

BIOGEN IDEC INC.
Form DEFA14A
March 10, 2010

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

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☒ Soliciting Material Pursuant to § 240.14a-12

BIOGEN IDEC INC.

(Name of Registrant as Specified In Its Charter)

N.A.

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

☐ Fee paid previously with preliminary materials.

☐ Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

Proxy communication statement:

Biogen Idec and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Biogen Idec in connection with the company's 2010 annual meeting of stockholders. The names, affiliations and interests of such individuals may be found in Biogen Idec's annual report on Form 10-K for the year ended December 31, 2009 and its proxy statement for the 2009 annual meeting, each of which are filed with the SEC. To the extent holdings of Biogen Idec securities have changed since such documents were filed, such changes have been or will be reflected in statements of change in ownership on Forms 3 and 4 filed with the SEC. Additional information regarding such individuals will be included in the company's proxy statement in connection with the company's 2010 annual meeting of stockholders when such document is filed with the SEC. Biogen Idec files annual, quarterly and special reports with the SEC. The proxy statements and other reports, when available, can be obtained free of charge at the SEC's web site at www.sec.gov or from Biogen Idec at www.biogenidec.com. Biogen Idec stockholders are advised to read carefully the proxy statement relating to the company's 2010 annual meeting of stockholders and any other relevant documents filed by the company with the SEC when they become available before making any voting or investment decision, because they will contain important information. The company's proxy statement will also be available for free by writing to Biogen Idec Inc., 14 Cambridge Center, Cambridge, MA 02142. In addition, copies of the proxy materials, including the company's white proxy card, may be requested after they have been filed with the SEC from our proxy solicitor, MacKenzie Partners, Inc., by toll-free telephone at 1-800-322-2885 or by e-mail at proxy@mackenziepartners.com.

CORPORATE PARTICIPANTS

Paul Clancy

Biogen Idec Inc. Executive Vice President and Chief Financial Officer

Al Sandroek

Biogen Idec Inc. Senior Vice President, Neurology Research and Development

Bob Hamm

Biogen Idec Inc. Chief Operating Officer

PRESENTATION

Eric Schmidt Cowen & Company

I am here to welcome you all to day three of our 30th annual healthcare conference. We are delighted that you were able to wake up bright and early and see our next presenting company, Biogen Idec. It's always a pleasure to introduce what's clearly one of the leaders in the biotech sector now for 15 or 20 years.

Today we have a full team of executives with us. We have Paul Clancy, the Company's Chief Financial Officer. Paul will be giving a talk that will probably last about 20 minutes and we will have some time immediately following that presentation in this room to take some of your questions.

During that time period, I think Paul will be joined by Bob Hamm, who is the Company's Chief Operating Officer. I am told Al Sandroock, Senior VP of R&D, is somewhere in the room as well. And I know Andrew Hirsch, VP of Strategy, is here too. So we'll have a full session after Q&A, a full breakout session next door as well, and that breakout is going to be in the northeastern room.

Paul Clancy

Thanks, Eric. We are very pleased to be here. It's actually a short commute for us, but we think this is a great conference, so pleased to speak on behalf of Biogen Idec.

I'm going to hit briefly early on in the presentation on our 2009 performance and a little bit look back on historical perspective for our financial results. And then I will spend the bulk—most of the time talking about our critical business drivers for the business as we go forward.

Given that we will be making forward-looking statements, I just want to start with this important information. I will be making forward-looking statements in—clearly I point you to the SEC filings as well as our press releases on an ongoing basis.

So just to take a look back at 2009 in review, we entered the year knowing that we were going to have some headwinds facing our business on the top line as well as the bottom line. We knew that we actually had some expiry as it related to the rest of world royalties on RITUXAN®. We knew foreign exchange volatility would create interesting dynamics, as well as the unemployment impact in the United States actually put pressure in our AVONEX® business with respect to free goods.

