecdotally we hear of some physicians considering treatment holidays, we do not see evidence in the TOUCH data that this practice is common. We believe that the optimal dosing and administration are as described in the label.

We are addressing discontinuations with physicians. For example, we are focusing educational efforts on clinical vigilance and benefit risk. We have also been enhancing our focus on patient communication. Most importantly, we continue to add new patients and prescribers each day.

In conclusion, we believe that our strong MS franchise of AVONEX, the best product to start with and stay with for the long term; TYSABRI, the product for those that need more efficacy; and a deep and broad MS pipeline positions us well to drive strong performance in the future. Nobody is doing more for MS than Biogen Idec.

I will now hand the call to Dr. Cecil Pickett, President, R&D.

#### Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

Thank you, Bill, and good morning, everyone. 2008 has been a year of important progress in our development pipeline. I will report on 2008 progress and recent updates and on upcoming data readouts.

First, a comment on TYSABRI. We are reporting today one new case of PML in the post-marketing setting confirmed yesterday. The patient is in the EU and had 12 months of TYSABRI

monotherapy. We chose to disclose this case ahead of the website update later today given the timing of our earnings call and in the interest of full disclosure and transparency.

Four of the five PML patients since 2006 relaunch are alive with varying degrees of disability. We would expect any further updates about these patients will be presented at upcoming medical meetings.

I think it is important to point out we have learned a great deal about the JC virus and PML in the past few years and are working actively on ways to identify patients at risk, improve early detection, and potentially mitigate the outcomes. Our goal is to detect PML early and make it a manageable side effect, and we believe we are making progress towards that end.

Turning to recent data releases and presentations. We and our partners recently announced the positive results of IMAGE, our radiographic study of RITUXAN and methotrexate-naive early RA patients, which further bolsters our data on RITUXAN in RA. The study met its primary endpoint with patients in the 1,000 mg treatment group showing significantly less progression of joint damage compared to methotrexate alone. We plan on submitting the data for presentation at EULAR and will make a regulatory filing decision early this year.

RITUXAN also featured prominently at ASH 2008 with positive data presented from both the first line CLL8 and the second line REACH trials, the largest studies ever conducted in CLL. We plan to submit BLAs for both CLL8 and REACH by the third quarter of this year.

We accomplished 11 data readouts in 2008 that enabled go/no go decisions. You can see all of the readouts on the slides. We recently reported positive data from our Phase II heat shock protein 90 inhibitor in gastrointestinal stromal tumors and BIIB14, our A2A receptor antagonist in Parkinson's disease. We will be taking them both forward to the next step in clinical development and you will see additional details on the data and clinical plans later this year. We also initiated three proof-of-concept studies in 2008 TYSABRI in multiple myeloma, BG-12 in rheumatoid arthritis, and AVONEX in ulcerative colitis. Five programs started first in human trials in 2008 an antibody against IGF-1R in solid tumors; an antibody against the cell surface antigen CRIPTO linked to [myostatin] in solid tumors; an antibody against TWEAK, a cytokine in rheumatoid arthritis; a long-acting recombinant factor 9 in hemophilia B; and a backup inhibitor, heat shock protein 90 inhibitor, for solid tumors.

Finally, you can see from these slides, six programs were transitioned from research to development.

I think you can see progress was excellent across all phases of the pipeline and I believe one of our most productive years in recent memory.

I will now touch on the late stage pipeline and 2009/2010 data readouts. A number of programs have potential data readouts in 2009 and 2010 including RITUXAN Phase III LUNAR study in lupus nephritis; the Phase II portion of the Lumiliximab Phase II/III study in relapsed CLL; long-acting recombinant factor 9 Phase I/II study in hemophilia B; daclizumab Phase II select study in relapsing remitting MS; CDP 323, the oral BLA-4 receptor antagonist, the Phase II study in relapsing remitting MS; and Ocrelizumab Phase III studies in TNF-IR and [Dmide IR RA].

We continue to make good progress on advancing and developing our late stage pipeline. We continue to enroll patients into our five ongoing registration programs BG-12 in MS, Lumiliximab in CLL, Galiximab in non-Hodgkin s lymphoma, lixivaptan in hyponatremia, and ADENTRI in acute decompensated congestive heart failure. In addition, you can see on the slides the additional registration programs in our CD20 franchise with our partners. We expect to

complete enrollment of the Phase II portion of the Lumiliximab Phase II/III trial and the first BG-12 Phase III trial over the next few months.

