BIOGEN IDEC INC.
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SCHEDULE 14A
PROXY STATEMENT PURSUANT TO SECTION 14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934

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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. On April 1, 2009, Biogen Idec filed a preliminary proxy statement with the Securities and Exchange Commission (the SEC) and will file a definitive proxy statement and other materials concerning the proposals to be presented at the Company s 2009 annual meeting. Information concerning the interests of participants in the solicitation of proxies is included in the proxy statement.

THE PROXY STATEMENT CONTAINS IMPORTANT INFORMATION ABOUT BIOGEN IDEC AND THE 2009 ANNUAL MEETING OF STOCKHOLDERS. Biogen Idec s stockholders are advised to read carefully the proxy statement, and any amendments or supplements thereto, and other materials filed by Biogen Idec in connection with the Company s 2009 annual meeting of stockholders, when available, before making any voting or investment decision. The Company s proxy statement and other materials, as well as the annual, quarterly and special reports filed with the SEC, 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. The Company s definitive proxy statement and other materials will also be available for free by writing to Biogen Idec Inc., 14 Cambridge Center, Cambridge, MA 02142 or by contacting 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 afternoon. I will be your conference operator today. (Operator Instructions). If you would like to ask a question during this time, simply press star, then the number one on your telephone keypad. Miss Woo, you may begin your conference.

Elizabeth Woo

Thank you. Welcome to Biogen Idec s earnings conference call for the first quarter 2009. Before we begin, I d encourage everyone to go to the investor relations section of our web site, BiogenIdec.com and print out the press release and related financial tables. You ll find these are particular helpful when our CFO, Paul Clancy, reviews the financial results and reconciliation to non-GAAP financial measures discussed today. We have also posted the slides on our web site that outline the topics discussed on today s call.

We ll start with the Safe Harbor statement. Comments made in this conference call include forward-looking statements about our expected future results including our 2009 financial guidance, our longer term operational and financial goals, the sales potential of TYSABRI and other products and pipeline advancement. These statements are

subject to risks and uncertainties which could cause actual results to differ materially from expectations. You should carefully review the risks and uncertainties that are described in our earnings release, and in item 1 A of our most recent annual and quarterly reports filed with the SEC. We do not undertake any obligation to publicly update any forward-looking statements.

In addition, we have filed a preliminary proxy statement with the SEC for our 2009 annual meeting of stockholders. Before making any voting decision about our annual meeting proposals, you should carefully review our definitive proxy statement and related materials which will be available free of charge at our web site or the SEC s web site.

On today s call, I m joined by Jim Mullen, CEO of Biogen Idec, Bill Sibold, Senior Vice President, US Commercial, Dr. Al Sandrock, Senior Vice President, Neurology R&D, Paul Clancy, CFO and EVP Finance. I ll now turn the call over to Jim.

Jim Mullen

Thank you, Elizabeth. Good afternoon, everyone. The first-quarter 2009 results were in line with our expectations and consistent with full-year 2009 guidance we provided in February. Revenue grew 10% year-over-year to more than $1 billion, non-GAAP earnings per share grew by 27%. In the face of a more challenging macro environment and foreign exchange unfavorability, we saw revenue growth of all three of our marketed products and signs of strengthening in TYSABRI trends in the back end of the quarter. We are controlling expenses aggressively, while at the same time investing in and advancing the pipeline that we highlighted at our R&D day in March. We have 20 programs in Phase II trials and beyond, and aim to have nine registrational programs ongoing by the end of the year.

Our marketed products posted strong business performance in the first quarter, total revenues grew 10% year-over-year, and the franchises remain strong. AVONEX remains the global market leader, and success is driven by the long-term safety and efficacy profile. The number of patients on TYSABRI continues to grow steadily, approximately 2,400 patients were added in Q1 for a net total of 40,000 patients on therapy. We have reoriented the marketing and sales efforts in TYSABRI, and are back to talking about the benefit risk profile. We have seen early signs of success in turning TYSABRI around. Leading indicators have been positive in the second half of the quarter, compared to the first half, a hopeful sign for continued strength and acceleration of patient additions as we move past the nadir in January and early February.

And just this week we received FDA approval for the high-titer manufacturing process and that follows European approval for the process in December. Revenue from RITUXAN unconsolidated joint business grew 13% to over $279 million. RITUXAN is on track to achieve two additional indications. The first is the RA DMARD-Inadequate Responder. File was submitted last year with the summer 2009 PDUFA date. Also the IMAGE data announced in Q4 should strengthen the competitive profile for RITUXAN in RA. Secondly, 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. Bill Sibold, the SVP, US Commercial, will take you through an update of commercial franchises in a few minutes. As you have heard from other companies that have reported recently, the impact from the economic downturn is becoming more measurable. And we ve been monitoring the business closely.

We face many of the same issues as others, but believe we have been buffered somewhat from the macro environment because of the severity of our diseases that our products treat as well as the expansion of our global footprint in recent years. With that said, we have seen signs of modest impact in our business from the downturn such as increased requests for free and subsidized products, and financial stress of a few of our supply chain partners. Paul will provide a few details for you. In the current environment we believe it is prudent to exercise some discipline and protect both the bottom line and the balance sheet, and we ve been working successfully toward that end.