Despite that, we had very, very solid performance. Revenue grew about 7.5% to just under \$4.4 billion. That was largely driven by great performance as it relates to TYSABRI®. TYSABRI achieved blockbuster status surpassing \$1 billion of total in market sales, so a very, very good year for TYSABRI. We grew the business 30% on the revenue front, 30% on the patient front, and we will talk certainly a lot more about that in terms of our plans going forward. Very importantly, we felt we made tremendous progress with respect to maturing and advancing our late stage pipeline. And I will note and point out three key accomplishments in 2009 and we will talk more about each of these programs later.

First, the PEGylated interferon program in June of 2009 had first patient in and we were granted fast-track designation, so very, very excited about that program. We'll talk a little bit more about it.

Our play with respect to an oral entry in MS, BG-12, both of the trials were fully enrolled in 2009. We are now working hard to prosecute those trials.

And the third thing I'd like to point out with respect to our late stage pipeline is we acquired the ex-US rights to fampridine. We will talk more about that. But very important milestones and achievements in 2009. With that said, on the product and pipeline performance, we also achieved double-digit earnings growth on the bottom line.

Then in October 2009, our Board of Directors approved \$1 billion share repurchase program. This was in addition to our normal share stabilization program and we made significant progress on that, which I will point out later in the presentation here.

So just to quickly put those 2009 results in a little bit of a framework, if you pan back a little bit further, this is our revenue performance over the last seven years as well as our bottom line non-GAAP earnings per share performance. It is quite strong financial results over this time period. On a compound annual growth rate basis, revenues have grown 15% over this time period and on the bottom line, we've gotten leverage to grow non-GAAP earnings per share 22%. Some years have been faster on the top line, some years slower, as well as the bottom line, but very, very solid results with six consecutive years of double-digit earnings per share growth over this time period.

And as a result during this time period, we've actually modestly diversified our revenue base on really two dimensions, on a product dimension and then on a geographic dimension. On the left hand side, you just kind of see the revenue stack of our products in 2003 and then in 2009 split between AVONEX, RITUXAN revenue as well as TYSABRI. Then on the right-hand side, you see the percentage of that.

So we have diversified our revenue basis with TYSABRI achieving blockbuster status in 2009 and importantly one of the strategic imperatives that we had a number of years ago was really to expand and have a geographic presence outside the United States, expand that international part of our business, and importantly as we go forward we think we can leverage and capitalize on that with respect to our pipeline.

So now moving forward let's talk about the critical business drivers for Biogen Idec. They really are in this simple kind of cartoon, it really takes our business plan and reduces it down to kind of four key quadrants. First, accelerating TYSABRI growth. We'll talk about our plans as it relates to TYSABRI and the initiatives that we have underway. Looking at our core franchises in AVONEX and RITUXAN and continuing to grow in those two lifecycle management. Third, prosecuting and advancing the pipeline. I think we are now at a point where we are actually bearing the fruit of a lot of the efforts over the last number of years.

And then we are in an enviable position with respect to the cash flow generation of the Company and certainly that puts important pressure on critical decisions as it relates to business development, M&A strategy, and then returning cash to shareholders. And the way we think about that is making sure that we have a disciplined use of that cash.

What I will do is now walk through these key business drivers for the balance of the presentation, starting with TYSABRI. This chart leaves out the in-market sales that were shared between Biogen Idec and Elan for TYSABRI. You recall in 2006 TYSABRI was brought back to the market in the United States in mid-2006 and about that same time period, we got approval in Europe, so very, very similar time period and we had a staged rollout, which is quite normal in Europe.

If you look at this, the third full year of TYSABRI in the marketplace has achieved blockbuster status. We have had steady, strong growth in terms of an uptake curve both in the United States as well as outside the United States. And in fact in 2009, sales outside the United States eclipsed those sales inside the United States, a dynamic that we had always anticipated for a number of years and had fully expected. And in fact, we always like to point out that the number of patients on disease modifying therapies outside the United States has far eclipsed the number inside the United States. So that's quite normal.

So very, very strong performance as it relates to TYSABRI over the last three plus time period. Nevertheless, we still think there's tremendous opportunity, right? Tremendous opportunity really can be framed up with even with this type of performance we are still at single-digit share of market as it relates to TYSABRI. So we continue to press forward as it relates to TYSABRI and it really is about driving forward the benefit risk profile of TYSABRI.