I will also highlight the growth in the number of registrational programs we have ongoing for novel molecules, which are expected to double from four at the start of 2008 to eight at the end of 2009. The next molecule expected to enter a registrational trial is a PEGylated form of Interferon Beta 1a going into Phase III in the middle of 2009. PEGylation at the N-terminal alpha amino group increases half-life and systemic exposure of the protein.

Phase I results indicated that the long-acting form has similar pharmacology to Interferon Beta 1a and was safe and well-tolerated. The Phase III trial will be a placebo-controlled study in 1,260 relapsed and remitting MS patients with annualized relapse rate at one year as the primary endpoint.

In conclusion, 2008 was a very active year on the R&D front and 2009 promises to be even busier. We continue to push to decision points for each of our programs. We have 22 programs in Phase II development or beyond and you will be able to see more detail of what we believe is a broad and deep pipeline at our Investor R&D Day on March 25th.

I will now hand it over to our CFO, Paul Clancy.

#### Paul Clancy - Biogen Idec Inc. EVP, Finance & CFO

Thanks, Cecil. I will review our quarterly and full-year financial performance. Additionally, I will detail in our 2009 financial guidance. The GAAP financials are provided in tables 1 and 2 of the earnings release. Table 3 includes a reconciliation of GAAP to non-GAAP results.

The primary differences between our GAAP and non-GAAP results for the quarter were \$91 million related to the amortization of intangible assets, \$8 million for pretax stock option expense, and a \$23 million tax impact. Our GAAP diluted earnings per share was \$0.70 in Q4 and \$2.65 for full-year 2008.

Now I will move on to the non-GAAP P&L operating performance of Biogen Idec, which we believe better represents the ongoing economics of our business and reflects how we manage the business internally and set operational goals. Our non-GAAP diluted EPS was \$0.93 for Q4 and \$3.66 for full-year 2008.

Now let s move through the fourth-quarter and full-year results in a bit more detail. Q4 total revenue was \$1.069 billion representing a 20% growth over the same quarter in the prior year. Revenue for the full year totaled approximately \$4.1 billion, which represents a very strong year on the top line, 29% over full-year 2007. Going through our product revenues I will begin with AVONEX. Q4 AVONEX worldwide product revenue was \$566 million, which represents a 13% increase over the same period last year. Worldwide AVONEX revenue for the full-year totaled approximately \$2.2 billion, representing an 18% year-over-year growth rate. Q4 US AVONEX product revenue was \$341 million, representing a 22% increase over Q4 2007.

US AVONEX revenue for the full-year 2008 totaled just under \$1.3 billion, representing an 18% year-over-year growth rate. US AVONEX inventory in the channel ended at just slightly over two weeks in the fourth quarter, unchanged from Q3. On a year-over-year basis units sold in the US declined approximately 5% in the fourth quarter. This was more than offset by price increases. On a sequential basis, Q3 to Q4, volume declined by just under 2%.

Q4 international AVONEX product revenue was \$225 million, representing an increase of 1% on a year-over-year basis. On a sequential basis, AVONEX international revenues declined by 11%, largely as expected. This was due almost equally to unfavorable foreign exchange, the work down of channel inventory in Germany arising out of a price increase, and normal fluctuations in our tender business.

International AVONEX revenue for full-year 2008 totaled \$926 million, which represents an 18% year-over-year growth rate. This was driven by high single-digit unit increase, foreign exchange favorability contributing mid single-digits, and the remaining due to price and mix.

Q4 TYSABRI worldwide product sales were \$156 million for Biogen Idec. TYSABRI revenue for full-year 2008 totaled \$589 million for Biogen Idec. US end-user TYSABRI sales totaled \$115 million, which represents a 6% quarter-over-quarter decrease. Biogen Idec booked \$53 million of this amount.

While patient numbers increased, we were unfavorably impacted by fewer shipping days in Q4 as compared to Q3. Our business normally ships on Mondays and Tuesdays, which just happened to have more in Q3 than Q4. International end-user TYSABRI sales totaled \$103 million, a 10% decrease from the prior quarter. This decrease was largely due to the strengthening of the US dollar and fewer shipping days similar to the US. Q4 [Pharma derm] revenue was \$11 million.

