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 2008 annual meeting of stockholders. On April 18, 2008, 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 2008 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 2008 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 2008 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 morning; my name is Janice and I will be your conference operator today. At this time I would like to welcome everyone to the Biogen Idec first-quarter conference 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). Ms. Woo, you may begin your conference.

Elizabeth Woo - ***Biogen Idec VP of IR***
Thank you. Welcome to Biogen Idec s first-quarter earnings conference call. Before we begin I d ask everyone to go to the investor relations section of our website, BiogenIdec.com, and 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 ve also posted the slides on our website that outline the topics discussed on today s call.
I ll 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 2008 financial guidance, our longer term operational and financial goals, sales potential of TYSABRI and plans for external growth and pipeline advancement. 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 the Form 10-K and Form 10-Q and in other periodic and current reports Biogen Idec files with the SEC. The Company does not undertake any obligation to publicly update any forward-looking statements.
In addition, because we have received a Board of Directors nomination and bylaw amendment proposal from one of our shareholders, we are obliged to inform you of this and to be sure that our stockholders have access to all information they might need around this process.
On today s call I m joined by Jim Mullen, CEO of Biogen Idec; Bill Sibold, Senior Vice President U.S. Neurology Business Unit; Dr. Cecil Pickett, President of R&D; and Paul Clancy, Chief Financial Officer and EVP of Finance. I will now turn the call over to Jim.

Jim Mullen - ***Biogen Idec CEO, President***
Thank you, Elizabeth. Good morning, everyone, and thanks for joining us. Q1 2008 was another great quarter. We delivered record revenues and outstanding financial results in the first quarter as we more than tripled TYSABRI sales compared to the same period last year and our core products, AVONEX and RITUXAN, continue to generate strong sales. We made an outstanding start to 2008 and we re well on our way towards achieving our goals for 2010.
We delivered record revenue and strong profits in Q1 and year-over-year revenues grew 32% and non-GAAP earnings grew 41%. We saw an acceleration of TYSABRI patient adds as physicians grow more comfortable with the safety profile. We added 5,000 new patients in Q1 with more than half of them internationally and, importantly, no new cases of PML have been reported since the relaunch.
AVONEX sales were very strong and outperformed expectations. AVONEX continues to maintain its worldwide leadership position in the competitive MS marketplace and provides a strong and growing cash flow contribution to the business. And we advanced our pipeline. Clinical trial activities ramping up significantly in 2008 and we re eagerly awaiting a series of new clinical data reports this year for products not yet considered in our long-term forecast.
So 2008 is shaping up to be another strong year from both a financial and clinical standpoint and we re raising full-year 2008 guidance. So let me just expand on a few points before I turn it over to others on the call.
RITUXAN U.S. net sales for Q1 were $605 million which is up 13% year over year. This translates into revenues from the related joint business were $247 million which is up 19% year over year. AVONEX worldwide sales were $536 million in Q1 2008 representing a 19% growth year over year. With TYSABRI we exited the first quarter at a run rate of over $600 million of in-market revenues globally. Between AVONEX and TYSABRI our MS franchise share continues to expand. Bill Sibold, the SVP U.S. Neurology, will take you through the good news for TYSABRI.

And as we start 2008 we see a continuing acceleration towards our goal of 100,000 patients on TYSABRI by year-end 2010. As a result we re raising full-year non-GAAP 2008 earnings guidance. CFO Paul Clancy will take you through the financial and guidance details.

A couple of comments on the pipeline our pipeline advanced for 2007 and we now have 15 products in Phase II and beyond and 2008 will be a year of a significant number of clinical readouts. We built this impressive pipeline with a balanced approach of organic development and execution of highly effective business development programs. Significant R&D investment has yielded a robust pipeline with four novel compounds in registration trials and another to start later this year.

While we re disappointed with the RITUXAN OLYMPUS trial and it was unable to meet the primary endpoint in the difficult-to-treat primary progressive MS setting, we have a number of meaningful data readouts as the year goes on and Cecil Pickett will review the pipeline accomplishments and upcoming milestones in his comments.

I ll conclude the introduction by saying the future of Biogen Idec is extremely bright as evidenced by our recent operating results. In my nearly two decades with the Company I don t believe the prospects for growth today and growth in the future have been any better for the Company. I ll now turn the call over to Bill Sibold, the head of the U.S. Neurology business.

Bill Sibold - ***Biogen Idec SVP, U.S. Neurology Business Unit***

Thanks, Jim. I m pleased to report that in Q1 we continued the momentum established in 2007. Biogen Idec s global MS franchise continues to grow everyday with more new patients entering the franchise.

No one is doing more for MS than Biogen Idec. We have the number one prescribed MS therapy today, AVONEX; we have the product that has established a new level of efficacy, TYSABRI, which has been shown to delay the progression of the disease and reduce relapses by two thirds; and we have the best and broadest pipeline of MS products for the future.

This reality distinguishes us from other companies in the market and positions us, unlike any other, for the future. More and more physicians that I talk to understand and appreciate this commitment which I believe positively impacts both the short- and long-term prospects for the business.

Our presence in MS was highlighted at AAN in Chicago last week where there were nine platform presentations and 27 poster presentations related to Biogen Idec products. This is double the next closest competitor for total presentations, once again demonstrating the breadth of our portfolio. We also had a corporate therapeutic update titled Multiple Sclerosis, Biogen Idec and the Future of Personalized Medicine which was oversubscribed with more than 500 attendees.

Turning to Q1 results global neurology revenues were $650 million $651 million, an increase of 10% versus the prior quarter and 36% versus the prior year. Our combined global franchise market share continues to grow. In the U.S. it is now at its highest level since 2005 and it is at its highest level since 2000 outside the U.S.