We have now as we talked about have three years of post-marketing experience since the relaunch and we are continuing to learn more about the efficacy of TYSABRI as well as the safety. When the FDA Advisory Committee recommended approval of TYSABRI, the drug was supported by the standard efficacy metrics, reduction in relapses and reduction in disease progression. The 68% reduction in relapse rate, the 54% reduction in disease progression. And these were unparalleled efficacy measures.

In addition, what we have seen is that the product actually has demonstrated tremendous benefits to patients above and beyond those standard failure-based efficacy metrics and in fact moving to ones of improvement or migrating in that direction.

About a year ago in Lancet, a publication demonstrated 37% of patients were free in a retrospective analysis of disease activity. So free of relapses, free of disease progression, and free of any kind of radiological measures. So really strong and this is what we see anecdotally with the strong efficacy of the product, that the quality of patients lives is fundamentally changing.

In terms of safety, TYSABRI is one of the most extensively monitored drugs for the treatment of MS with one of the most robust risk management programs. We believe PML is likely the result of a confluence of factors and we have been and continue to invest significant time evaluating all the risk factors.

In terms of management of PML outcomes, we have seen an improvement in PML outcomes vis-a-vis the clinical trials. And that is really the result of incredible strong clinical vigilance and the work we are doing with respect to plasma exchange and drug screening for more effective ways of managing PML risk.

With regard to prediction and prevention, we are exploring both viral and patient factors. There appears to be factors specific to individual patients that may make him or her more vulnerable to developing PML including prior treatment with immunosuppressants as well as prior exposure to the JC virus. If we're able to isolate these factors, we may be able to identify patients who are more or less at risk for developing PML.

So this really kind of lays out a large set of initiatives that we have underway to drive future TYSABRI growth. It spans a lot of what we just talked about in terms of stratifying patient risk to basic blocking and tackling in terms of continuing our geographic expansion in 2010.

Specifically with respect to the JC virus antibody assay, we now are undertaking two clinical trials, one we call STRATIFY-1, STRATIFY-2, and we have initiated STRATIFY-1 in terms of patients into the clinical trial. Looking for JC virus incidents as well as the utility for this as a tool for risk stratification.

We have plans underway and pretty far along with respect to evaluating a switching study. This would be a study to evaluate taking patients that are already on disease-modifying therapy and switching them either to TYSABRI, Rebif® or Copaxone® and understanding the clinical outcomes going forward.

Plans are underway to expand into other indications including secondary progressive MS. A large part of the MS population that was really a tremendous amount of unmet need. We are

looking hard at developing a subcutaneous formulation and expanding plans to expand this year in 2010 in Mexico, Brazil, Turkey, Columbia, Argentina, and Egypt.

Now moving to AVONEX, AVONEX is a tested, tried and true product for Biogen Idec. If you look here, we have had double-digit compound annual growth rate over the last five years. It is now a \$2.3 billion brand with \$1.4 billion in sales in the US and the balance in the rest of world. Highlights over the last couple of years I would just like to point out is that in August of 2009, we were granted an additional patent on a method of use for AVONEX, which provides protection for the product extending into 2026.

Very importantly, we initiated a first patient in with respect to our PEGylated interferon trial in the middle of 2009 and plans we're pushing forward on that trial in terms of accruals.

Our sales and marketing teams are leveraging the CHAMPIONS 10-year trial information, 10 year results, and it's really the only product in the MS space that has this length of data demonstrating strong efficacy over a long period of time. And we have significant efforts underway to reinvigorate the US business, which we feel from a unit perspective has underperformed our expectations.

We've changed around a lot of leadership as it relates both on the medical affairs as well as the sales and marketing front and brought to bear a tremendous team. We are now working hard on solidifying strong clinical messaging and really executing hard on a sustainable sales and marketing plan.

Moving to RITUXAN, we have also enjoyed double-digit compound annual growth rate over a similar time period, five plus years, and we think the area going forward is to continue to expand indications as it relates to RITUXAN, making it the cornerstone of therapy in non-Hodgkin's lymphoma and expanding it into indications elsewhere.

