

BIOGEN IDEC INC.
Form DEFA14A
March 20, 2008

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:

Final Transcript

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

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. Information concerning the interests of participants in the solicitation of proxies will be included in any proxy statement filed by Biogen Idec in connection with the Company's 2008 annual meeting of stockholders. In addition, Biogen Idec files annual, quarterly and special reports with the Securities and Exchange Commission (the "SEC"). The proxy statements and other reports, when available, can be obtained free of charge at the SEC's web site at www.sec.gov or from Biogen Idec at www.biogenidec.com. Biogen Idec stockholders are advised to read carefully any proxy statement filed in connection with the Company's 2008 annual meeting of stockholders when it becomes available before making any voting or investment decision. The Company's proxy statement will also be available for free by writing to Biogen Idec Inc., 14 Cambridge Center, Cambridge, MA 02142. In addition, copies of the proxy materials may be requested from our proxy solicitor, Innisfree M&A Incorporated, by toll-free telephone at (877) 750-5836 or by e-mail at info@innisfreema.com.

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

CORPORATE PARTICIPANTS

Jim Mullen

Biogen Idec CEO

CONFERENCE CALL PARTICIPANTS

Eric Schmidt

Cowen and Company Analyst

PRESENTATION

Eric Schmidt *Cowen and Company Analyst*

My name is Eric Schmidt. I'm a member of the Cowen Biotech Research Team. It's my pleasure to welcome everyone again back to the Cowen and Company 28th Annual Healthcare Conference and a special welcome to Biogen Idec who I think has participated in a great majority of these conference historically. Today we're delighted to have with us the Company's Chief Executive Officer, Jim Mullen. I see we also have Paul Clancy, the Company's Chief Financial Officer; Elizabeth Woo, Vice President, Investor Relations; and Eric Hoffman, Director of Investor Relations. So we have the whole Biotech the whole Cowen excuse me, the whole Biogen team here. And Jim says he should have some time to take your questions both in this room and if we run over, upstairs in conference room Provincetown, we'll be hosting a further breakout session. So, Jim, please?

Jim Mullen *Biogen Idec CEO*

Thank you very much, Eric. Good morning, everyone. Glad to see you here this morning. As always, we'll start with the forward looking statements and of course we have a new addition to this one, the proxy solicitation statement. Of course this presentation is going to include some forward-looking statements including expectations about revenues, earnings, cash flow, progression of pipeline, execution of our strategy. I think you guys all know that results could actually differ fairly materially from what we either are hoping for or express today or imply. So I encourage everybody to continue to go back to the securities filings.

Now the second part of this, as many of you probably know, we received a board of director nomination and bylaw amendment proposal from a shareholder recently and as a result we're obliged among other things to inform you of such and to be sure shareholders have access to all the information they might need around this process. So with that, let me get into the presentation. It always feels like a downer to start with a forward-looking statement.

But this is probably the most exciting time for me having been associated with the Company now for 19 years. I've never been in a position to have this kind of fundamental underpinning to the business with also a great developing pipeline. So you'll see that the three main products, AVONEX, TYSABRI, and RITUXAN are all growing very nicely. We're coming off some very strong performance. We've now developed a pretty rich and late stage pipeline with 15 products in Phase II or beyond and we've done that all with very, very good strategic with good, good financial results. I think the strategy that we put in place a number of years ago has obviously been paying off. But more important, I think this is going to continue to pay off as we work forward here into the future.

So let me touch on sort of the underpinnings, the fundamentals. This purplish bar is the AVONEX sales. You can see it's been a nice progression since the merger in '04. Almost \$1.9 billion. We think that this product and this brand can still grow modestly, particularly as we continue to take market share and increase penetration outside the U.S. and add new regions.

And as TYSABRI takes hold here, we do expect, and we're very committed to maintaining our competitive position in the ABCR market. RITUXAN, the \$926 million you see there is our share of the profit share. We've got the enviable number one position in Non-Hodgkin's Lymphoma but the future growth story really is about the autoimmune indications. So a couple of years ago, we launched in rheumatoid arthritis in the TNF inadequate responder segment. Earlier this year we announced positive Phase III results in the DMARD inadequate responder

Final Transcript

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference
population. So we'll file for a label expansion along with our partner Genentech there. We're very anxiously awaiting to get trial results on lupus and on the primary progressive MS trials which I'll come back to in a moment.