We expect this trend to continue in step with TYSABRI s growth. AVONEX remains the product to start with and TYSABRI for those patients needing more efficacy. With their clear positioning and strong product profiles the bulk of relapsing remitting MS patients are candidates for either AVONEX or TYSABRI. As our pipeline matures we will have new options for additional patients in need.

Looking specifically at the products, AVONEX s $536 million in global revenue in Q1 was up 19% year over year and 7% quarter over quarter. AVONEX s revenue was up 14% year over year in the U.S. and 27% year over year internationally.

With over 135,000 patients on therapy worldwide and over 1 million patient years of experience, AVONEX remains the foundation of our global MS business. After 11 years on the market, AVONEX remains the only once-weekly product and is the only product indicated to both slow the accumulation of physical disability and be effective for patients who have experienced a first clinical episode and have MRI features consistent with MS.

Perhaps this is why it is the treatment most associated with patients in the early stages of the disease and with those patients who lead an active daily lifestyle and why it is the number one MS therapy in the world. AVONEX disrupts disease, not patients lives.

Now to TYSABRI. TYSABRI continues to build momentum with in-market revenue of $160 million in the quarter which is 23% growth over the prior quarter and an over three-fold increase over the prior year. At the AAN meeting in Chicago last week we announced the latest patient

numbers for TYSABRI. As of late March there were approximately 26,000 patients on TYSABRI worldwide in the commercial and clinical trial setting. There were approximately 15,300 TYSABRI patients in the U.S. with about 2,750 prescribing physicians, which is a doubling in the number of prescribers since last year. Internationally there were about 10,200 patients on therapy.

Finally, we announced that there were over 9,900 patients on therapy for over one year and over 3,600 on therapy for more than 18 months. The update was very well received by physicians who are growing more and more comfortable with the benefit/risk profile of TYSABRI.

Also at AAN, a poster was presented that showed that TYSABRI treatment significantly increases the proportion of patients with MS considered to be disease free. According to post-talk analysis of the AFFIRM and SENTINEL clinical trials about one-third of patients were shown to have no relapses, no disability progression and no new MRI markers.

Additionally, at AMCP and AAN last week, a poster was presented with results from a recent study of 451 patients on TYSABRI. The study showed that over 95% of patients reported doing as well or improving in their quality of life, functional status and disease step levels as early as three months after starting TYSABRI.

Additionally, over half of the patients reported improvements in their ability to do physically demanding tasks and feeling well in the same period. These data suggest the real-world efficacy of TYSABRI.

Also since the last call, our partner Elan has launched TYSABRI for Crohn s Disease and TOUCH online has been rolled out and has been extremely well received. TOUCH online offers substantial service benefits to our prescribers and infusion sites.

Additionally, we continue to see encouraging trends in the market. Worldwide, TYSABRI is considered to be the most effective MS therapy by neurologists. In the U.S. the number is over 94% of neurologists responded this way. Positive switching trends continue with TYSABRI being the most switched-to therapy. And on the subject of switching, in the U.S., Copaxone with its everyday injection remains the largest single source of TYSABRI patients. Finally, about 80% of TYSABRI patients in the U.S. and nearly 90% of TYSABRI patients internationally are new to the Biogen Idec franchise. We believe TYSABRI will continue to build momentum throughout the remainder of 2008.

We had a strong Q1. There continues to be positive new data about TYSABRI as evidenced at AAN last week, and in July TYSABRI celebrates two years on the market, which is a significant milestone. All of these things make us more confident than ever that TYSABRI will achieve the previously stated goal of 100,000 patients on therapy and eventually become the leading MS therapy in the world.

In conclusion, with the number one prescribed MS therapy today, AVONEX, a product that has established a new level of efficacy, TYSABRI, and the best and broadest pipeline of MS products for the future, Biogen Idec is the leader in multiple sclerosis. Our goal is to provide products and services for MS patients from diagnosis to disease resolution. We are extremely pleased with the results of the first quarter and optimistic about the rest of the year and the future. I will now hand the call to Dr. Cecil Pickett, President R&D.

Dr. Cecil Pickett - ***Biogen Idec President R&D***

Thank you, Bill, and good morning, everyone. Today I ll report, as usual, on accomplishments in the quarter and upcoming data readouts. First I ll review recent progress and data readouts.

As you know, our sBLA on TYSABRI to treat Crohn s disease was approved by the FDA on January 14th. Our partner, Elan, has since launched the drug and TYSABRI for Crohn s has been available in the U.S. since the end of February, with final stages of education and training completed during the second week of March. Crohn s patients have started to receive TYSABRI therapy in the U.S. and we are pleased to offer them this important option.

We had a recent data readout and were disappointed that our RITUXAN OLYMPUS trial in primary progressive MS failed to meet the primary endpoint. The unmet medical need remains high in this difficult-to-treat disease.

Next I ll mention some data on TYSABRI. Starting with PML mitigation, Dr. Fox presented at AAN a sub study from the PLEX trial on leukocyte transmigration that suggested plasma exchange could be an effective means of removing TYSABRI and allowing the immune system to reestablish more rapidly. In theory this may allow a patient to better fight off a reactivated JC virus.