Now moving on to the RITUXAN collaboration revenues, which is referred to as revenue from unconsolidated joint business. We recorded \$303 million in revenue for the quarter, representing an increase of 20% on a year-over-year basis. Revenue for the full-year increased 22% to \$1.13 billion.

This number has three elements. First, we receive our share of US RITUXAN profits. As reported by Genentech, US RITUXAN sales were \$677 million in the fourth quarter, up 14% versus prior year. And our Q4 profit share from that business was \$206 million, up 21% versus prior year. This includes a \$12 million payment associated with Roche opting into the Olympus primary progressive MS data.

Second, we receive revenue on sales of rituximab outside the US and in Q4 this was \$83 million, up 21% versus prior year. As mentioned in our Q3 earnings call, we expect a decline in rituximab rest-of-world revenues in 2009 as the agreements with Roche expire in a number of EU countries. We expect for the full-year 2009 revenues from RITUXAN rest-of-world to be approximately \$270 million, dependent on sales growth and exchange rates. Third, we were reimbursed \$14 million for selling and development costs incurred related to RITUXAN. Q4 royalties

Now turning to the expense lines in the non-GAAP P&L, which include the adjustments that I described earlier. Q4 COGS were \$101 million or 9% of revenues. Q4 R&D expense was \$288 million, or 27% of revenue.

Quarter-over-quarter R&D expenses increased, primarily due to the one-time \$31 million opt-in payment to Genentech for GA101.

were \$29 million for the quarter and \$116 million for the year.

R&D spend for the full-year totaled \$1.06 billion, which was about 26% of full-year revenue, an increase of 16% on a year-over-year basis. Increase in R&D expenses were driven by our continued advancement of the pipeline as detailed by Cecil.

Q4 SG&A expenses were \$225 million, representing 21% of revenue and a 19% year-over-year increase. This was driven by investments to support our TYSABRI growth, investments to

support the AVONEX business, and the ongoing geographic expansion of our commercial operations. Specific for the fourth quarter, we did benefit from the strengthening US dollar.

Continuing down the P&L, our collaboration profit sharing line totaled \$38 million in expense for the quarter. As a reminder, this line is our payment of 50% of profits outside the US to Elan and the reimbursement of third-party royalties incurred by Elan outside the US.

Now moving to other income and expense. Other income and expense for the quarter was a loss of \$36 million, which was \$34 million unfavorable on a year-over-year basis. The loss included a \$20 million impairment of our marketable securities portfolio; a \$9 million impairment in our strategic investments portfolio, which is largely comprised of public and private biotech companies; and a \$5 million accounting charge related to the ineffectiveness on our interest rate swaps.

We did capitalize on the historically low yields in the fourth quarter by unwinding the interest rate swaps on our 10-year notes. This contributed cash proceeds of \$54 million. This gain will be amortized over the life of the 10-year notes, thereby locking in a lower effective rate.

Last quarter I discussed the composition of the marketable securities portfolio. During the fourth quarter we continued to rebalance our portfolio. At year-end 80% of our portfolio holdings were in US treasuries, government-sponsored investments, money market funds, or other cash equivalents. The balance of the portfolio consists of high-grade corporate bonds, non-government mortgage securities and asset-backed securities.

Additionally, in Q4 we continued to implement our share stabilization program with the purchase of 3.8 million shares of stock. In January of 2009 we purchased an additional 1.2 million shares.

Q4 our tax rate was approximately 28%. We benefited from the recently passed R&D tax credit legislation which was offset by certain tax reserves and a greater mix of business in the US. This brings us to our Q4 non-GAAP diluted earnings per share of \$0.93 and our full-year non-GAAP EPS of \$3.66, representing a strong 34% increase over full-year 2007.

Now I would like to provide our 2009 financial guidance. Revenue growth in 2009 is expected to be in the high single-digits. This includes both the expected decline in the RITUXAN rest-of-world revenues as well as the impact of the strengthening US dollar. If adjusted for those two impacts, our revenue growth would be in the mid-teens.

We expect operating expenses, excluding collaboration profit sharing expense line, to grow below revenue growth in the low to mid single-digit range to between \$2.0 billion and \$2.1 billion. R&D is expected to be approximately 26% to 28% of total revenue. Growth in R&D dollars is expected to be in line with revenue growth, yet will be dependent on the progression of the pipeline.