Strategically, our pipeline is focused on first in class or best in class specialty products and diseases with high unmet need and global application. We presented many of our pipeline programs in great detail at our R&D day in March. We provided unprecedented detail on some programs as well as access to people driving the pipeline forward. From the feedback we ve heard, I think many of you better understand the excitement we have for our pipeline, and those of you who attended witnessed firsthand the excitement and passion of our scientific leaders. In particular, some of

you saw the potential for the PEG interferon to extend our AVONEX brand. We will have additional PEG interferon data at AAN later this month.

In a few minutes, Dr. Al Sandrock will highlight the neurology franchise and pipeline presentation that we will be making at the upcoming AAN meeting. In addition to the positive feedback on R&D day, we recently received independent validation of the quality of our pipeline from Moody s. Among 12 large US-based pharmaceutical and biotech companies, Biogen Idec ranked highest on late-stage pipeline quality, and in the top third on pipeline diversity. And finally, with respect to performance, our goal for 2007 to 2010 is to deliver 15 and 20 top and bottom line compounded annual growth rate. With five strong quarters on the book, we re on track to achieve these financial goals. We continue to expect 2009 non-GAAP earnings per share above $4.00, and we expect cash flow to exceed earnings.

Three variables that may have impact on 2009, include the pace and timing of TYSABRI growth, the speed of advancement of late stage clinical trials, and the impact of the ongoing economic downturn. In conclusion, the quarter turned out as we expected consistent with full-year 2009 guidance. We managed through some challenges and worked to deliver bottom line performance and enhance the balance sheet. We have strong franchises, cash flows, and balance sheet and we ended the quarter with approximately $2.5 billion in cash and marketable securities. We continue to focus on products, pipeline, and performance as the drivers of long-term shareholder value creation. I ll now turn the call over to Bill Sibold, the head of the US commercial business. Bill.

Bill Sibold

Thanks, Jim. In the first quarter, our global neurology business delivered approximately $720 million in revenue. This is up 11% versus Q1 of 2008, driven primarily by the growth of TYSABRI over the last year. AVONEX s $555 million in global revenue in Q1 was up 4% year-over-year. This over $2 billion annual run rate reflects the strength of AVONEX s market-leading position with approximately 135,000 patients on therapy worldwide. TYSABRI had in-market revenue of $227 million in the first quarter, a 42% increase compared to the prior year, keeping it on a growth trajectory comparable to other biologics that became blockbusters such as Enbrel and Remicade.

As you can see from the press release, we continue to increase the number of patients on TYSABRI in the US and internationally. We now have over 40,000 patients on commercial and clinical therapy, and approximately 6,800 patients have been on therapy for over two years. Now a little bit about AVONEX and TYSABRI in 2009. AVONEX will celebrate its 13th year on the market this year. We continue to be excited about the new data that is coming out about AVONEX. Specifically, I am referring to two significant studies. First, the assurance data that was released at ECTRIMS showed that patients who remained on AVONEX for up to 15 years since the original pivotal trial had reduced disability progressions, greater quality of life, and significantly greater sense of independence and self-care versus those patients who had either switched to another therapy or discontinued therapy.

Second, data from the 10-year CHAMPIONS extension trial will be released at AAN later this month. This is the first trial looking at the long-term impact of treatment in early MS patients. AVONEX is the only product with this type of proven efficacy, which we know is very important in this market. The combination of AVONEX s proven efficacy and best in class compliance is why it is the #1 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 may recall at the beginning of the year, I said that we have three key objectives for TYSABRI in 2009. First, refocus communications on TYSABRI s unprecedented efficacy. Second, help physicians increase their comfort in diagnosing and managing PML. Third, translate resulting improvement in TYSABRI s benefit risk perception into increased and sustained use. Progress against the first objective has been encouraging. The percent of MS-prescribing physicians who believe that the benefits of TYSABRI outweigh the risks has remained very high since December, and is in line with pre-July 31, 2008, levels. We believe that this is a result of our significant efforts and the expanding efficacy picture for TYSABRI.

While the other MS therapies discuss efficacy in terms of decreasing relapses and slowing disability, TYSABRI has been able to demonstrate that in some patients the disease activity halts, and in other patients, physical disability associated with MS improved. On the second objective, through the early part of this year, we increased the level of

education about PML and clinical vigilance to increase prescribers awareness and comfort in diagnosing and managing the disease. We have also launched a number of other promotional initiatives to assist physician necessary discussing TYSABRI with their patients and to encourage patients to have open conversations about their therapy needs with their physicians. We are looking forward to the upcoming AAN meeting where an update on TYSABRI safety and utilization will occur.

With respect to TYSABRI trends, we continue to closely monitor international [INAUDIBLE]. We continue to closely monitor international and touch data to understand trends in TYSABRI prescribing patterns with obviously the most detail available for the US. As you are aware, there was moderation in patient growth in Q3 that was driven by both the slowdown in the rate of new patient adds, as well as an increase in discontinuations and that trend stabilized in Q4. Q1 appears consistent with Q4. However, in the last two months, February and March, we have seen further improvement in the trends for both new patient starts as well as discontinuations. We are optimistic that this trend will continue.

The type of patients coming to TYSABRI appear to be unchanged based on both their time since diagnosis with MS and their prior therapy. Copaxone is still the largest source of switchers. Additionally, we continue to see about 4% to 5% of TYSABRI patients naive to therapy. We are actively engaging multiple channels to gain insight into the markets, feedback from our customers, and to promote TYSABRI. We create touch points with not only physicians and patients but also payors, regulators, and patient associations. Specifically on the promotional front, we optimize and reach our frequency of messaging to physicians and patients. We do so through our sales force and patient services group, as well as numerous live peer-to-peer and patient programs, direct mail, and email.