Staying with PML mitigation, we have initiated a program to test the anti-malarial Mefloquin in HIV patients with PML. Mefloquin has shown some antiviral activity in an in vitro screening of JC virus replication.
Moving to safety, at the recent AAN meeting our global head of drug safety, Dr. Carmen Bozic presented an update of TYSABRI safety and, as you know, we ve seen no new PML cases. As Bill mentioned, physicians are growing more and more comfortable with the benefit/risk profile of TYSABRI.
To provide additional perspective, PML is associated with a growing list of immunosuppressive drugs. So it may be time to start considering PML as a potential side effect of any powerful therapy that modulates the immune system and not as something specific to TYSABRI.
Next, we had a number of R&D accomplishments this quarter. We continue to make good progress on advancing and developing our late stage clinical pipeline. We currently are accruing patients to our four ongoing pivotal registration programs with novel molecules, lumiliximab and CLL, galiximab in non-Hodgkin s lymphoma, BG-12 in relapsing remitting MS, and lixivaptan in hyponatremia. In addition, we expect to initiate another pivotal program during 2008, ADENTRI in acute decompensated congestive heart failure.
We have completed enrollment for the RITUXAN Phase III LUNAR trial in lupus, nephritis and the baminercept alpha Phase IIb respond trial in rheumatoid arthritis. We have achieved first patient enrolled for the daclizumab Phase II SELECT monotherapy trial in relapsing remitting MS; the volociximab Phase II combination trial with DOXIL in ovarian cancer; our lead HSP-90 inhibitor Phase II trial in gastrointestinal stromal tumors; and the anti-IGF-1R Phase I trial in solid tumors.
Finally, we have active INDs for TYSABRI in multiple myeloma and anti-Cripto-DM4 for solid tumors. We also published an in vitro study of Neublastin in nature and neural science. Neublastin promoted regeneration of damaged sensory nerve cells and restored sensory and motor function. And also keep on the lookout for a number of abstracts from us at the upcoming ASCO and UR meetings.
I ll end by reminding you about the number of data readouts expected by the end of 2008. Soon we anticipate results from Explore, the Phase III RITUXAN study in SLE. The BILAG scale will be used to assess SLE disease activity in this study and is a comprehensive, reliable, sensitive to change and effective in capturing the waxing and waning nature of lupus. Major or partial clinical response will be assessed at 52 weeks. The unmet medical need remains high in this sizable indication.
We also expect to see clinical readouts in 2008 from a number of novel programs including Phase IIb data on baminercept alpha in RA, BIIB14 for Parkinson s disease, and long-acting Factor IX in hemophilia B. Also our heat shock protein 90 inhibitor in volociximab in solid tumors.
So in conclusion, I remain very impressed with the caliber of both the pipeline and our R&D team. 2008 is a very active year on the R&D front and on average four times as many patients in clinical trials compared to 2007. We are as eager as you to see the data from the ongoing trials. With that I ll hand the call over to Paul Clancy, our CFO.

Paul Clancy - ***Biogen Idec CFO, EVP Finance***
Thanks Cecil. We delivered another strong quarter of financial results. Our impressive top-line and bottom-line growth is a solid testament to Biogen Idec s economic growth engine and our focus on delivering tangible results and building shareholder value.
We achieved 32% top-line growth with strong performance across all products in all geographies and over 40% earnings growth on a year-over-year basis. We delivered these excellent financial results while simultaneously investing heavily in our pipeline, a key imperative for sustainable long-term growth.
Now I ll walk through the P&L in more detail. The GAAP financials are provided in Tables 1 and 2 of the earnings release. Table 3 is a reconciliation of the GAAP to non-GAAP financial results. So let s begin with our GAAP to non-GAAP reconciliation. In accordance with Reg G we ve provided Table 3 which breaks out the items by major driver.
The main items excluded from the non-GAAP P&L in Q1 were first, we adjusted $75 million for the amortization of intangibles; second, we adjusted $25 million related to the contingent consideration payment associated with the Conforma acquisition; third, we adjusted $6 million in employee stock option expenses, approximately half of this is in SG&A and the remainder in R&D; and fourth, we had $18 million of tax impact for the items I just mentioned.

Now I ll move on to the non-GAAP P&L operating performance. We believe it s important to share this non-GAAP perspective with shareholders because it better represents the ongoing economics of our business and it reflects how we manage the business internally and set operational goals.

In Q1 we delivered $0.54 diluted EPS on the GAAP P&L and, after the adjustments shown in Table 3, our non-GAAP diluted EPS was $0.83. Both of these numbers increased by over 40% versus Q1 2007.

Now let s move through the first-quarter detail in a bit more. Q1 total revenue was $942 million. This represents an impressive 32% growth over the same period last year. Key drivers again across all products, all geographies, the continued revenue growth of the AVONEX business, the increasing penetration of TYSABRI, and the continued growth of the RITUXAN franchise.

Now I ll go through the product revenues; I ll begin with AVONEX. Q1 AVONEX worldwide product revenue was $536 million representing a 19% increase over the same period last year. Q1 U.S. AVONEX product revenue was $308 million representing a 14% increase over the same period last year. This revenue growth was supported by the strength of the AVONEX brand and its ability to support price increases in 2007.

Q1 international AVONEX product revenue was $228 million representing an increase of 27% on a year-over-year basis. Approximately 10% of that increase was driven by favorable foreign exchange rates and the balance driven by volume and mix increases.

Q1 TYSABRI worldwide Biogen Idec product revenue increased to $115 million. As Bill highlighted, TYSABRI continues to make strong progress. TYSABRI financial highlights include inpatient total sales of $160 million worldwide. U.S. end-user TYSABRI sales totaled $86 million representing a 13% quarter-over-quarter increase. Biogen Idec booked $41 million of this amount. International end-user TYSABRI sales totaled $73 million which is a 39% increase from the prior quarter.

Moving to other product revenue, Q1 FUMADERM revenue was $12 million and Q1 ZEVALIN product sales, which really represents our supply agreement with CTI, were $2 million.

Now moving on to the RITUXAN collaboration revenues, which is referred to as revenue from unconsolidated joint business, we recorded $247 million in revenue for the quarter representing a 19% year-over-year increase. This number has three elements first, we receive our share of the U.S. RITUXAN profits. As reported by Genentech our partner, U.S. RITUXAN sales were $605 million in the first quarter, up 13% versus prior year. And our Q1 profit share from that business was $158 million, up 16% versus prior year.