SG&A is expected to be approximately 19% to 20% of total revenue, down on a percentage of sales from full-year 2008. The collaboration profit sharing line will be a function of the international TYSABRI trajectory.

Our non-GAAP tax rate is expected to be between 28% and 30%. GAAP tax rate is expected to be between 32% and 34%. Non-GAAP diluted earnings per share is expected to be above \$4, achieving leverage top line to bottom line. GAAP EPS is expected to be above \$2.80.

Our capital expenditures are expected to be in the range of \$210 million to \$250 million down from 2008. As a result, we expect cash flow to grow faster than earnings per share.

So in conclusion, 2008 was a very strong year. Our top-line revenue grew 29% for the full-year, our non-GAAP earnings per share grew 34% for the full-year, our cash flow was strong, and we ended the year in an enviable cash position. With this exceptional year of performance we look forward now to continuing to deliver strong financial results and advance our clinical pipeline.

I will hand it back over to Jim for his closing comments.

#### Jim Mullen - Biogen Idec Inc. President & CEO

Thank you, Paul. I will be very brief in the close here. In summary, business performance for 2008 was extremely strong. While we know we face some headwinds in 2009, I believe that the strong fundamentals of the business across all products and geographies will continue to deliver robust results and create significant value for our shareholders. With that, Elizabeth, let s open this up for Q&A.

#### Elizabeth Woo - Biogen Idec Inc. VP, Investor Relations

Thanks, Jim. Joining us for the question-and-answer session is Dr. Al Sandrock, our Senior Vice President of Neurology Research and Development.

Operator, before opening the call to Q&A we would ask that participants limit themselves to one question and then re-enter the queue to ask follow-up questions. And please state your name and company affiliation. We will try to end the call around 9:30. Operator, you can take the first question.

#### **QUESTION AND ANSWER**

#### **Operator**

Michael Aberman, Credit Suisse.

#### Michael Aberman - Credit Suisse

I am wondering if you could just I guess going first I will ask the TYSABRI question. Your patient numbers grew and yet revenue shrunk in the US. I know there is less shipping days, but can you help us understand that more? And if you can in the same TYSABRI vein talk about the trends you are seeing in January.

#### Jim Mullen - Biogen Idec Inc. President & CEO

Let me try to take that Michael. I think it s a great question. I know it s on the minds of many people.

The big impact was, as I had noted, foreign exchange, and I think that is relatively clear in the international business, that was the big effect. The other one is shipping days. We literally had essentially 14 weeks of shipping in the third quarter and only 13 weeks of shipping days in quarter four. So, depending on how you account for that, it s an \$8 million impact, you could double the amount in essence. And that is on our P&L, actually. So on the full collaboration it s slightly exaggerated from that.

The other color I would give you is we have obviously tried to look hard at this. In the US we do with the touch program have visibility of the number of infusions that are, which really is not a function of shipping days or anything like that. It s literally our version of store sales going off the retail shelves.

We saw, in the fourth quarter, a slightly moderating growth of number of infusions in the United States vis-a-vis the patient adds. That was highly, highly attributable to Thanksgiving week as well as the last two weeks of the year. So it does look like there was an effect of patients pausing on infusions right around the holiday. We saw that pick up in January.

I will turn it to Bill just to talk about how our January trends are doing.

## Bill Sibold - Biogen Idec Inc. SVP, US Commercial

As we said in Q4, there was a general stabilization and it s fair to say that that is what we are seeing in January of this year so far. So we are in a generally stable period.

#### **Operator**

Geoffrey Porges, Sanford Bernstein.

#### Geoffrey Porges - Sanford Bernstein

Thanks very much. Wondering if you could just give us the additional information on the PML case that you provided before—the patient—s clinical picture, their treatment, degree of disability. And also if you could provide us just with a sense of the progress of the patient that you have reported most recently, the one in the US?

## Jim Mullen - Biogen Idec Inc. President & CEO

Thanks for the question. I think as I mentioned, the patient is the patient from the European union, 12 months of TYSABRI monotherapy. The patient is currently hospitalized. We think it is most appropriate to wait in terms of any updates on patients, to wait until they are presented at upcoming medical meetings. So we are really not going to comment any further on the patient s status.