And then lastly, you see the smaller blue bars on the bottom but growing very quickly and the performance has been great on TYSABRI. You may remember that in the late third quarter last year, September, I put out a goal, I said, I think we can get to 100,000 patients on product in MS and Crohn's Disease by the end of 2010. I would say that was received with some skepticism by the investment community. But I'm going to sort of take you through what underpins that because I think you're going to see that we really are on track to do that.

So you may recall, we said 21,000 patients, we exited the year in December 31. And I want to give you a few reference points. On the left are the number of patients on AVONEX treatment today in just the MS alone. So on the bottom of that, that's the U.S. sales. The top is ex-U.S. sales. And you'll see it's a little bit more in the U.S. than outside the U.S. I'm going to come back to that in a moment.

So if you just took the run rate of accrual of patients as we exited the year and just took that linearly forward you'd get to about 75,000 patients. Now we've been watching this market obviously unfold for a while and in every market that we've been in, we've seen increased depth and breadth of prescribing. As such, we're seeing a gradual acceleration of the accrual rates in every market that we're in today. We're seeing a nice ramping of that and that was evident throughout all of last year. So if this gradual acceleration continues, getting to the 100,000 mark is certainly well within reach.

The other thing you'll see is that we expect that there's going to be more sales outside the U.S. than inside the U.S. and that's really driven from a couple reasons. The first is that we're just starting from a much stronger foundation internationally than we were in 1996-1997 when we were launching AVONEX outside the U.S. We're direct in 25 countries outside the U.S. That's a much different position. The second is we've actually just got more patients to go after. And the third is those markets are a little less penetrated than the U.S. marketplace. So we see the international growing faster than the U.S. market and by 2010 it will be larger than the U.S. market.

I think as we come through this year and if the safety profile continues to hold up particularly favorable relative to the label, I think you may very well be saying, Jeez, Jim. I think you underestimated the real potential for this product in MS and Crohn's Disease. I'll be thrilled if that happens.

I'm very excited about the pipeline. This is really the first time where this year you're going to start to see a lot of proof points over the pipeline. In 2004, 2005 after the merger we knew it. You guys reported it. All the analysts knew it. We probably didn't have enough pipeline to reliably grow this Company over the long-term. We spent a lot of time both accelerating internal development but importantly, putting a lot of focus on business development. We've brought in about ten compounds, really through all stages of development.

So as we come into 2008 we've got four products in registrational trials, we'll have a fifth in registrational trials by yearend. As evidence of how quickly this pipeline is maturing and the large late stage trials, we'll have four times as many patients in clinical trials in '08 as '07 and that's a big step up over '06. As I've said before, 15 programs in Phase II or beyond, I think that is a nice, broad pipeline.

We've got eight important data readouts coming here in 2008. We've already reported out the first one in the first half of the year. They're all RITUXAN just as it would happen to be and we've already reported out the top line results for the Phase III DMARD inadequate responders. And so we will apply for that label expansion with the FDA. The RITUXAN lupus, we've got a Phase II-III trial in SLE. We also have a Phase III trial ongoing in lupus nephritis. That will report out next year. And then of course the RITUXAN primary progressive MS. This is a pretty exciting area because there's virtually nothing to help these patients in a pretty aggressive form of multiple sclerosis.

In the second half of the year, we've got a number of readouts. The BIIB14 program is a small molecule orally available A2 antagonist for Parkinson's disease. So we'll see Phase IIa results there. The HSP90, this is our lead oral program in the HSP90 area. We also have some backup programs of that. And we're in Phase I-II in GI stromal tumors. We're very excited about the HSP90 area in solid tumors and also potentially taking that into some other degenerative diseases.

The baminercept in RA and I m going to focus a little bit more attention on that in a couple of slides. We ll report out Phase IIb. We reported out IIa last year. RITUXAN in chronic lymphocytic leukemia. That will be a Phase III trial in the second half of the year. Volociximab which is a monoclonal antibody we have in partnership with PDL BioPharma we have in Phase II in ovarian. We also have it in several other Phase I trials. And then a recombinant factor IX which we ve just got the IND approval for and moving forward on and I ll spend a minute on that program as well.

Final Transcript

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

I want to highlight just a couple of programs that should give people a sense of really what's the potential behind some of these products. So let me start with RITUXAN in lupus. The standard of care today in lupus is not fabulous. It's steroids, immunosuppressants, chemotherapy, cellcept. There's really not been any significant advancements in decades there. There's been 1.5 million active SLE patients worldwide. A very big population, huge unmet need.