Second, we receive royalty revenue on sales of rituximab outside the U.S. and in Q1 this was $77 million, up 35% versus prior year. Third, we were reimbursed $13 million for selling and development costs incurred related to RITUXAN. Q1 royalties were $24 million for the quarter. Our Q1 royalty revenue reflects a step down from Q4 driven by ANGIOMAX which I described in our last call.

Now turning to the expense lines on the P&L, which includes the non-GAAP adjustments that I described earlier. Q1 COGS were $101 million representing 11% of revenues. Q1 R&D expense was $255 million which is approximately 27% of revenues. Increases in our R&D spend was driven by our continued advancement of our robust pipeline.

As Cecil mentioned, we have several programs in registrational trials including BG-12, lixivaptan, galiximab and lumiliximab, and we expect ADENTRI to join this group by the end of the year. We expect these late stage programs coupled with our advancing early-stage pipeline to drive significant increase in the number of patients on clinical trials when comparing 2008 to 2007.

Q1 SG&A expenses were $213 million which represents 23% of revenues and a 17% year-over-year increase. Drivers of the year-over-year increase in absolute dollars included investments to support TYSABRI growth. Specifically several international markets including Germany and France as well as the Crohn s launch in the U.S. in the first quarter of 2008.

Continuing down the P&L, our collaboration profit-sharing line totaled $21 million of expense for the quarter. As a reminder, this line represents Biogen Idec s payment of 50% of the profits outside the U.S. to Elan and the reimbursement of third-party royalties incurred by Elan outside the U.S. We expect this number to continue to grow in the coming quarters reflecting the growing profitability and uptake of our international TYSABRI business.

Now moving to other income and expense. This represented a $500,000 loss for the quarter, a significant change to our OIE line since the same period last year is the impact of our $3 billion share repurchase in June of 2007 which

equated to 16% of our shares outstanding. Specifically this line has been impacted by the loss of interest income from a reduction in cash and the addition of the interest expense from taking on debt.

I ll also note that during the quarter we converted our $1.5 billion temporary bridge loan to $1 billion in permanent debt. The $500 million difference was paid down with cash. The permanent debt offering included $450 million in principal at 6.0% due 2013 and 515 $550 million in principal at 6-7/8% due 2018.

Additionally, in Q1 2008 we repurchased 4 million shares under the 20 million share repurchase program authorized by our Board of Directors in October of 2006. The purpose of this program is for share stabilization. Since the close of the quarter an additional 5 million shares have been purchased as well. Even after our impressive share buybacks our cash position remains strong and growing.

Q1 tax rate on a non-GAAP basis is 29% which brings us to our Q1 non-GAAP diluted EPS of $0.83, again representing a 41% increase over the same period last year.

Now I d like to conclude by discussing our updated 2008 guidance. Given our strong Q1 performance we re raising our 2008 financial guidance. We expect annual revenue growth of 20% over 2007 driven in large part by strengthening TYSABRI uptake. This is now at the high end of our previous revenue guidance.

We expect operating margin leverage to be similar to previous guidance and the combination of non-GAAP R&D and SG&A expenses for the year to be approximately $2 billion. This number may be impacted by potential business development activity and the pace of patient accruals in our important four, and moving to five, late stage development programs.

I ve excluded from I ve excluded are collaboration profit line from the $2 billion expense guidance for 2008. I should note that we do expect this line to grow each quarter, again reflecting the uptake in increasing profitability of the international TYSABRI business.

Our non-GAAP tax rate is expected to be between 28 and 30% and this assumes the renewal of the R&D tax credit legislation. Non-GAAP diluted EPS is expected to be in the range of $3.25 to $3.45, this represents a 19 to 26% year-over-year growth rate.

In addition to increasing our guidance we ve slightly widened the range to reflect the potential impact of business development activities and the pace and success of clinical trials, notably again the four to five programs in late stage. GAAP EPS is expected to be in the range of $2.28 to $2.48.

Overall this full-year guidance provides strong top-line and bottom-line growth and is an important steppingstone in achieving our longer-term operating and financial goals. So in conclusion, extremely strong performance for the quarter with a solid testament to our strategy and our focus on creating shareholder value. We delivered 32% in the top line and grew non-GAAP EPS by 41%, all while aggressively investing in our pipeline. Now I will hand it over to Jim for his closing comments.

Jim Mullen - ***Biogen Idec CEO, President***

Thanks, Paul. In summary, we re very pleased with the Q1 2008 financial results and the strength across all products. Given the strong momentum underway and the key data readouts expected later this year the prospects for the Company have never been better.

We continue to grow our MS franchise share. By year-end several thousand patients will have been on TYSABRI therapy for two years which will provide the MS community with a better understanding of the impact of duration of TYSABRI s safety profile.

We re moving our pipeline programs forward and a number of data readouts on late-stage programs will come over the next month. The next readout will be the top-line results for RITUXAN in lupus which will be available soon, certainly in this quarter.

The future of Biogen Idec is bright; we continue to work to bring more meaningful therapies to patients in need which in turn we believe will generate strong growth that will create significant value for our shareholders. Just as we did successfully over the prior four-year period, we re confident we will achieve our 2010 goal. And just to reiterate those 2010 financial goals, it s 15% revenue compounded annual growth rate, 25% GAAP EPS compounded annual growth rate, and 20% non-GAAP EPS compounded annual growth rate. With that I ll turn it back over to Elizabeth and open it up for Q&A.

Elizabeth Woo - ***Biogen Idec VP of IR***

Thanks, Jim. Operator, we re now ready to open up the call for Q&A and we d ask participants on the call to please limit themselves to one question and then reenter the queue for any follow-up questions. Please state your name and company affiliation. Operator (multiple speakers) first question.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS). Mark Schoenebaum, Bear Stearns.