#### **Operator**

May-Kin Ho, Goldman Sachs.

#### May-Kin Ho - Goldman Sachs

Can you comment a little bit about what you are planning to do with the long-acting Factor 9 program?

## Jim Mullen - Biogen Idec Inc. President & CEO

Currently, the idea behind this program is that the way in which the recombinant factor 9 is constructed that it would have a longer half-life. And in preclinical models I think we have tested it now in four preclinical models and all of the preclinical models have demonstrated a longer half-life compared to recombinant factor 9.

We are currently engaged in recruiting patients into a Phase I/II study to look at safety and tolerability, and just to confirm that, in fact, it has a longer half-life in people. And I think based on that data we will make a decision about what a registration program will look like. We anticipate it will be a fairly small number of patients and I think something that we can do fairly rapidly, looking at clotting times in hemophilia B patients.

## Jim Mullen - Biogen Idec Inc. President & CEO

May-Kin, this is Jim. The theory of the case on factor 9 and then of course on the factor 8 program, which is a similar program behind it, is with the enhanced pharmacokinetics/pharmacodynamics you have got the ability to expand utilization, particularly in the more prophylaxis setting. So that is the theory, the case. We will see how that plays out in real clinical data.

#### **Operator**

Ian Somaiya, Thomas Weisel Partners.

## Ian Somaiya - Thomas Weisel Partners

Just a question on the PEGylated AVONEX program. Cecil, I was just hoping to get your perspective on what you think the profile of the drug will be relative to AVONEX and just thoughts on why not conduct a head-to-head study versus AVONEX to maybe tease out the differences or improvements?

#### Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

That is a very good question. We are going to test it in the Phase III program, both twice monthly as well as once monthly in terms of the dosing regimen, and it s going to be a subcutaneous. As you are aware, the AVONEX is currently IM, dosed weekly. So we think in terms of patient compliance that it will be a significant improvement. There is I have had a lot of experience with another PEGylated interferon called PEGylated PEG-Intron. And with that PEGylated product the assumption and this was to treat hepatitis C patients the assumption basically was that the safety profile would be pretty much comparable

and that the efficacy profile would be comparable to the wild type interferon alpha. It turned out that the efficacy profile was actually better because of greater systemic exposure and the safety profile was about the same. Again, I am not definitely going to extrapolate that directly to the PEGylated interferon beta. But I think one potential upside is that based on systemic exposure, etc., that there is a chance that the efficacy could be improved. But I think what we are really aiming for is comparable efficacy with either twice-a-month dosing or once-a-month dosing.

# Jim Mullen - Biogen Idec Inc. President & CEO

I think it s very important to note, and I think you guys have all heard me say it before or Cecil the last couple of calls or conferences, we have an agreed path forward registration path forward with the European regulators and the US regulators. Your idea of doing head-to-head is probably a good idea that is maybe the next step after this one, I would say. Given the endpoints, etc., it probably requires larger, longer trials to actually tease that out would be my sense.

# Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

Again, I think it s also point out that the endpoints agreed upon was annualized relapse rate at one year. And I think that is very important.

## **Operator**

Geoff Meacham, JPMorgan.

## Geoff Meacham - JPMorgan

Thanks for taking the question. You have previously given the US source of patients for TYSABRI in earlier conference calls. I am wondering if you can let us know the percent of patients coming from AVONEX versus those new to the market or those on COPAXONE, just in the fourth quarter?

#### Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

If you look back at previous quarters it s generally stable from what we have seen in the mix of where patients are coming from. That hasn t changed significantly throughout 2008.

#### **Operator**

Jim Birchenough, Barclays Capital.

Jim Birchenough - Barclays Capital

Just a question on plasmapheresis and whether in suspected cases of PML you are seeing plasmapheresis being used, and in those instances whether there is any report of immune reconstitution syndrome. Just related to that, just wondering if the patient in Europe was plasmapheresed and if there is any issues with immune reconstitution syndrome specifically there?

Jim Mullen - Biogen Idec Inc. President & CEO

Maybe Al could take that.

Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

Al, would you mind taking that question?

#### Dr. Al Sandrock - Biogen Idec Inc. SVP, Neurology Research and Development

There have been a few patients who have received plasma exchange in the US in the case of the fourth full confirmation. But in a sense that is consistent with our advice, which is to suspend TYSABRI dosing unless PML can be ruled out.