In conclusion, we remain excited about the remainder of the year and the future. The new data on AVONEX extends beyond that of any of its competitors in the ABCR market, and further reinforces that it is the right product to start with and stay with for the long term. TYSABRI s emerging efficacy profile continues to impress and reinforce its positioning as the product for patients that need more efficacy. And finally, our 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. Al Sandrock, Senior Vice President Neurology R&D. Al?

Al Sandrock

Thank you, Bill. As Jim noted, we provided a thorough update of our development pipeline less than a month ago at R&D day. And the slides are up on our web site. On today s call I would like to highlight our activities at the upcoming American Academy of Neurology meeting which will occur later this month in Seattle. The AAN meeting is an important venue for us to exchange ideas and information with our neurology colleagues and interact with the MS community. There will be 25 company-sponsored platform and poster presentations at AAN covering the five compounds that are marketed or in the later stages of development. These include AVONEX, TYSABRI, BG-12, PEGylated interferon beta 1-a, and daclizumab. Biogen Idec is a leader in advancing therapeutics for multiple sclerosis and is already redefining success for patients living with MS. For example, with TYSABRI we are moving beyond slowing the progression of the disease in that some patients may become free from disease activity, or even experience reversal of physical disability during treatment. And if our preclinical experiments are any indication, we may one day even be able to repair the central nervous system that has been damaged by the disease.

The AAN will demonstrate that we have one of the most robust MS pipelines in the industry, with drugs targeting the multiple biological pathways thought to be critical for disease onset and progression. To date, many of these programs have shown compelling results in clinical trials, and we look forward to their continued development. One poster will show that daclizumab, which was shown to reduce MS lesions visualized by MRI scans in the randomized double-blind, placebo-controlled Phase II choice trial appears to reduce T-cell activation during treatment. There will be two BG-12 posters at the Congress which will provide further evidence of a potential dual anti-inflammatory and neuroprotective mechanism of action for this oral therapy.

I want to note here that during the quarter, we completed enrollment in the DEFINE Phase III trial of BG-12, a trial with over 1,200 patients randomized at 200 clinical centers around the globe. And at the second Phase III trial, CONFIRM, is expected to complete enrollment later this year. There will be two Company-sponsored posters on PEGylated interferon beta-1a at the AAN. One on safety and tolerability and the other on the PK/PD profile of the

drug as observed in the Phase I trials. These data support the advancement of PEGylated interferon beta 1-a into a registrational trial, which we expect to commence within a few months. This trial which will enroll over 1,200 patients will test two subcutaneous dosing regimens, once every two weeks and once every four weeks. As I have already noted, we will be also be showing new data on our marketed products, AVONEX and TYSABRI at the AAN. There will be six company-sponsored posters and presentations on AVONEX, including one on the CHAMPIONS ten year extension study which followed patients for a decade after starting AVONEX therapy just after the first demyelinating clinical event that heralded the onset of MS. There will also be 14 company-sponsored TYSABRI posters and presentations in Seattle. Among these will be a poster on the post talk analysis of the Phase III AFFIRM trial which showed that a substantial proportion of patients realized an improvement of physical function as measured by sustained decreases in EDSS over the course of the two-year trial. Another poster will show data that indicates that the TYSABRI treatment may promote remylenation in MS patients as assessed by novel imaging technique.

Finally, as we have been doing at the major neurology meetings, there will be a platform presentation that will provide updated TYSABRI safety and utilization information. All in all, we believe that our activities at AAN will highlight our extensive efforts in research and development and will underscore Biogen Idec s commitment to improving the lives of patient s living with MS. With that I ll now hand it over to our CFO, Paul Clancy.

Paul Clancy

Thanks, Al. Our Q1 financial results were right on track with our business plan to achieve 10% top-line growth and 27% non-GAAP earnings per share growth on a year-over-year basis. The GAAP financials are provided in tables 1 and 2 of the earnings release. Table 3 you ll find a reconciliation of GAAP to non-GAAP results. Our GAAP diluted EPS was $0.84 cents in Q1. The primary differences between our GAAP and non-GAAP results for the quarter were $89 million related to the amortization of intangible assets, $7 million for pretax employee stock option expense, and $35 million tax impact related to these items. Now I ll 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 $1.05 for Q1. Q1 total revenue was $1 billion 36 million, representing a 10% growth over the same period last year.

Going through our product revenues, I ll start with AVONEX. Q1 AVONEX worldwide product revenue was $555 million, representing 4% increase over the same period last year. Q1 US AVONEX product revenue was $340 million which represents a 10% increase over the same period last year. On a sequential basis, US AVONEX revenues were essentially flat, as price increases offset a 4% unit decline. We had approximately one less shipping week in the quarter versus Q4, which was offset by inventory in the channel modestly up to 2.4 weeks. Q1 international AVONEX product revenues were $215 million, representing a decrease of 5% on a year-over-year basis. This decrease was primarily due to unfavorable foreign exchange as the dollar-to-Euro exchange rate strengthened from on average 1.51 in Q1 2008, to 1.31 in Q1 2009. This FX movement had approximately $30 million impact to AVONEX international sales. Units were flat versus prior year, as an increase in our direct markets was offset by a decline in our distributor markets. The decline in the distributor markets was attributed to our tender business.