Mark Schoenebaum - ***Bear Stearns Analyst***

Thanks for taking my question, I really appreciate it. Can I ask about RITUXAN for lupus? And obviously I know you don t know the data yet, so I m not going to put you in that uncomfortable position of trying to handicap those data. But maybe you can just help the Street perhaps understand this market a little bit better.

There have been all kinds of sell side reports coming out and Genentech has given out I think 200,000 eligible patients. I see on your slide it looks like it s closer to 300,000 eligible patients. In reality, kind of at peak, if the trial works and works well, how many patients do you think are actually could be on RITUXAN in kind of a peak normalized year?

Jim Mullen - ***Biogen Idec CEO, President***

Hey, Mark, I ll take that because the answer is while we have, I think you well pointed out, it s fairly rough estimates of what the total patient numbers are available out there, which by our experience is pretty typical in these marketplaces, particularly in something like lupus where the line of exactly how they re classified tends to move around a bit.

But the real answer comes with the data and how strong is the data, and how compelling is the data and then all the other factors that surround that. But until we ve really seen the data, anything would just be a finger in the wind at this point.

So we re anxious to see that data, be able to really analyze the data, understand subgroup analysis, understand safety so remember, all we re going to get on the first day is sort of top-line stuff. And then you ve got an ability to start taking it back out and talking to real practitioners to understand what the real world relevance of the results are.

Mark Schoenebaum - ***Bear Stearns Analyst***

And what kind of subgroups are you talking about?

Jim Mullen - ***Biogen Idec CEO, President***

Well, it is a very heterogeneous disease by definition. So you re going to be looking at everything from gender to age to prior treatments to organs involved, etc. So I think there will be a huge treasure trove of data to go through which will help guide us where to go in the future.

Mark Schoenebaum - ***Bear Stearns Analyst***

Okay, thanks. Good luck.

Operator

Yaron Werber, Citi.

Kareem De Felipe - ***Citi Analyst***
Hi, this is actually [Kareem De Felipe] dialing in for Yaron. Thanks for taking my question. My question is in terms of the strong AVONEX growth you ve been seeing; can you perhaps give a little more detail if it s just a volume increase or just price increases? And how much room do you have for more price increases both in AVONEX and TYSABRI? Thank you.

Paul Clancy - ***Biogen Idec CFO, EVP Finance***
Yes, this is Paul. I ll try to take that. We certainly benefited from foreign exchange outside the United States sales and then from the benefit of the price actions inside the U.S., the price actions that were taken in full-year 2007. Nevertheless, I would characterize Q1 as very solid with respect to our unit trends and, in fact, in both geographies we saw some of the best unit trends that we ve seen in a number of quarters. Which is testimony to, in the United States, some of the new marketing programs that we ve put in place are really taking hold as well as outside the United States kind of continuing a very, very strong momentum.
With respect to forward-looking price, we really don t as a policy talk about that. And so I d kind of probably just leave it there at that for now.

Kareem De Felipe - ***Citi Analyst***
Okay, great. Thank you very much.

Operator
Joel Sendek, Lazard Capital Markets.

Joel Sendek - ***Lazard Capital Markets Analyst***
Thanks a lot. Actually, I wanted to follow up on that last question and with regard to what you said about unit trends. Can you help us understand if the instance of patients with MS is increasing and maybe you re getting more patients off the sidelines in the TYSABRI into the TYSABRI fold and maybe that could be increasing the potential patients on AVONEX as well even though it s kind of counterintuitive given the potential cannibalization?

Paul Clancy - ***Biogen Idec CFO, EVP Finance***
Joel, I think that what we re seeing in terms of unit trends outside the United States is actually quite good. Inside the United States I d say that it s probably characterized by slowing growth in 2008 as we saw in 2007. But the penetration in other geographies and just kind of expansion across the world is actually beginning to help us.
We now with respect to disease-modifying therapies, there are actually now more patients across all disease-modifying therapies on therapy outside the United States than inside the United States. So I think it s one of the things that we ve tried to talk about over the last year or two is the importance of the business outside the United States. And I think our strategy is really starting to pay off as it relates to that.

Operator
Michael Aberman, Credit Suisse.

Elizabeth Woo - ***Biogen Idec VP of IR***
Why don t we go to the next question?

Operator
Geoff Meacham, JPMorgan.

Elizabeth Woo - ***Biogen Idec VP of IR***
Are we having technical difficulties, operator?

Michael Aberman - ***Credit Suisse Analyst***
Yes, we are.

Jim Mullen - ***Biogen Idec CEO, President***
We ve lost a queue or something?

Operator
One moment, sir.

Jim Mullen - ***Biogen Idec CEO, President***
If we can reload those and start with Michael if we can find him again here and then go to Geoff.

Operator
One moment, please. Mr. Aberman, could you please press star 1 again? Okay, Mr. Aberman, your line is open.

Michael Aberman - ***Credit Suisse Analyst***
All right. Are you guys there? Fantastic. You had me in a panic. Looking at the trends for TYSABRI, in the U.S. the actual number of patients added was flat compared to the fourth quarter whereas in ex U.S. you had a significant increase. Going forward was there something unique about Europe in terms of this quarter in terms of the rollout in countries where we think this might temper a little bit going forward? Or should we think of this as a run rate in the U.S. based on this new updated safety would you expect an inflection in the outer quarters or the next few quarters given the recent safety update?

Bill Sibold - ***Biogen Idec SVP, U.S. Neurology Business Unit***
So this is Bill. So internationally we did see the benefit of additional countries coming on board and we expect that that effect will continue through the year and into the future. In the U.S. Q1 was what we had expected and we expect that there will be a steady growth in the number of new patient adds which puts us on track overall for 2010 of our goal of 100,000 patients.