Any kind of relapse activity or disease progression on TYSABRI is extremely uncommon because the drug is so effective. So we are advising physicians to be very vigilant. If you suspect PML, stop dosing and some patients have even gone so far as to get plasma exchange even before full confirmation.

#### **Operator**

Jason Zhang, BMO Capital Markets.

## Jason Zhang - BMO Capital Markets

Thanks for taking my question. When you were talking about TYSABRI market dynamics, you talked about stabilization because you referred to the TOUCH program. Were you mainly talking about US, or was the same chain of dynamics also true in ex-US? If there is a difference, can you tell us what is the difference there?

#### Bill Sibold - Biogen Idec Inc. SVP, US Commercial

Thanks, this is Bill. The stabilization, it would be fair to say that it is US and international.

#### Jim Mullen - Biogen Idec Inc. President & CEO

Clearly, when we talk about very specific stuff, Jason, the visibility that we have in the United States is far greater than the visibility that we have outside the United States through the Touch program.

#### **Operator**

Joel Sendek, Lazard Capital Markets.

## Joel Sendek - Lazard Capital Markets

Thanks, I have a question about the EPS guidance, specifically about the \$4. I am wondering if there is any upside beyond that? Could it potentially be significantly higher than \$4 a share? How much flexibility do you have on the expense side, for example?

#### Paul Clancy - Biogen Idec Inc. EVP, Finance & CFO

Somewhat expected question, Joel, but we have elected to say we have got a goal of getting above \$4. I wouldn t think of that as a wide range. I would think of that as a similar range as what we have had in the past or tighter. We are obviously going to work hard to drive as much shareholder value as we can for the year.

#### Jim Mullen - Biogen Idec Inc. President & CEO

Joel, to the extent that we see some buoyancy on the top line with products, I would expect that the vast majority of that falls right through.

## **Operator**

Mark Schoenebaum, Deutsche Bank.

#### Mark Schoenebaum - Deutsche Bank

Thanks for taking the question. I am pleased that Dr. Sandrock is on. I was wondering if, maybe if he would be willing to kind of give his opinion of some of the emerging new data on some of the oral compounds that have come out and key outstanding questions, namely the cladribine data and the FTY data. And since the PEG AVONEX program the FDA is okay with the one-year trial with relapse rates as an endpoint. Do you think that is any indication the FDA is allowing single trials for registration now?

#### Jim Mullen - Biogen Idec Inc. President & CEO

Mark, that was only four questions.

#### Mark Schoenebaum - Deutsche Bank

But it was a run-on sentence.

#### Dr. Al Sandrock - Biogen Idec Inc. SVP, Neurology Research and Development

If I can remember the whole thing, I will try. Let me take the last question first. I do not believe the FDA has significantly lowered the hurdle for approval of new molecular entities in multiple sclerosis. I think they made an exception to this to the PEGylated interferon situation because it s an interferon and the safety of interferons is well described. And, moreover, they have experience with PEGylated interferons in the past. So I believe they made an exception, if you will, for PEGylated interferon.

With respect to your question about the recent data readouts from competitors, I don thave a lot of information beyond what you have with respect to the oral cladribine trial. I have the efficacy readout as the placebo rate being approximately 0.33 and the cladribine in one of the dose groups being 0.14 on the annualized relapse rate, which translates to an efficacy difference of one relapse every five years.

So the question there is, is that difference—under scrutiny, will that difference still be convincing? For example, we know the drug is a bone marrow suppressant. Were the physicians who rated the relapses adequately blinded or could they have been tipped off by CBCs, complete blood counts, on their patients? But assuming the raters were adequately blinded, we would want to know whether or not that primary endpoint was supported by secondary endpoints in particular and points like the stability progression.

We understand that they might be positive, but we were given no data on that. So how robust is the stability data, for example. We are assuming the MRI data will support since prior trials of IV cladribine have shown an effect on MRIs. We have been given very little information about safety. We are hearing rumors, I think as you have, that there are malignancies in the cladribine groups. I don't know that for a fact. I am going to wait to see the data at the upcoming scientific meetings. We know that IV cladribine has a pregnancy category D and it is teratogen which is, I think, going to be of concern for MS patients since many of them are young women of childbearing age.