We have gotten positive results on the PRIMA study for the first-line maintenance results and expect and have plans to file for approval in 2010. Very recently, we have been granted in terms of our label with respect to CLL. It also points out we have efforts are under way with respect to our next-generation molecules, a humanized version of CD20 both for ocrelizumab as well as GA-101.

Roche and ourselves released a press release early this week notifying that we are suspending dosing as it related to ocrelizumab in immunology. It's really too early to tell what plans are for going forward. We will have to really understand that data going forward. Nevertheless GA-101 continues to move forward in the oncology setting and Phase III with respect to CLL.

Now let's transition to talk about our pipeline. Before we get into kind of a lot of the nitty-gritty in terms of the programs, I'd like to just frame up the two phases as it relates to our R&D efforts at Biogen Idec over the last handful of years.

If you go back six or seven years when we brought Biogen and Idec together, I think we really believed that we had insufficient pipelines to sustain further growth going into the next decade. And as a result, the first phase—as a result, subsequent to the merger of Biogen Idec, was very focused on external growth, very focused on business development and efforts to bolster the pipeline. If you look across our pipeline, we actually have over a third to close to half of our pipeline that was externally sourced.

In the neurology pipeline, the great majority of that pipeline was actually externally sourced. In the bottom right-hand quadrant of this slide, what we call just simply our emerging pipeline, essentially all of that pipeline was externally sourced. In the oncology and immunology, one or two programs each externally sourced. So that was a big phase is to really bring in a lot more

products into the pipeline through in-licensing, through collaborations, as well as tuck-in acquisitions.

In mid-2006, I think we moved into a second phase in terms of our R&D leadership and our pipeline management, and that was all about prosecuting the pipeline. We brought in talent from outside of the Company that had expertise in drug development. We reorganized the Company around these therapeutic areas and we worked really hard and have moved made significant progress. We are actually now starting to bear fruits of that progress to the point that we actually have six programs in registrational trials in 2010.

Now if you take a closer introspection of the pipeline and really look just like at a subset of the neurology pipeline, really it highlights the strong MS franchise that we have in the pipeline, and that ranges from the ex-US rights to fampridine as well as to anti-LINGO, which is in early stage, now has moved into Phase I that actually has the potential to reverse the disease.

In between is obviously AVONEX and TYSABRI, which are on the market that offer AVONEX offering great opportunities for patients for first line therapy and TYSABRI when patients need further efficacy. We are studying PEGylated interferon, which is a real interesting play in terms of interferon, BG-12 oral entry, as well as daclizumab which may offer a new, more novel mechanism of action. So a real franchise is being built with respect or has been built and continues to be built with respect to multiple sclerosis.

I would like to now kind of just highlight three or four programs that are further advanced in our pipeline. And the first one being fampridine. In June 2009, we entered into agreement with Acorda for the ex-US rights of fampridine. And since that time, we have really worked hard to prosecute the filing of outside the United States. In December of 2009, we filed in the EU and recently have filed in Canada, Switzerland, and Australia. We actually have plans to continue to file in countries around the world, leveraging our global footprint.

We have a global neurology salesforce and as a result from a business point of view, this fits hand in glove with our existing MS infrastructure. As a result, the investment in terms of operating expenses going forward as we turn into 2011 is quite manageable and the business can be accretive on both the top line and on the bottom line very, very quickly.

Prelaunch efforts are under way right now that range from pharmacoeconomic research to packaging development to manufacturing inspection.

Second program I would like to point out is BG-12 and last year in 2009, I had pointed out earlier we have completed the enrollment last patient in for both Phase III clinical studies DEFINE and CONFIRM. The studies have over 2500 patients enrolled across 30 countries across 300 sites across the world. This is our oral therapy entry into the MS market. Clearly oral is a high unmet need for MS patients. We think we can actually compete in the emerging oral segment with the point of differentiation being safety.

I think what I would like to just point out is FUMADERM, which is a version of oral FUMADERM has a 15-year track record in psoriasis in Germany, so if that track record can convey to BG-12, we actually think we can compete on a safety differentiation.