Paul Clancy - ***Biogen Idec CFO, EVP Finance***
Hey Michael, this is Paul. I d just add and try to echo the fact that as we ve articulated our longer-term goals we ve always thought about the contribution of TYSABRI in terms of patients to be kind of in the 60% outside the U.S., 40% inside the U.S., and that s just based on kind of market projections and planning. In the early read, based on Q4 and Q1 now, is that that assumption may really start to be coming to fruition.

Michael Aberman - ***Credit Suisse Analyst***
Thank you very much.

Jim Mullen - ***Biogen Idec CEO, President***
Can we find Geoff Meacham again?

Operator
Geoff Meacham, JPMorgan.

Geoff Meacham - ***JPMorgan Analyst***
Hey guys, can you hear me?

Jim Mullen - ***Biogen Idec CEO, President***
We can, Geoff.

Geoff Meacham - ***JPMorgan Analyst***
Okay, so to ask Michael s question a different way, I guess now that you re a few quarters in the EU launch of TYSABRI is there any data you can give us on the source of patients? So basically the EU version of slide 10 in your deck.

Jim Mullen - ***Biogen Idec CEO, President***
The EU version of slide 10? Probably what I d say is it looks better outside the U.S. than inside the U.S. in terms of the number of patients that are kind of new to the franchise. So few are coming from AVONEX, more are coming from the competitors. And probably the return to the market is about similar to what we ve seen here. So where we say four out of five TYSABRI patients in the U.S. are new to the Biogen Idec franchise, it s probably closer to nine out of 10 outside the U.S. And interesting, there are a couple of markets where TYSABRI is pretty quickly moving to the number two position.

Geoff Meacham - ***JPMorgan Analyst***
And just as a follow-up, do you see in Europe, any bias towards use of TYSABRI in first-line patients in Europe?

Jim Mullen - ***Biogen Idec CEO, President***
No, I don t know that we ve seen a lot of change for physicians yet to initiate patient newly diagnosed patients on TYSABRI. It happens in some circumstances but that s still a minority.

Operator
Eric Schmidt, Cowen & Co.

Eric Schmidt - ***Cowen & Co. Analyst***

Congrats on the strong first quarter. My question has to do with the AAN meeting, maybe either for Bill or Cecil. We noticed there were a couple of poster presentations at AAN that talked about monitoring patients for JC virus reactivation. I m just kind of wondering what Biogen s take would be on some of that data.

Dr. Cecil Pickett - ***Biogen Idec President R&D***
Yes, I guess you re specifically talking about the poster from Dr. Sadiq s study.

Eric Schmidt - ***Cowen & Co. Analyst***
That s right.

Dr. Cecil Pickett - ***Biogen Idec President R&D***
Just to back up just for a second, just want to remind everyone, as of the end of March of 2008 there were approximately 26,000 patients on TYSABRI with no new cases of PML. That s very important. Dr. Sadiq s study identified two patients with JC virus, one in the blood and one in the cerebral spinal fluid. I want to point out that these patients did not have PML and there is actually no data that exists to suggest that they are at increased risk of developing PML. So we believe the best approach to monitor for PML is through examination and clinical vigilance.

Operator
William Ho, Banc of America.

William Ho - ***Banc of America Analyst***
Hey guys, congratulations on the quarter. I guess my question comes I guess with respect to your current views of PML and the mechanism, given the FDA s recent advisories due to PML from Novartis Myfortic and Roche s CellCept, what are your future or your going-forward thoughts on the risk of PML? Is it a TYSABRI-related event or is it just due to immunosuppression and do you see clinicians becoming more comfortable with the use of TYSABRI?

Dr. Cecil Pickett - ***Biogen Idec President R&D***
Well, I think what mycophenolic acid, which is CellCept it s the ester of mycophenolic acid is basically CellCept it inhibits sort of the key enzyme in purine metabolism. And because of that it actually blocks proliferation both of T-cells and B-cells. So it s a pretty powerful immunosuppressant. So my take on that although the data is limited to date, but my take on that is that any potent immunosuppressive agent may induce an increased risk of PML. And I think you ve heard from Bill that physicians are becoming much more comfortable with the benefit/risk profile of TYSABRI.

Operator
Jim Birchenough, Lehman Brothers.

Jim Birchenough - ***Lehman Brothers Analyst***
Hi, guys. Let me add my congratulations on the quarter. Just a question on the PLEX study results and implications for the market. Maybe you could just comment on the number of infusion centers that have apheresis capabilities and whether you think the data will give some comfort, not only around PML, but for patients that might have to transition from TYSABRI to an immunosuppressive quicker than the three-month lag time?

Dr. Cecil Pickett - ***Biogen Idec President R&D***

Well again, I mean, the PLEX data basically suggested that three plasma exchanges actually reduces TYSABRI levels quite significantly in the plasma. And the in vitro transmigration assay that was done also suggests that with PLEX, with a plasma exchange, you can basically reconstitute the immune system. So I guess we also have done some modeling which suggests that if you go out to five cycles that you really significantly reduce TYSABRI levels to the extent I guess of greater than 95%.

Jim Birchenough - ***Lehman Brothers Analyst***
I guess the question is in terms of practically are infusion centers in a position to plasma pherese.

Bill Sibold - ***Biogen Idec SVP, U.S. Neurology Business Unit***
Yes, we don t see that as being a barrier.

Operator
May-Kin Ho, Goldman Sachs.

May-Kin Ho - ***Goldman Sachs Analyst***
Hi, I have a question on the Lupus study. If that study is negative what kind of sorry, what kind of conclusion should we draw with respect to the upcoming trial for nephritis lupus nephritis?