I think there's pretty strong evidence that the B cells implicated in the pathology of this disease, that makes RITUXAN an ideal product here. RITUXAN of course has been on the market for ten years. We know what the safety profile looks like. It's been in the RA market for a couple of years. I think there's a comfort level with how to use this product at the rheumatologist's office and also with the safety profile. So we've got, as I've said, a Phase II-III trial in SLE and a Phase III in lupus nephritis.

If you look at the market size today, it's a fairly small market. It's all generic products that are going in there. We think with some advances with some reasonable amount of success this market can grow pretty quickly. If you just think about a 10% penetration or something of that 1.5 million patients, that's a \$1 billion opportunity or greater for RITUXAN. So we think that's a big, big opportunity.

Baminercept in Phase IIb rheumatoid arthritis. This is some exciting new biology and we've got a great IP position and a great know-how position in this area. And we're really excited about this, not only in RA but in a lot of other diseases, lupus, Crohn's, ulcerative colitis, MS, transplantation, just to name a few. Now we started in rheumatoid arthritis for the same reason a lot of people start in rheumatoid arthritis. First, there's still a lot of unmet need in this market place particularly for a product with new biology. And then secondly, you know what the clinical endpoints are. They're well understood. The regulators know them. You know what you need to do and you can get the readouts relatively quickly before you move on to more complicated diseases like lupus.

If you just take a look at those bar charts on the left, there's 1.5 million patients that have DMARD therapy or TNF therapy and you can see in the blue portion, the majority of those patients are really non-responders or inadequate responding. So the only way to get after these folks is really to bring some new biology, a new product, new mode of action. We're pretty excited about that. We saw the Phase IIa results in the middle of last year. We immediately accelerated this into IIb and expanded the trials, one going after the DMARD segment, one going after the TNF segment. So we do expect a Phase II readout for this in the second half of the year.

And then I just want to touch on the Factor IX program. This came in via our acquisition of Syntonix. We have a Factor IX program. The IND's been approved. We have a Factor VIII program behind this. We think this is a growing market but more importantly, there's a fairly significant unmet need here for a longer acting Factor IX and Factor VIII to really get more into the prophylaxis treatment. So that's the thesis that we're pursuing. This has the advantage of you know the target, you know what you have to do to hit the target. If you hit the target, the product works, this is really a question of, can we hit this target, get the half-life that we're looking for and a safety profile that's acceptable. Relatively rapid trial, relatively small numbers. This could get done, the Phase I-II in '08. It may tip over into '09. Just depends how the accruals run out on this one. We think this is a big opportunity and this is hyperconcentrated market that does not take a lot of commercial infrastructure to get after. And as I said, we've got a Factor VIII program behind this one.

Not going to spend any real time on these. I can do it in questions and answer. But just to remind you of some of the other late stage programs. BG12 is an oral, small molecule in MS. It's in Phase III. We had completed trials in psoriasis. Those were successful but we're actually we've prioritized MS as the first trial. So this has been in a lot of patients over many years. We're pretty excited about that program as potentially the first oral molecule in MS. Galiximab which is a monoclonal antibody for Non-Hodgkin's Lymphoma. This would be used in addition to RITUXAN. So we think there's a opportunity to really increase impressively the response rates. Lixivaptan, a program that we in-licensed. It's in Phase III for hyponatremia associated with congestive heart failure. Lumiliximab, another monoclonal antibody out of our pipeline for CLL. That's in registration trials, the Phase I-II, impressive results. We saw a 52% response rate versus the 25% of the typical standard of care and of course ADENTRI will enter Phase III trials in the later part of this year in congestive heart failure.

This just gives you a quick snapshot of what the financial performance looked like. On the left, you can see the performance of the shares against the BTK on a one year or four year view. I think we've nicely outperformed the BTK in either one of those metrics. And then on the right hand side you see revenue EPS growth.

When Bill Rastetter and I were putting together these two companies into one in 2003, we did establish a number of goals, two of which were the financial goals and the goals were from '04 through '07, end of '07 that we felt we could get 15% top line growth and 20% bottom line growth. I think we got very close to that, on the top line a little over 14% and we exceeded that a bit on the bottom line. So I think we've had good financial performance and strong metrics here.

Final Transcript

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

I want to change gears a little bit, elevate the discussion a little bit more to corporate strategy and some of the challenges facing the industry and what are we doing as part of our strategy to address some of those challenges. So, first I'll just focus on the left hand side, these global industry challenges. We read it in the newspapers every day. Healthcare expenditures are going up and up and up, pricing pressure is in the discussion in the U.S. every day. The U.S. is really going to be the last place to arrive at real price pressure and price control because that's what's really going on every place else in the world. Part of our advantage of having a more global footprint is we've really learned how to address these issues and thrive and know what the pressure points are but we're going to have to address it. It's a challenge for everybody in the industry. In the developed world you've got slowing economic growth. I don't think that's any surprise to anybody. This was written, by the way, before this week. So it may be even slower than we thought.