Q1 TYSABRI worldwide Biogen Idec product sales were $165 million, a 44% increase versus Q1 2008. US end-user TYSABRI sales totaled $116 million, of which Biogen Idec booked $54 million of this amount. US channel inventory ended modestly lower in in Q4 2008. International end-user TYSABRI sales totaled $111 million. Before I move on to RITUXAN, I ll like to briefly touch on the current economic environment and its impact to the MS franchise. As Jim noted, MS is a severe disease and our business has been modestly impacted by the current economic downturn. Our international business is somewhat buffered from the economic downturn in the short run, as most drugs are centrally reimbursed.

Nevertheless, in the US we have seen an increase in the number of patients who are receiving free supply of TYSABRI and AVONEX. We ve also noticed that co-pay assistance has increased. Specifically, the number of patients on free drug, has trended up very much in line with the US unemployment rate. For the quarter, we estimate

that this had approximately $6 million to $10 million impact on the top line. We ll continue to monitor this on our business. It s important also to note that foreign exchange impact on our product sales, including what I had mentioned on AVONEX international, was approximately $40 million in total or 4% to our top line for first quarter compared to prior year.

Now moving on to the RITUXAN collaboration revenues referred to as revenue from unconsolidated joint business. We recorded $279 million in revenue for the quarter, representing an increase of 13% on a year-over-year basis. Our RITUXAN revenues are broken into three components. First, our share of the US RITUXAN profits. Net US RITUXAN sales were $642 million in the first quarter, up 6% versus prior year. And our Q1 profit share from that business was $180 million, up 14% versus prior year. The year-over-year increase benefited from price increases taken during 2008, and lower operating expenses in the collaboration.

Second, we received revenue on sales of rituximab outside the US. And in Q1 this was $84 million, up 10% versus prior year. And last, we were reimbursed $15 million for selling and development costs incurred related to RITUXAN. Q1 royalties were $24 million for the quarter. The decrease on a sequential basis was primarily due to the stepped down royalty tier on Angiomax. Now turning to the expense lines in the P&L, which includes the non-GAAP adjustments that I described earlier. Q1 COGS were $98 million or 9% of revenues. COGS on a year-over-year basis modestly benefited from the expiration of a third-party royalty on AVONEX. Q1 R&D expense was $275 million which was approximately 26% of revenues. R&D expenses increased 8% on a year-over-year basis driven by our continued advancement of the pipeline.

Included in Q1 were milestones paid to Aveo, the oncology antibody licensing agreement, and to Neurimmune in the aggregate of $10 million. Q1 SG&A expenses were $217 million, representing 21% of revenues and representing a 2% year-over-year increase. SG&A benefited from FX in the quarter as compared to prior year. Continuing down the P&L, our collaboration profit sharing line totaled $43 million in expense for the quarter. This represents our payment of 50% of profits on TYSABRI outside the US to Elan, and a reimbursement of third-party royalties incurred by Elan outside the United States.

Other income and expense for the quarter was a gain of approximately $7 million, which was $4 million favorable on a year-over-year basis. We ended the quarter with a strong cash and marketable securities position of $2.5 billion, generated interest income of $15 million, which was offset by interest expense of approximately $10 million. We repurchased 1.2 million shares under our share stabilization program in Q1. Our Q1 non-GAAP tax rate was approximately 24.5%, much lower than our normal tax rate. The effective tax rate for the quarter was favorably impacted by a one-time discreet item related to recently enacted state legislation. This will allow us to utilize certain R&D investment tax credits.

We expect our non-GAAP tax rate for the remaining quarters in 2009 to be between 28% and 30%, and likely be at the lower end of this range for the full year. This brings us to our Q1 non-GAAP diluted earnings per share of $1.05, representing 27% increase over the same period last year. We re confirming our full-year 2009 guidance outlined in February. Top line growth in the high single digits, and non-GAAP earnings per share above $4.00. Additionally I d like to just add some perspective on cash flow.

We re also targeting to increase free cash flow growth over the rate of EPS growth. So our business plan is to achieve leverage from the top line to the earnings line, and further leverage in the free cash flow growth. Q1 was a solid quarter for Biogen Idec. We re increasing our efforts in educating the physician and patient community on the benefits of TYSABRI. We re progressing in investing in our pipeline. Our EPS growth was impressive as we continued to exercise discipline, and we continue to generate significant operating cash flow and have a strong balance sheet. I ll turn the call over to Jim for his closing comments.

Jim Mullen

Thank you, Paul. In summary, business performance for the quarter was as expected, in line with our full-year guidance. We continue to look for the best ways to maximize value for the shareholders, whether through investment or returning cash to shareholders. In our discussions with numerous shareholders, some see current asset values as a buying opportunity while others see share buybacks as the best use of cash. We re carefully evaluating

both ends of that spectrum, as well as all of the options in between. While we face some challenges in the remainder of 2009, I believe 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 it up for Q&A.

Elizabeth Woo

Great, thanks, Jim. Joining us on the call for the Q&A session is Dr. Cecil Pickett, our President of Research and Development. So Ashley, we re ready to open up the call. We d ask the participants on the call to limit themselves to one question and then re-enter the queue for follow-up questions to allow most people to get their questions in. And please state the name and company affiliation. So Ashley, we can take the first question now.

Operator

Our first question comes from Jason Kantor with RBC Capital Markets.