Dr. Cecil Pickett - ***Biogen Idec President R&D***
Very difficult to say. I think many of us in this field for several years have thought that there was a significant B-cell there is a significant B-cell involvement in Lupus. And so we ll get the data and see what the data tells us about the Lupus study and sort of go from there. So I don t think actually we completed enrollment in the lupus nephritis study also so we ll get data from both of those studies. And we don t have to sort of guess, we can base our decisions on actual data.

May-Kin Ho - ***Goldman Sachs Analyst***
I was just really trying to refer to with SLE maybe you were less organ specific and with lupus nephritis you are more selective there. So trying to figure out in terms of trial design or the biology can one really extrapolate anything?

Dr. Cecil Pickett - ***Biogen Idec President R&D***
I don t think so. I don t think so.

Operator
Bill Tanner, Leerink Swann.

Bill Tanner - ***Leerink Swann Analyst***
Thanks for taking the question. A question for Bill Sibold maybe. Just as we thinking about TYSABRI and looking at all the numbers that we have, obviously the ones that you guys provide, but if we look at the numbers of patients per physician in the U.S., I guess the glass half-empty way of looking at it is the growth really has come from new physician adds. The glass half-full I guess would be that you ve got perhaps physicians still dipping a toe in the water and you ve actually establish broader physician adoption.

So as you do the market research in understanding that two years is really epidemiological or pathologically not a meaningful milestone, I mean do you get the sense that physicians are going to begin to do more than just dip a toe in the water going forward?

Bill Sibold - ***Biogen Idec SVP, U.S. Neurology Business Unit***
Yes, we believe that it s not just the two years, but it is the release of utilization updates like at AAN and other positive data as well as just the physician experience which is taking place. One of the things that we are hearing from physicians is some very compelling results with the MS patients that they treat.
So we really believe that with time, with the continued use of the product we re hearing stories of what other colleagues are doing, etc., that there will be a continued increase in the use of the product from both a depth perspective, so the physicians that are currently writing, and also from a breadth perspective that we expect additional neurologists will start to utilize TYSABRI.

Operator
Mike King, Rodman & Renshaw.

Mike King - ***Rodman & Renshaw Analyst***
Thank you for taking my question and let me add my congratulations. Sorry to belabor the questions on Lupus, but I was wondering I think one thing we could benefit from would be to understand how the actual BILAG results are going to be presented to the Street. And perhaps again, without trying to get the results from you, just how are they going to be represented? Will they be broken down into the major and minor? Will we see one large number? Can you just give us some context of how those results are going to be conveyed to investors?

Jim Mullen - ***Biogen Idec CEO, President***
Well, I think what you re going to get so first, Genentech has been running the trial and our experience working with Genentech is they re very prompt at doing analysis and getting the top-line results out, but that s really all you re going to get at the beginning because they will do a very thorough but fairly quick review which means there s a lot of other thinking and analysis to be done after that.
So I think you re going to get the top-line results did it meet the primary, didn t it meet the primary and I don t know that it will be much more than that when we have it. I think the details will follow as is the tradition for any of the companies, but especially Genentech and Biogen Idec at appropriate scientific forum where they ll drill into the data and a fair bit of detail with investigators.

Mike King - ***Rodman & Renshaw Analyst***
Okay. But just to understand correctly, the primary is major and minor?

Elizabeth Woo - ***Biogen Idec VP of IR***
Correct.

Jim Mullen - ***Biogen Idec CEO, President***
Correct.

Elizabeth Woo - ***Biogen Idec VP of IR***
Mike, that s correct.

Mike King - *Rodman & Renshaw Analyst*
Thank you.

Operator
Geoffrey Porges, Sanford Bernstein.

Unidentified Participant
Hi, it s actually Isaac calling in for Geoff. Congratulations on the quarter again. I was hoping you guys could provide a little bit more color on TYSABRI and Crohn s disease. Both have the status of a potential approval here in the EU, as well as some color on your conversations with physicians ahead of the U.S. launch or following the U.S. launch, how you think the roughly 10,000 patients on TYSABRI and MS is going to aid that and any safety concerns. And then finally, any assumptions you guys have made for like TYSABRI uptake in Crohn s for that 100,000 patients on TYSABRI by 2010?

Jim Mullen - *Biogen Idec CEO, President*
Okay, so it s probably premature to raise the 100,000 number seeing as I ve spent the last nine months or so getting people warmed up to the 100,000 number. But I ll be pleased to be accused of sandbagging by the end of the year on the 100,000 number.
With respect to Crohn s in the EU, just to take everybody back to what the issue there was, and I think you properly put your finger on it it was the question of risk-benefit profile. And certainly as we get more patients exposures in the EU, U.S. in MS but especially in Crohn s, there is just more real data to bring to that discussion.
So the plan right now is we re re-engaging the EU regulatory authorities in that conversation. I think it s premature to say where that s going to go exactly and what they re going to look for. Hopefully within the next call or two here we ll be able to give you more specific guidance on that.
With respect to the U.S. launch, what you re witnessing now is just what we witnessed at the launch with MS. There s a big educational phase in qualifying physicians. There has been a number of scripts written, but I don t think there s anything you can conclude from the very early going. So I think we just have to watch this evolve over the next couple of quarters. And Elan is leading the commercial effort there, so they will be the company with a little bit more specific finger on the pulse there as we roll forward.

Operator
Maged Shenouda, UBS.

Maged Shenouda - *UBS Analyst*
Hi, so my question has to do with RITUXAN and SLE. Genentech has been cautious with regard to the ability to file for SLE with RITUXAN only with positive Explorer results, I was just wondering if you share that caution. And then also, realistically, what labeled indication do you ultimately anticipate for the product?

Jim Mullen - *Biogen Idec CEO, President*
Well, I ll take that one. What do we ultimately and with positive results in SLE positive results in nephritis is a fairly broad label. That s assuming a lot so I guess we have to see the data. We know the first trial is it will be analyzed relatively soon; the second trial is fully accrued I believe, isn t it? So we ll have those results in early 2009.