And then I think there is an outstanding question about how safe is long-term lymphophenia. So I think in the end it s going to come down to are these risks and unknowns worth the small benefits observed in the placebo-controlled trial. As far as the FTY720, I think very similar comments. All we know are the top-line data from the AVONEX comparison trial and the laundry list of adverse events include liver function abnormalities, bradycardia with pulmonary problems, malignancies, particularly skin malignancies, two fatal viral infections, and macular edema, all in a relatively short trial with a fairly high discontinuation rate. So, again, these are pills which is an advance, but how much are you willing to trade off safety for the convenience of a pill?

#### Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

I think the other thing, just to add just a comment to Al s update on cladribine, cladribine is a purine analogue. And, interestingly, it actually inhibits DNA synthesis as well as DNA repair. So in rapidly proliferating cells, obviously, inhibiting DNA synthesis has an impact and that is why one would expect myosuppression.

The inhibition of DNA repair in resting cells is a concern in terms of long-term treatment, because those cells where you get mutations which will make a normal cell prone to a malignant cell, those mutations cannot be repaired. And so I think that in terms of long-term use of cladribine will potentially be an issue.

#### **Operator**

Eric Schmidt, Cowen & Co.

#### Eric Schmidt - Cowen & Company

A question for Paul Clancy on the expense guidance for 2009. It looks like you are doing a great job controlling the SG&A, but I was surprised to hear you talk up R&D as a percent of revenue, R&D going up year-on-year. I think in the past you had mentioned that it was a goal of the Company to bring R&D down as a percent of revenues. So maybe you or Jim can kind of talk about what is going on there?

#### Paul Clancy - Biogen Idec Inc. EVP, Finance & CFO

Yes, it is a goal. Absolutely. We made tremendous progress on that goal in 2008, Eric. So I think with the top line being somewhat impacted by the strengthening dollar, we don t want to hold back on the R&D in the progression of the pipeline. I think that is too important for us to, in a one-year basis, try to get too focused on marching down in a linear fashion on the R&D as a percentage of the sales.

We are still are certainly focused on that over the long haul and we will continue to put things in place. I think we think about it, and we have talked about SG&A and R&D and we certainly want to continue to do that, but we want to think about it in the total operating expenses and total kind of profit margins and getting progress on that. So if we can get a little bit more in SG&A one year and not as much on R&D, I think we would be okay with that. Jim, did you have another thought?

#### Jim Mullen - Biogen Idec Inc. President & CEO

Yes. The absolute increases in 2008 in R&D expense, and certainly it s even more the case in 2009, is almost entirely focused at progressing late-stage clinical trials. So it s external clinical trial expense and that is why I highlighted in my comments the biggest variable in the expense part of the P&L is how rapidly do the late-stage trials advance. And then the sort of unsaid, but I think also important point to that is, because most of this is external expense in running clinical trials it is not part of a permanent burn and build of infrastructure.

#### **Operator**

Steven Harr, Morgan Stanley.

Steven Harr - Morgan Stanley

I had a question on just the TYSABRI safety profile. Did you say you are seeing a decrease of rates in PML? You now have eight cases of PML in total and only 4,500 patients over two years and you have 10,000 patients over 18 months. It seems like that is relatively consistent with the label given the frequency with which this occurs late in the longer patients are on the drug.

So two things. Number one, what gives you the confidence to say that the rate is down given that we have now seen a clustering of cases over the last six months? Two, what are your restrictions with your FDA label that say you have a 1 in 1,000 rate around what you can say about the rate of PML?

# Dr. Cecil Pickett - Biogen Idec Inc. President, R&D

I will have Al come in on this, but in the post-marketing setting there has been five cases, just to clarify. We feel that the rate is still clearly within what is currently contained within the label. Al, any other comments?

#### Dr. Al Sandrock - Biogen Idec Inc. SVP, Neurology Research and Development

I am not sure those numbers were quite right. I believe we have more than 20,000 people who have been on the drug for a year at least and so I m not sure the denominators that the caller was using were correct. But we have been tracking the rate very carefully and doing a lot of modeling and simulations and we believe we are well within the risk.

Again, I think Jim Mullen has made this point in past calls that when you think about the risk of PML it s not just the incidents but the outcome. When we were re-approved the assumptions were that the risk of PML was 1 in 1,000 and that it was almost universally fatal. I believe that when you look at the outcome from the post-marketing cases and also the incidents, we are well within what the label states.