Jason Kantor RBC Capital Markets

Wow, great. First up. Could you be more specific, exactly what are you tracking in the TYSABRI numbers that you re saying, you re seeing an uptick in and what gives you confidence that things are getting better? And how sensitive are these leading metrics to, for example, another case of PML should it occur?

Jim Mullen

Sure. Why don t I this is Jim. Why don t I ask Paul to make a couple comments as well as Bill on that.

Paul Clancy

Well, you know, our practice has been to provide the patient data on a quarterly basis. And we ll kind of continue that pattern. So we won t be giving a detailed monthly or weekly data. But Bill can provide some additional color on the recent trends we ve been seeing.

Bill Sibold

Well, while the quarter as a whole saw steady patient growth we saw signs of strength more recently. And looking back over the last few months, we see that December and January net patient adds were very soft. But we were moderately higher than that, in the back end of the quarter. And more specifically, March was the highest month of net patient adds in the past five months, in both the US and in international. And in addition, we are seeing some hopeful signs from leading indicators such as touch forms in the US, and finally discontinuations have started to return to pre-PML levels from what we can see.

Jim Mullen

So just to finish off the question, so the measurement is obviously more accurate in the US, where we have the TOUCH program than it is internationally where it s a little bit of triangulation. Relative to the sensitivity to another case of PML, I think we ve been through all of that. And not much has changed with the last couple of cases of PML. So presuming that the rate stays more or less where it is, I don t think there s a lot of sensitivity to a case or two of PML. The next question?

Operator

Our next question comes from Geoff Porges with Bernstein.

Geoff Porges Bernstein

Thank you for taking the question. If I could follow up with something that you mentioned on the call. I think you said there was one left shipping week in Q1 than Q4. And there were some changes in inventory that also reflected you in Q1 versus Q4. Could you give us a little bit more color on that, and whether I misheard you or not about that, and just talk us through what the actual changes in inventory were and also the shipping days Q over Q and year-over-year?

Paul Clancy

Yes, so Geoff, this is Paul. What I ve referred to you picked it up spot on. What I referred to was AVONEX. And I think the way to think about it, there was an extra week in Q4 as opposed to Q1. We re back to a normalized kind of quarter of essentially 13 weeks of shipping in Q1. So I think you just want to be mindful of that when you look at sequential, but not when you look at overlapping on a year-to-year basis. We have distributor relationships in the United States on AVONEX, and a couple of the relationships had asked for additional they had changed their distribution locations and asked for additional weeks in the channel. We had as a result, AVONEX channel, weeks in the channel have moved up, from roughly about 2.1 to roughly about 2.4 weeks in the channel for AVONEX. That s a permanent change. So I don t think you ll see that wiggle and woggle around over the next couple of quarters. And then, to some extent that increase was offset by we actually saw it decline a little bit on the TYSABRI business.

Operator

Our next question comes from Michael Aberman with Credit Suisse.

Michael Aberman Credit Suisse

Hey guys thanks, I have a question about TYSABRI. You had in the US I ll start off with I haven t even gotten to do the math ex-US but it looks like you had another sequential increase in patient numbers, and a 3% price increase at the end of fourth quarter, yet end-user sales are not up enough to really account for that. And even looking back third quarter to fourth quarter a similar situation with number of patient net adds increasing but the actual revenue not tracking with that. Can you help us understand what s happening there with doses per quarter, and how that might be playing a role in the revenue? And you think that s going to change?

Paul Clancy

Yes. This is Paul. Michael, thanks for the question. I think this brought two dynamics that we are looking at and pointing to. One is kind of this in essence, the macro trend and the increase in free goods if you will, as a result of the patients for both AVONEX and TYSABRI. That is certainly pronounced in TYSABRI, given the uptick curve. And then the other trend we re seeing is a very modest decline on a quarter-to-quarter basis in terms of infusions per patients over the course of a quarter. It s not anything that we see as alarming. We saw this actually early in the AVONEX days, in the launch days years ago. So I think it s nothing that we see alarming. Obviously, you know, people are mindful of thinking about it as drug holiday, but we aren t pointing to it that way in any regard.

Operator

Our next question comes from Geoff Meacham with JPMorgan.

Geoff Meacham JPMorgan

Hi, guys. Thanks for taking the question. Just wanted to question here, sort of bigger picture on TYSABRI. As you guys accumulate PML cases over the next few years, how do you see it playing out commercially? Do you think docs will look to common futures such as duration of therapy or baseline ability to manage patients? How will that work do you think in practice?

Bill Sibold

Hi, yes, this is Bill. I think as we look at the evolving landscape, if you look into the pipelines of any of the products which are going to be launching in the coming years, there each certainly appears to have its own benefit and risk profile associated with it. And part of what we are seeing is, we expect that the neurology community will evolve in its approach to benefit risk, as they have more products to that they have to make that evaluation. Just to draw comparison to rheumatology where you ve got, you know, three blockbuster anti-TNF for years before the TNF launched rheumatologists had the opportunity to get comfortable with benefit risk for methotrexate. And you can see also that TYSABRI s tracking in the period post launch very well with those products.

So, you know, we think that there s going to be kind of an evolution of the specialty feeling more comfortable with benefit risk. And I think certainly with PML, they will become more comfortable with that. And, certainly it will depend upon what happens from here and what the outcome of the cases are.

Operator

Our next question comes from May-Kin Ho with Goldman Sachs.