But you've also got slowing population growth in all of the developed world. You've got population growth 1%, 2%, 3%. You've got slowing economic growth and then you've got demographic shifts which are making the population's getting older and older and older. This is just going to put more and more pressure on the healthcare system.

On the flipside, you do have a couple of rapidly emerging economies - India, China, where the wealth is increasing rapidly. Latin and South America. So being able to really approach the global market, think about how to do global development and think about how to amortize and extract your value from the product and build those values and amortize that over larger markets is critical.

R&D productivity, big problem for everybody. In spite of all the advances in biology, the fact is the regulatory hurdles on efficacy, on safety, have been going up and up and up. The time to do trials and the cost to do trials is going up and up. And I see nothing to abate that. Again, I think this puts the emphasis on what can you do to maximize the value of the products you have, good life cycle management, et cetera, and do you have access to all the important markets in the world?

As we go into the next decade, we are going to start to see what, of course, big pharma saw in the late '80s which is the entry of bio generics. It will probably be not quite the same version that we saw with the small molecules but nevertheless, we're going to have to figure out how we address all those issues and, of course, we all have the challenge of attracting, retaining, cultivating talent.

So what we're doing - and these are really not meant to be a one for one match up. But I touched on a couple of these points already. Develop and commercialize blockbuster brands. You've got to take them globally. You've got to make sure you've got aggressive lifecycle management. You've got to make sure that you take them in all the indications that really are valuable. So it's not development to some degree almost starts when you get your first approval for these products and that's the mentality you've got to think about these products.

We're going to continue to expand our geographic reach. We're now direct in 25 countries outside the U.S. We're direct in a couple of big markets in South America, Argentina, and Brazil. And we've opened up in India and China. So we're going to continue to aggressively expand our geographic reach and we've done that with a very good formula which in almost every market we've gone into we've been profitable in a very, very short period of time.

Advancing the pipeline, a challenge for everybody. In our case, we've got a great pipeline now. This is really an execution challenge. Those are the kind of challenges you like to have. There is a lot of competition out there for clinical trial patients so you've got to be creative on where you do your trials and how you conduct them. But this is really an execution problem.

The next point really is different. Accelerating innovation internally and externally. That's a culture problem. That's a question of how do you keep the innovation and productivity of these smaller companies as you advance and become a larger company. And we've approached this from a couple of different ways. One is how we've organized ourselves. We organize these things in teams that are big enough to really have all the expertise but small enough to really keep the passion around the products and to give you a more vertical structure around getting from development, discovery, into development and through into commercialization.

And second is the venture investing strategy that we've had. We put in place venture investing four years ago. It gives us the front seat in a lot of companies. But importantly, the different thing that we did is we integrated it very closely

with our R&D organization. So we've got scientists in the R&D organization championing these deals and following these deals. It's not just a financial instrument because in the end we're interested in products and technology. It's also led to a couple of significant acquisitions, Conforma being one and Syntonix being the other, that if we were not in that network we probably would not have seen those opportunities.

Final Transcript

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

And then lastly, we saw a gap in the funding ability of the venture capitalists on bringing some great projects out of academia and financing them initially. The venture capitalists have gone a little bit later. There's been a gap there. So we tried a new approach with this incubator strategy. So where we fund some projects coming out of academia, we bring those scientists with them, we have some product right, we surround it with a little bit of infrastructure and then leave them off to do the science with some specific milestones attached. So we're going to try a number of these experiments. I don't know which ones are going to work. But we're going to try to be creative. But it does create a mindset of continuous innovation internally.

We've had a great position in biologics for years. We continue to have great biology in the discovery labs and that goes right through our ability to attract compounds in on business development because we know how to develop them, get them to the regulators, and we also know how to manufacture them at high quality in large quantities. And of course the strong financial performance, the impact of that on stock price is obvious but maybe what's less obvious is that we're in an enviable position because we are in a position to really look at opportunities and take advantage of those opportunities as they may appear in the marketplace, particularly interesting when you go through a lot of stress in the marketplace as we—as the biotechs have been through and are likely to go through.