Third program also in MS is the PEGylated Interferon beta program. This is another very novel molecule, first in class compound that could offer patients a more convenient dosing option with efficacy either equivalent or better to current interferons. If you think about it, it takes the best attribute of AVONEX once a week and extends that to either twice a month or once a month and it takes probably the least attractive attribute of AVONEX, intramuscular injection, and moves it to subcutaneous injections.

So with the potential for a very well-known safety and efficacy profile, a subcutaneous injection with dosing once or twice every month, PEGylated Interferon really has the potential to be quite strong for Biogen Idec. Phase III trials are initiated in June 2009. The enrollments are progressing largely as planned. And I'd just like to continue to point out that we have had regulatory agreements that this would be a one-year trial.

The last program I'd like to point out is a new market for us, hemophilia. This is a case where our R&D as well as our biologics manufacturing expertise came together to have the potential to create significant value. In 2007, we acquired Syntonix, a small biopharmaceutical company developing therapies using fusion protein technology. This also required significant manufacturing expertise. As a result, Biogen Idec was a perfect fit.

The business case for us was also very strong. Hemophilia therapy is a multibillion-dollar market with a clear unmet need around a more reasonable treatment regimen. Our goal is to take the treatment regimen which really often required up to 150 injections a year down to close to 50 injections a year.

In October with our partner, Biovitrum, we announced the decision to move our Factor IX product into registrational trials and late in 2009, we moved Factor VIII into the clinic also. We recently announced a restructured collaboration which clarifies roles and decision-making between the two parties. We will actually bear a higher R&D burden in the short term for better economics downstream.

Lastly, I would just like to point out some highlights as it relates to our disciplined use of cash. As noted, our Board of Directors announced in October 2009 that they had approved a \$1 billion share repurchase with the objective of returning cash to shareholders. As we proceed on this share repurchase program, shares are being retired. It was designed as an open market program with an open-ended time period. Nevertheless, we've made significant progress in the fourth quarter and then right through our earnings call in early 2010. And in fact, of the program we have taken in \$712 million over that time period and we think that it will be largely complete in a very short period of time.

So to summary, four key business drivers around the Biogen Idec story, accelerating TYSABRI growth, really driving forward both the efficacy as well as making progress on the risk profile of TYSABRI, extending AVONEX and RITUXAN, continuing to generate cash flow of that business, advancing, maturing, and bearing the fruits of what is becoming an interesting pipeline and ensuring that we have a disciplined use of our cash.

I think we have time, Eric, for 10 minutes or so for questions. Al, if I would like you to come up front and join us, so myself, Bob Hamm, our Chief Operating Officer; as well as Dr. Al Sandrock, our Senior Vice President of Neurology R&D will be here to talk about questions.

Given that this is webcast, we will actually repeat the questions for those that are following through the webcast.

QUESTION AND ANSWER

Unidentified Audience Member

You were mentioning stratification as important to grow the TYSABRI franchise. What is happening spontaneously in the field as we speak?

Paul Clancy

Al, do you want to just help a little bit on that question? Come on up. I think the only place we have a mic is up front. So the question was with respect to the TYSABRI risk stratification efforts, what is actually happening in the field as we talk about I think I will just editorialize and say cut across key opinion leaders as well as kind of community neurologists?

Al Sandrock

Well I think people right now are making benefit/risk decisions for their patients and the most common reason that people come to TYSABRI is that the first-line therapies have not been of adequate benefit for them. And that's the key reason that people are coming now.

On the risk side, there aren't a whole lot of things that people can use. That's one of the reasons why we are initiating these anti-JCV assay studies to provide some more tools on the risk side.

Unidentified Audience Member

Paul, there's a lot of M&A activity out there. I am wondering if you have an opinion on Facet for \$27 a share, whether you are going to share that with us.

Unidentified Audience Member

(inaudible question)

Paul Clancy

So a two-part question. Surprised it took it to the second question. But the first part of the question was as it relates to Facet, any comments on that? And then more broadly as it relates to augmenting our pipeline through business development efforts.