May-Kin Ho Goldman Sachs

Hi. Can you talk a little bit about AVONEX in terms of reimbursement or insurance coverage? How many percent of the patients are commercial insurance? How much of that is pharmacy benefit, what kind of tier it is? And I heard you mentioned that there were some drug holidays for TYSABRI patients that you saw before. But we all know that the current economic condition is quite different than what we saw previously. So do you expect to have more patients basically stretching out a time, maybe taking drug holidays and are you seeing delays in patient starts because of the economic conditions?

Jim Mullen

Okay. May-Kin, we re going to forget all of the questions that were in that. But you did it in one sentence, so we ll give you credit. Maybe I can let me start with the last one, because I think Bill is trying to see if he can dig out some of the data that you asked for on the first. What do we see? We are seeing patient requests for free goods or subsidized goods track more or less with unemployment. You can probably infer some of that into people thinking about how to stretch their budgets, too. You might see a little bit more of that stretch out as we go through and bottom out here on employment numbers. It s very hard to predict, but we we can see a few percent impact on the business there. In terms of some of the other questions, Bill, do you have the directional answers, or are we going to have to

Bill Sibold

Yes. We can get a little bit more specific. To start off with, AVONEX is in a very favorable position from a reimbursement perspective. In most of the plans, it enjoys just very good positioning. And we have seen that not be a barrier to getting use of the product. We the vast majority of the patients have a fixed co-pay along the lines of $20 to $30 a month. And a small number have co-insurance which would be typically in that 20% cost. So I think from a since it s covered it s covered under pharmacy benefit, it s got great positioning, and we feel feel very comfortable with AVONEX.

Operator

Our next question comes from Joel Sendek with Lazard.

Joel Lazard Lazard

Hi. Thanks. I have a question about the high titer process. Will that have any material impact on the gross margin? And if so, when?

Jim Mullen

Yes, Joel. The answer is it will have an impact on the gross margin. You re not really going to see much of that this year as we work through the various stages of inventory we have. And as you can probably appreciate we ve got to build some inventory here before we want to move that one into the market, as well. But we ve got I don t really think you re going to see much of it this year. And when you look at the gross margin, we ll get some pickup there. But a lot of what s in the gross margin are third-party royalty payments to other people. So that s a pretty good chunk of what s in our cost of goods now. So, a little pickup, but think of it as a percent or two maybe.

Paul Clancy

Joel? I just this is Paul. I just add the way it comes I think Jim talked about that as it relates to kind of from a TYSABRI collaboration point of view. The way it comes into our our P&L is slightly different than a normal into the gross margin or cost of goods line. Most pointedly would be in the economic the US and the purchase price economics.

Operator

Our next question comes from Jim Birchenough with Barclays Capital.

Jim Birchenough Barclays Capital

Hi, guys. Just trying to understand better the impact of your education program around PML risk. And with better surveillance we ve seen better outcomes. I m just wondering what the results of that, have been in terms of suspected cases coming to you guys. Are you seeing physicians more expert at teasing out what s a real high risk for PML case? Or are you seeing just a lower sensitivity to suspected cases being reported to you guys? Just wondering what trend we re seeing there.

Jim Mullen

Al, can I ask you to pick that one up?

Dr. Al Sandrock

Yes. I think what we re seeing is that patients are being picked up earlier. I don t think that we re getting a big change in terms of suspected cases. What we re seeing is earlier recognition and earlier use of some of the tools that we ve provided in terms of managing the cases.

Operator

Our next question comes from Yaron Werber with Citi.

Yaron Werber Cititbank

Well, I have two questions for you. One, can you just help us understand a little bit the TYSABRI draw down in inventory that happened in Q4? I don t know if you can quantify that in days or in millions. Second question. Just help us understand the tax rate a little bit more. I m sorry if I missed why it was so low in the quarter, and you re guiding it sounds like to the lower end of your range. Help us understand how would the tax rate slowly ramp up.

Paul Clancy

Yes. Let s take the first one. TYSABRI, what I had referenced was Q1 versus Q4. So not that it was drawn down in Q4. Just the quarter-to-quarter change on weeks of inventory in the United States is modestly down. And we re talking in the less than a week kind of so half a week type of down on weeks in channel. In terms of the tax rate,

we benefited from a discreet item a one time. There was a change in tax in state legislation, tax law, we set up what we call Fin 48 reserves.

We set up reserves over the long long haul, as it relates to our taxes, and embedded in those reserves is certain embedded in that is legislation. The legislation changed which gives us high probability and certainty that we will be able to capture reserves for a number of the years in certain states. That s a one-time benefit, it s not sustainable. So all I was pointing to in terms for the balance of the year is that we drive back up to our normal rate. Without that discreet item, when you combine three quarters with of a normal rate with one quarter with kind of a depressed rate, it s likely at the lower end of the tax range.

Jim Mullen

Basically allows us to capture some R&D tax credits that were otherwise hung up.

Operator

Our next question comes from Eric Schmidt with Cowen and Company.

Eric Schmidt Cowen & Company

Good afternoon. A couple financial questions for Paul. First is the is the gross margin in Q1 a real number that we can use going forward for the year? And second, your EPS guidance remains kind of open ended for 2009. Do you expect to grow the bottom line over the subsequent three quarters?