It s of course safe to say that the agency has become quite conservative. That s not unique to this particular product or Genentech or Biogen Idec. So has it been tougher to get things moved through the FDA? I d say my perception is the answer to that is, yes. Having said that, you ve got RITUXAN, here s a product that s been out there for 10 years. It s been in the autoimmune setting for a couple of years now with RA. So it does have a broad safety experience.
So I think some of the concerns that the FDA would typically bring to a review like this, our answer given the huge database you now have of real-world experience. So with a positive outcome on the data I think you can be optimistic that you can move that through. Will it require both trials? I think you assume yes until you know otherwise.

Elizabeth Woo - ***Biogen Idec VP of IR***
Operator, we ll take a couple more questions.

Operator
Adam Walsh, Jefferies & Co.

Adam Walsh - ***Jefferies & Co. Analyst***
Hi, good morning. Jim, can you hear me, first of all?

Jim Mullen - ***Biogen Idec CEO, President***
Yes.

Adam Walsh - ***Jefferies & Co. Analyst***
Terrific. Jim, you ve said in the past that we might expect to see additional PML cases with TYSABRI and I m curious to know what your market research with neurologists has suggested that new cases of PML, how they might impact prescribing behavior near-term and long-term and whether or not remind us whether or not your 100,000 patients on TYSABRI by year-end 2010 would include an assumption of new cases?

Jim Mullen - ***Biogen Idec CEO, President***
Good question. So I almost always get beat up by somebody whether it s on a message board or some place shortly after I make a statement that we should expect PML. But realistically what we have is a black box warning. We have an educational program around this specifically and it would be just irresponsible for me to say that otherwise and it would open up this company to an enormous amount of litigation.
So until as the data continues to play out we ll see the statistics. But once you have that kind of association on a label it s going to be there. But what changes over time of course is the perception of risk/benefit, and it s not just the risk side of the equation which the data plays out, but it s the benefit, it s what the physician actually sees in front of them in the clinical experience over a number of patients over a significant sweep of time.
Now we ve assumed in everything that we ve done that we would see cases of PML. I think all of it s going to be fact and circumstances specific. If it s one here, one there, what do you learn from the cases? If it s a cluster, what do you learn from those cases that you can then use to educate physicians about the risk or how to monitor?
So we ve assumed that we would continue to see some. We ve assumed though that the safety profile will continue to unfold in a, if you will, somewhat more favorable than what s in the label, and I think that s already probably statistically true today. But the label is the label until it gets changed.

Elizabeth Woo - ***Biogen Idec VP of IR***

Operator, we ll take one or two more.

Operator
Jason Zhang, BMO Capital.

Jason Zhang - ***BMO Capital Analyst***
Yes, thanks for taking my question. I actually wanted to go back to slide number 10. You gave a picture of TYSABRI users from three different sources. I assume that s a recent picture. If you compared this to the very beginning, what would be the difference? Do you see the shape shifting one way or another? Do you expect to see more of the patients switch from the other interferons and Copaxone continue going into the future?

Bill Sibold - ***Biogen Idec SVP, U.S. Neurology Business Unit***
So we ve seen the this is Bill the shift that we ve seen in time is perhaps more patients coming from the AVCRs which we would expect, that as patients are in need of more efficacy that are on current therapy that they will be switching to TYSABRI. And just the data, this is looking at the end of March timeframe.

Jason Zhang - ***BMO Capital Analyst***
And if you compare this slide, the pie chart to about a year ago what would be the breakdown?

Elizabeth Woo - ***Biogen Idec VP of IR***
Not a huge change.

Jim Mullen - ***Biogen Idec CEO, President***
Not a huge change.

Jason Zhang - ***BMO Capital Analyst***
Not a huge difference?

Jim Mullen - ***Biogen Idec CEO, President***
No.

Jason Zhang - ***BMO Capital Analyst***
Okay. That s very helpful. Thank you.

Elizabeth Woo - ***Biogen Idec VP of IR***
Okay, we ll take our last question.

Operator

George Farmer, Wachovia Securities.

George Farmer - ***Wachovia Securities Analyst***
Thanks for squeezing me in. Given I guess some of the concern about the presence of JC and BK virus in CF, cerebrospinal fluid, and perhaps serum, is there in MS patients treated with TYSABRI, is there any data out there that has looked at the normal levels of viral presence in healthy individuals? Do you know how that could be compared to the MS situation, TYSABRI?

Dr. Cecil Pickett - ***Biogen Idec President R&D***
I m not aware of any data.

Jim Mullen - ***Biogen Idec CEO, President***
Boy, we haven t looked at that for a few years. We extensively reviewed all of that information that was available back at the time of the withdrawal and through that summer. I just don t remember off the top of my head exactly what that data said. We also did a fairly extensive look across some MS patients from data of a [Carolina] scan too, and there s nothing there to find. So it s a great answer. We ll dig that out for you and try to give you some more specific references to that. Maybe you can follow up with Elizabeth (multiple speakers).

George Farmer - ***Wachovia Securities Analyst***
Yes, I haven t seen anything; I was just wondering if you guys had any data on that.

Elizabeth Woo - ***Biogen Idec VP of IR***
As Jim referred to, there was that study of the MS patients that were not pretreated and they didn t see anything in the cerebral spinal fluid. And as we know, JC virus can be found in normal, healthy, in the plasma but it s not meaningful in terms of any predictive or diagnostic value.

George Farmer - ***Wachovia Securities Analyst***
Great. Thank you very much.

Elizabeth Woo - ***Biogen Idec VP of IR***
Thanks, everyone, for joining us on the call today.

Operator
Ladies and gentlemen, this concludes today s conference call. You may now disconnect.