The first part of the question is, look, we welcome a new partner into the Biogen Idec fold. We have tremendous respect for Abbott. I love traveling to Chicago, great people there. So we actually just welcome into the fold and we will now continue the collaboration just with a new partner as we go forward. That's the plan assuming that their offer goes through.

As it relates to kind of business development and augmenting our pipeline, I had noted that we've kind of gone through a couple of phases as it related to our R&D efforts. A big phase five, six, four years ago in that time period was really a tremendous amount of efforts that was very fruitful on the business development front, in-licensing, collaborations, and some tuck-in acquisitions.

And I think we have been a little bit spotty on that as it relates over the last couple of years with certainly the notable exception of fampridine last year. I think that's a tremendous and it continues to be proven out and we are very, very hopeful that that will be proven out to be a tremendous in-licensing deal for Biogen Idec as well as for that matter for Acorda.

I think what we should be moving towards in terms of our next phase is doing them both at the same time, bringing in on a continuing basis, replenishing the pipeline across all different parts of the pipeline. The reality is it's easier to replenish pipelines in a pre-proof of concept manner,

but I think we continue to do that and simultaneously prosecute the organic as well as the pipeline that we brought in.

Unidentified Audience Member

You've been working on kind of rejuvenating AVONEX sales for a while now, several months. Are there any early signs, Bob, that you want to point us to? Any thing that you need to execute on before we see any success?

Bob Hamm

I think we should see some benefit in the second part of the year frankly. The new teams (inaudible) and it's a matter of share voice and increasing our clinical presence (inaudible).

Unidentified Audience Member

Many of your PML cases have come from Europe. Is clinical practice in Europe changing as a result of this?

Paul Clancy

Great question. I'll ask Al to answer the question but for folks on the webcast, the question is the essence of it is that many of there's been a disproportionate number of patients that have gotten PML from outside the United States, from Europe, and in fact even more specifically, country of Germany. Do we have a point of view on that with respect to clinical practice as well?

Al Sandroock

Well, we know that at least part of the reason might be the use of immunosuppressant drugs. We know that there's differences in clinical practice between Europe and US and the frequency that these kind of drugs are used. That may relate in part to the risks that we are seeing.

Unidentified Audience Member

Do you see the clinical practices changing?

Al Sandroock

Well, we are not we don't see any major changes at this point but

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Paul Clancy

Yes so the question is with respect to the disease modifying therapies in MS, have had price increases over the last few years. What is our expectation going forward?

We don't plan for it essentially. So our business plan going forward is for very, very modest if any price increases. I think that's probably reflective of the way we think about the marketplace going forward.

Unidentified Audience Member

Al also mentioned starting some studies on TYSABRI in secondary progressive MS. What is the rationale there and what is the timeline?

Al Sandrock

Well, we haven't established the timeline yet. The rationale is that when we look at registries and when we talk to patients, we hear that cognition is improved. When you look at registries of large cohorts like in Sweden, cognitive measures such as the SDNT seem to improve in patients more than we would expect from chance alone or from practice effects.

So it's that kind of thing and as you know, cognition is worse in people with SPMS. It's a major unmet need. There's really nothing to address that. So that's one of the reasons why we are very interested in that.

Unidentified Audience Member

(inaudible) regulatory authority?

Al Sandrock

Welcome that needs to be the question was is cognition is there an endpoint for cognition with regulatory authorities? There's been no precedents for drug approved for cognition in SPMS but there's clearly precedents for other diseases including diseases that were not previously linked very closely with cognition such as Parkinson's disease.

That's a movement disorder but there are drugs now that are approved for cognition in Parkinson's disease and I don't see why the same couldn't apply in the multiple sclerosis.

Unidentified Audience Member

Are you seeing steady or accelerating growth of TYSABRI sales compared to the fourth quarter?

Paul Clancy

Yes, so the question is are we seeing steady or accelerating growth compared to the fourth quarter? In the middle of the quarter, we just as a matter of practice don't use and give investor conferences generally to comment on our sales outlook. So apologize, but we will have to wait until we turn to our quarterly results to kind of see the pace of that.