Paul Clancy

So gross margin is what we are looking at now is probably indicative of the balance of the year plus or minus. In terms of earnings per share, I go back to Jim s point in the opening, the kind of three big variables will be rate of uptake on TYSABRI. The macro environment that, we re not terribly concerned about, don t want to kind of get that point across, but we re being mindful about. And then the rate of acceleration of the R&D business. Had a good quarter on the bottom line this quarter. I mean you can all do the math. Obviously, we want to grow the earnings for the balance of the year. But we just want to try to make sure that we re still definitely being able it achieve our full-year earnings per share target.

Operator

Our next question comes from Mark Hillenbaum with Deutsche Bank.

Mark Hillenbaum Deutsche Bank

Okay. Thanks. But I get it. So I keep it in one sentence and I can it ask multiple questions. I m going to try to do this.

Jim Mullen

Mark, it wasn t thats not what I meant.

Mark Hillenbaum Deutsche Bank

Okay I just took a deep big breath. On TYSABRI, should we model current dollars if the dollars per patient calculation that this quarter s results would spit out, you said you weren t alarmed by the misconfusions, but what I m trying to understand is this a run rate that we should use going forward in our models when we think about modeling TYSABRI revenue from our patient add calculations? And then just to be clear, for this one less shipping week, was that only for AVONEX, or did that also apply to TYSABRI?

Paul Clancy
Let me take it in the reverse. It actually also applied to TYSABRI. And then with respect to TYSABRI and keep in mind I think it s twofold of what s going on including the impact of additional free patients in the TYSABRI business. So that one for me is likely harder to predict. And who knows. It could go up or could come right back down. But both of those effects are affecting the revenue per patient on the TYSABRI business. But absent that, that dynamic, it s probably not a bad thing to model.
Operator
Our next question comes from James Zhang from BMO Capital Markets.
Jason Zhang BMO Capital Markets
Thanks. The question is on the economic impact that you mentioned on patients freezed or increased. There are also probably more patients need to get co-pay assistance. I m wondering for co-pay assistance, how is that affecting revenues? Is that because of delayed reimbursement or delayed infusion? How is that? And you gave us the number about freezing the impact of that could be $6 million to $10 million. Can you actually quantify the impact of co-pay assistance? Also whether you think this is going to get worse or mostly be a Q1 phenomena?
Bill Sibold
So this is Bill. With co-pay assistance, that is something which is actually a program which for AVONEX launched last year and TYSABRI really this year. And we certainly have made provisions in planning, thinking that it s going to be a program that will be utilized this year. And so far, we re still in the early stages of it. And the feedback s been very positive. And, we ll continue to track it as the quarters go on and compare it to the economic environment.
Operator
Our next question comes from Maged Shenouda with UBS.
Maged Shenouda UBS
How much more pricing leverage do you think you have for AVONEX? And also should we start thinking about aggressive price increases for TYSABRI?
Paul Clancy
Maged, we actually don t comment on our forward-looking pricing. So I think best thing I can share with you is that we don t build it into our business plans, the price increases that we ve seen.
Jim Mullen
On the TYSABRI, keep if mind that, you know, that that keep in mind that that one is going to be ASP plus six kind of pricing. You really have to be careful about pricing increases there, the frequency and the amount. Or you can put the physicians under water.
Operator
(Operator Instructions). Our next question comes from Chris Raymond with Robert W. Baird and Company.
Chris Raymond Robert W Baird & Company
Thanks for taking the question. I know you guys have have answered this question on prior conference calls, but can you walk through actually the mechanism I think you mentioned before you have some a natural hedge of

sorts against FX fluctuations. But you mentioned $30 million of AVONEX FX impact. Could you maybe also reiterate what the TYSABRI FX impact was and then also two-part question here obviously. Describe what that hedge is, thanks.

Paul Clancy

Yes. Okay. So in total it was about $40 million. That was $30 million for AVONEX International, the balance of $10 million or $11 million for TYSABRI International was the impact on the quarter, 2009 versus quarter 2008, from essentially going from, you know, 1.51 on average US to Euro to 1.31 on average in Q1 2009. We hedge our business, generally speaking, we hedge the annual plan. We generally do that as we get conclusion on our annual plan. So it s usually late in one year, we ll go out and hedge the following year. And we buy contracts that essentially try to to hedge the cash flow impact to the business. So the natural hedge so it wouldn t hedge the natural hedge.

The natural hedge that we have is essentially our sales and marketing in G&A infrastructure that s in Europe and other parts of the world and some modest amount of our R&D business. The impact in Q1 versus Q 2009 versus Q1, 2008, that we benefited was roughly less than half of the amount that was detrimental to us on a quarter-to-quarter basis on the top line. So, in essence we picked up probably $15 million or $17 million on a quarter-to-quarter basis in operating expenses.

As a result, the difference between the two is what from earnings per share, that $0.04, $0.03 or $0.04 is what the impact was on a quarter-to-quarter basis earnings per share. All of the hedge gains and losses are netted against the AVONEX International business. So there are quarters where we have a hedge gain. If we had if we had locked in numbers that that were above or below and vice-versa that we have hedge losses. In Q1, 2009, it was essentially deminimus. Hope that helps.

Operator

Our next question is a follow-up from Michael Aberman with Credit Suisse.

Michael Aberman Credit Suisse

Hey, sorry. I I didn t get to ask multiple questions in one sentence. So I m getting back in queue. But I many of then have been asked and answered. I guess I have a housekeeping question. On the other income maybe this has already been addressed. But you ve had some losses over the past few quarters.