#### **Operator**

Bill Tanner, Leerink Swann.

#### Bill Tanner - Leerink Swann

Thanks for taking the question. Maybe a question for you, Bill, just on the regrowing TYSABRI. Just thinking about is AAN going to be sort of next big medical conference at which the Company can begin to address some of the concerns that physicians have?

And then maybe if there is a possibility to get a little bit more color or understanding that things have sort of stabilized, but wondering on is there been a plateauing in the numbers of physicians that are treating? What do you see in terms of size of practice as to the recent treatment patterns and what do you see community docs versus academics?

Bill Sibold - Biogen Idec Inc. SVP, US Commercial

So first of all, there is not an intent to wait until AAN to continue to move the needle, so to speak, with TYSABRI. We have a lot of efforts underway with what we are doing commercially with the product. Throughout 2009 there will be additional presentations made at medical meetings like AAN. There will be publications that we are expecting. All of these things we think put the benefit-risk profile of the product more in perspective; delivering some new information about analyses looking at the data of TYSABRI.

Really as we take a look towards the future with the confidence of where we derive our confidence in this brand starting with the disease, MS still remains a serious and debilitating disease. We see that by the amount of switching we commented on in the ABCR market, where we have 20% of patients switching each year. Also in the pipeline, with so many products headed towards MS, there is clearly a high unmet need.

TYSABRI, when you look at the efficacy, it really is delivering a new level of efficacy. And as we stated, in some patients actually reverses disability. I think that this profile, the benefit risk with PML is certainly getting put more in perspective in time as we have the results of patients. As Cecil mentioned, four out of the five patients are alive. We also look at the number of patients globally, approaching 40,000, and they product is approaching blockbuster status. So we have a lot of confidence that those positive details, along with the efforts that we have throughout this year, will be beneficial.

Now as to your question about the plateauing in the number of patients or physicians or different practices, let me take that on. We see in the US the number of prescribing physicians continues to increase steadily. Clearly, there is a breadth of physicians prescribing that we believe is sufficient to handle the number of patients that are seeking therapy. And size of practice, any of the results that we have seen doesn t seem to be tremendous differences between large practices, small practices, academic or rural, above the trends that we have seen, which as we have stated is general stabilization.

#### **Operator**

Rajiv Kaul, Fidelity Investments.

#### Rajiv Kaul - Fidelity Investments

Good morning. Thanks for taking my call. I just had a question on antibody titer testing to the JC virus and I was wondering how quickly that could be incorporated into the program. Because my understanding is that it is a pretty simple blood test and that and if you look at the literature, I think about 30% of MS patients probably have no antibody titers to JC viremia, not to viremia, to the virus.

And so the implications of that would be that potentially a large number of MS patients that may have never had exposure to the JC virus. If that is true, currently TYSABRI s penetration is only about 8%. So that would give us a lot of leg room here and could diminish the risk of PML. So I just wanted to get your thoughts on this and wanted to get a sense for how quickly we could move forward with some of this testing?

Dr. Al Sandrock - Biogen Idec Inc. SVP, Neurology Research and Development

The caller is right that in the past, with respect to PML risk mitigation, we had focused on the treatment side. And for those reasons we did the plasma exchange study and we are initiating the mefloquine study. We believe that that plus the pharmaco vigilance and the clinical vigilance that we advise has helped in the outcome from PML.

This year, in 2009, we are going to turn our focus on to risk mitigation. A major push in that respect will be the prior exposure to JCV as a risk factor and the serologies that were mentioned is a key aspect of that. We believe that we can get into testing certainly we believe by around mid-year we can start testing. But certainly by the end of the year we hope to be doing testing in patients. We are doing many of the preliminary steps and experiments now but it is a major goal for 2009.

# Elizabeth Woo - Biogen Idec Inc. VP, Investor Relations

Thank you. I think given the time, unfortunately, that has to be our last question. So thank you for joining us today. The replay number is available. Thank you.

Jim Mullen - Biogen Idec Inc. President & CEO Thank you.

Thank you

# Operator

Ladies and gentlemen, this does conclude the Biogen Idec fourth-quarter earnings call. You may now disconnect.