Eric Schmidt *Cowen & Company*

Is there one last question perhaps? Okay, we can go next door then.

Paul Clancy

Okay, so for those that want to, we are going to moving next door to the northeastern room, Eric, and for further Q&A. Thank you very much.

BREAKOUT SESSION

Eric Schmidt *Cowen & Company*

Thank you to everyone for joining us. For those of you that weren't in the session earlier, we are joined here by the majority of the team at Biogen Idec. We've got Paul Clancy, the CFO; Bob Hamm, the COO; Al Sandrock, VP of Neurology, and Andrew Hirsch, who is the VP of Strategies. They would be happy to take any questions that you've got.

Paul Clancy

So this is webcast, so we will repeat the questions. Al is actually Senior VP, so we don't want to give him a demotion out of the gates here.

Unidentified Audience Member

A couple things we know. We know the CD20 mechanism works in NHL, CLL, it works in RA, it works in MS. There haven't been any problems with RITUXAN. We haven't seen any problems yet with GA-101. So is there an issue with ocrelizumab itself that is causing these infections in this—the second or third trial that's been halted or stopped?

Paul Clancy

Yes, so the question—I will repeat questions just given that we are in a webcast—is can we glean any information as it relates to ocrelizumab vis-a-vis what we know about RITUXAN's safety profile as well? This is really the backdrop being the news that came out earlier this week with a press release with Roche as well as Biogen Idec around suspending dosing on the ocrelizumab RA trials and lupus trials.

We are very early into this in terms of that, so I think that we are probably premature in trying to jump to any conclusion. Al, if you can any further

Al Sandrock

I agree. We certainly are just beginning to look at the data. It's very complicated because there's regional differences in where the use of ocrelizumab occurred versus it's occurring now within RITUXAN. There is just a lot of complicated factors. I think it's too early to tell.

Unidentified Audience Member

(Inaudible question)

Al Sandroek

The MS trial with ocrelizumab continues to go on. There's an extension study from the Phase II. Patients are being dosed in that.

Unidentified Audience Member

(Inaudible question)

Al Sandroek

Yes, well, the drug safety monitoring committee will meet and discuss the safety and the wisdom of continuing dosing in the MS extension study. But that's a separate—it is a separate benefit/risk discussion. The concomitant meds are separate so I think it just needs to be a separate discussion and we will wait for that.

Unidentified Audience Member

(Inaudible question)

Bob Hamm

Sure. The auto injector is simply a means to have people that really are averse to injections not be reminded of it by seeing a long needle. So its immediate impact, withdraw, and therefore it mitigates the concern about the intramuscular injection.

Titration is a way to mitigate the flu-like symptoms that emerge by bringing up the dose over time and that's simply the benefit to the convenience of the patients.

Unidentified Audience Member

(Inaudible question)

Bob Hamm

Yes they are.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

The question was have we disclosed any data from the daclizumab trial. The only trial that data have been disclosed is from the CHOICE study. It was an add on trial where daclizumab, two doses of daclizumab are added to interferon placebo-controlled double-blind trial that was presented a couple of ECTRIMS meetings ago by Javier Montauban and colleagues. That's the only trial where data have been disclosed.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Well, we believe that it's going to have substantial efficacy superior to first-line therapies and the safety profile is going to have its own unique safety profile. It's an immunomodulator, so there will be some risks but it will be unique to daclizumab, we think.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

A design of Phase III? Well, we are actually in the process of discussing with investigators a protocol. We have met with investigators. We have agreement with regulators on the actual design to some extent and we are very close to initiating the trial.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

I'm sorry, could you repeat? I didn't quite hear it.

Eric Schmidt *Cowen & Company*

Can you talk about STRATIFY?

Al Sandrock

Oh, STRATIFY. So STRATIFY is the study that is being initiated right now to look at the anti-JCV virus to get the assay done and to know whether or not there is validity and whether or not the result of that assay is predictive of the risk of PML.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Well, if you look at the clinical trials, the Phase III trials of the interferons and Copaxone, the majority of people have at least one relapse over the two-year trial period and many of them also have progression of disability. So a substantial proportion of people will have at least one relapse and some will have more than one and it's not a small number.