Jim Mullen

Yes.

Michael Aberman Credit Suisse

And do you have a benefit this quarter can you explain to us where that s coming from. What we should expect going forward? What s happening there?

Paul Clancy

Yes. I think that the run rate we saw in this quarter is a little bit high. I would expect it to It was a $7 million benefit OIE. I would expect that to be down a little bit for Q2, 3, and 4. And not because of any meaningful writeoffs. Just because we picked up a little bit on some stuff that s outside of interest income and interest expense. Just a couple million dollars. We are our portfolio is in a very conservative position right now of $2.5 billion of cash and marketable securities. Close to 85% of that is in government, agency backed or cash and money market accounts.

We are now down at the end of the first quarter to $22 million in non-agency mortgage-backed securities. And, have a commitment to our company and our board to kind of get out of that in an orderly fashion. So what we saw in the

back half of the year, we re hopeful that we won t see anything of any kind meaningful going forward. The only caution I point is that we do have strategic investments in public and private biotech companies that we do for strategic reasons. And those can ebb and flow over the course of multiple years.

Operator

And our next question is a follow-up from Geoff Meacham with JPMorgan.

Geoffrey Meacham JPMorgan

Yes, thanks for the follow-up. Question for you on TYSABRI. When you guys give the net adds, obviously its new starts minus discontinuations. I m wondering how you classify a discontinuation versus a simple dose skip. Is there a certain amount of doses that a patient missed to be charged against the net add number?

Bill Sibold

Yes. This

Jim Mullen

We got it.

Bill Sibold

Yes. So what we do is we and this is, again, very specific to the US with TOUCH because we have obviously greater insight with the with the data we received through that program. And we have if a patient has missed a certain number of days of from their expected infusion at the 30-day mark where we would expect them, if it extendS out beyond that to beyond 45, 60 days and beyond, we start to classify that as a potential that they aren t coming back. What we do, though, is through the TOUCH program, we do reach out, and we look for confirmation. And a discontinuation form is actually sent in. And that is truly what what we ultimately measure.

Geoffrey Meacham JPMorgan

Okay. Helpful, thank you.

Al Sandrock

Geoff I d just add, we also kind of triangulate on the question you re asking. We also look at the average time of the whole patient data base between doses. And that has not shown a meaningful change. So that would show a meaningful change if we ve got patients in our data base that, really aren t patients anymore I think is what you get. On the international front, we we use a combination of patient registries where we can get them. And then looking at shipping data into physicians where where we obviously have it, and build our patient data base and our patient expectations based on that. That that actually as a result lines very much up with shipments. So, it s not going to be suspect to kind of this type of issue that we re talking about.

Operator

And our next question is a follow-up from Mark Hillenbaum with Deutsche Bank.

Mark Hillenbaum Deutsche Bank

Okay, thanks for taking my follow-up. On Europe, the ex-US AVONEX number, a little below consensus. And you mentioned FX, I was wondering if you could comment on price. Novartis launched a new version of an old beta interferon over there. Has there been any increase in net price over the big European markets?

Paul Clancy
No. In fact, Mark, we ve actually seen some price advances in Germany. And we ve managed we ve managed over the last let s probably call it 18 months to realize price advances from trying to control some some parallel trade between a couple of the countries. Now over the next couple of years, I d say that we need to be we re watching it as each country in different times in different stages actually comes up for renewal on the reimbursement front. So we we are watching that. Related to the competitive threat of Extavia, we have our ear to the ground. Salespeople are very focused on it, but it has not had a meaningful impact yet.
Elizabeth Woo
Operator, I think we have time for maybe, at most two questions.
Operator
Our next question is a follow-up from May-Kin Ho with Goldman Sachs.
May-Kin Ho Goldman Sachs
Hi, this May-Kin, this is a short question. I don t know that I heard correctly. Did you say that you are actually going to file the FDA application on volociximab?
Elizabeth Woo
No, we were talking about Reach and CLL8.
May-Kin Ho Goldman Sachs
Ah, okay.
Elizabeth Woo
For RITUXAN.
May-Kin Ho Goldman Sachs
Okay. Thank you.
Elizabeth Woo
Sure. Last question.
Operator
Our final question comes from Yahn Weber with Citi.
Yaron Werber Cititbank
Hi. Can you? One of the things I m just looking at is your you ve talked over time to show operating leverage. I m just trying to understand as we look help us understand a little bit the SG&A line. From what I understand, your business pretty much is fully scaled up from an expense perspective, so you can just lever that up from now on. Can you just help us understand how is that going to flow over the on a quarterly progression sort of, showing synergies there or showing improvements there? I m referring to the SG&A spending.
Jim Mullen

Yes. So this is Jim. So the SG&A spending, I mean we expect to get some modest leverage on that of course as the sales increase. But I think the caution on that of course is, that we also have to be very careful that we maintain a strong competitive position on share of voice, because we know share of voice moves the market around over time. So, sometimes we ll be doing some modest adjustments to the resource levels as we look at just whatever the new competitive framework might be. But, we would seem to get modest leverage there over time. I wouldn t expect to see dramatic leverage, though. I guess is what I would say. Paul, do you have

Paul Clancy

Yes, no.

Jim Mullen

Great.

Elizabeth Woo

Well, thank you, everyone. It was nice to be able to take so many questions on the call today. We ll see you on our next earnings call. Thank you.

Operator

This concludes today s conference call. You may now disconnect.