But in the clinical trials, it's about 75% or so will have a relapse.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Well, TYSABRI is generally recommended for people who have had an inadequate response. There are no quantitative guidelines in terms of what that means. I think that's left up to the clinician. In Europe, they are more specific.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Well, the question was about side effects with daclizumab and I'm not aware of any reports of leukemia. So just to answer your question specifically. The CHOICE study, the MS study that I just referred to, the add-on to interferon, there was a slight increase in infections and in the daclizumab group compared to placebo and there were some skin reactions. That's what I recall from Professor Montalban's presentation two years ago.

Unidentified Audience Member

(Inaudible question)

Paul Clancy

Yes, so the question was is the plan for pricing on AVONEX different today than it has been in the past? Our plans going forward really kind of assess a very modest if any price increases going forward. So that's the way we think about it from a business planning perspective which probably is the best indication of the way we think about it from in terms of what our expectations are going forward.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

The STRATIFY trials have already been initiated. STRATIFY-1 has been initiated. STRATIFY-2 is very close to enrolling the first patient, but the other one has already enrolled.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

In terms of results, that depends on how rapidly we can get blood tests done and how many cases of PML we get to know whether or not the blood test predicts PML. It's very hard to know exactly.

Unidentified Audience Member

(Inaudible question)

Paul Clancy

Yes, so the question is can we comment on the fampridine regulatory process? We have filed for approval with the EMEA. Actually it was December 2009. I think we announced it early in one of the investor conferences in the first or second week of January. We've additionally filed in Canada, Australia, as well as Switzerland, and have plans to actually file in other countries throughout the year.

So we think it's it has been the first order of business subsequent to entering into the agreement with Acorda for us in terms of our activities is to work hard on getting filings under way and actually we've beat our timetables.

With respect to the second part of the the active comparator.

Al Sandrock

Well, this is a first in class molecule and it's a functional modifier. There is no other drug approved for functional modification in MS. So there is no comparable drug to compare with.

Unidentified Audience Member

When is the launch?

Paul Clancy

We don't know. It's up to obviously EMEA, but generally speaking kind of it's probably not our planning contemplates kind of a 12 to 15 month time period.

Unidentified Audience Member

(Inaudible question)

Paul Clancy

So the question is do we know how many patients in are taking the compounded version don't? We actually don't have insight into that at this point.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

So the question was whether we can use retrospective samples that we collected from other studies. And in fact, that's what we did. We were lucky enough to have 11 blood samples one to three years prior to the diagnosis of PML. These were collected either within our own extension studies or they were collected in the context of registries. And all 11 were positive for the JCV antibody according to our assay. And as you know, about 50% of people would be expected to be positive.

So for that reason we think there's interesting preliminary data and that's why we're initiating these STRATIFY-1 and STRATIFY-2 studies.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

No, because most people don't collect blood and store them in practice in clinical practice. So these were we were just lucky that some people had collected blood in the context of registries because for example in Sweden, they are very interested in biomarkers of MS. So they happen to collect blood and we were able to pull it out of the bank and test.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Yes, yes, so the question is what about all the patient do you have samples from people? Yes, we have looked that's how we got our 53.7% seroprevalence rate. We looked at about 900 850 to 900 patients from our one of our long-term MS studies. We have other studies that we are currently also looking at to confirm what we saw and fortunately, it was from a broad geographical distribution as well. And we had longitudinal samples. So that's where we got the data that gave us some confidence that the assay had analytical validity.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Yes, I believe they were all prior to TYSABRI. They were clearly one to three years prior to the onset of PML and in most cases, I think all, it was before TYSABRI.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

The current design is a superiority head-to-head trial monotherapy.

Unidentified Audience Member

(Inaudible question)

Al Sandrock

Yes.

Unidentified Audience Member

(Inaudible question)

Al Sandroek

Yes.

Paul Clancy

Any Red Sox questions? Okay, if there are no further questions, thank you all for attending.