Now, execution of strategy is not a straight line and I want to just touch on this slide because it draws out a couple thing on strategy for us. When Bill Rastetter and I were looking at the two companies going back to 2003, 2002, one of the challenges you had was did you have enough pipeline, did you have enough resources that you could reliably continue to bring products to the market and grow the Company. That was a big challenge that we both had. What we spotted was an opportunity to really put two companies together where we could make use of capabilities that already existed in the other company and then reallocate resources and capital to the pipeline. Alright? That's really the essence of the merger and the thinking.

Shortly after that we really got down to it with the board and we worked through the strategy and we realized that we could develop a pipeline quick enough just on internal developments. We were going to have to be aggressive and competitive on BD. And we made sure we had the room in the financial structure, in the capital structure, and in the P&L to be able to do that and we went off and did that.

Along the way we had all the excitement, TYSABRI launching, it was going to the moon. And unfortunately in early 2005 we had the big disappointment and we had to retrench. And we focused on that question. This is the second product—this is only the second product that's ever been brought to the market and I think it will be the first one that gets back to blockbuster status. I think we're well on our way.

Along the way, we've continually asked the question, what are we doing? How is it going to create value? And if we're doing something and you can't answer the question of how it's going to create value in the future, irrespective if it created value in the past, then it needs to be divested, shut down, or those resources refocused. You can see sort of along the top line, we've sold hard assets, we've sold product assets, we've restructured the work force. And we've done that on a pretty continuous basis.

As we got back into TYSABRI comes back to the market and it became a little clearer where we were going with that, I started to focus on a little bit longer term strategic plan for the Company. I touched on a little bit of that in the prior slide. I'm not going to get into that today. But we are thinking long-term, that's why we're doing venture investing. That's why we're doing incubators and those kind—that's why we're expanding geographically. Last year, we did a \$3 billion share repurchase. We weren't excited about assets that we could buy out there. We decided our stock was the better value. We did that very quickly, in 30 days, we repurchased \$3 billion worth of shares.

And as you know, with all the excitement around the MedImmune acquisition by AstraZeneca earlier in the year, there was enthusiasm among investors that this was going to be the time when big pharma started to go after the more developed biotech assets. We tested that thesis late in the year and at least for now, that's not going to be the case. But we remain open to every way to think about how do we really create shareholder value as we go forward here.

So I'm going to finish up. I think we've got a very strong investment thesis. We've got great fundamentals. We've got strong growth across all these products, strong growth across every region of our business. We've got a rich pipeline. And this is going to be the year—this is really the first year where the investment community's really going to get a lot

of data about this pipeline and we're all going to know how much value is sitting in that pipeline and that's going to unfold over the course of the next nine months and it will continue to unfold as we go into '09, '10. And I think we have demonstrated we've got a proven strategy to deliver financial results in good times and bad. Our '08 guidance is 15% to 20% top line, 17% to 20% bottom line and we think we can continue that kind of performance through that 2010 timeframe as we move into '09, '10, you're going to see the pipeline, we're going to see the pipeline, and we can all sort of set the trajectory beyond that.

So, with that, do we have time to take a few questions right now? Yes? Great. I'm going to repeat the questions because it is a webcast. And then we're going to more upstairs, later.

Mar. 18. 2008 / 11:00AM ET, BIIB Biogen Idec Inc. at Cowen and Company Health Care Conference

QUESTION AND ANSWER

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. The question is biosimilars that could affect the AVONEX franchise. Let me split it into two parts of the world or three parts of the world.

Europe, where right now, the next product to come on the market isn't truly in the category of a biosimilar. There's some patents that protect that for a little bit of time as well as our product and that's the old bio-partner's product. And so that will come, probably not super competitive initially because that's really the low dose, Rebif strategy. So they're going to have to do a little bit more to expand that. You probably will see a second brand, Betaseron coming out of Novartis. Unclear precisely what their strategy is but I would say that's prepared for FTY 720, down the road is to get their feet into the MS market.

In the U.S., the legislation is not in place. My guess is it might get in place in '09, '10. As a practical matter, the patents go out into the early part of the next decade, '13 or '14 depending on how you read them.

Outside of those two areas there are a few biosimilars that have been in the marketplaces in Mexico and Cuba and Iran. There are a few places like that. They've really had not a significant impact on the business and they've been out there for a few years. Okay? Yes, sir?

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

The question is around Copaxone's high dose study and if it were to show superior efficacy. Well, if it shows superior efficacy to Copaxone, the low dose, of course that's going to be an important marketing tool for Copaxone. They are a very strong marketing company and we assume they're going to continue to be strong in the future. You can't take it away from them. They've done a good job developing products.

But those are all products that are still sort of back in the interferon-like efficacy. TYSABRI, if it continues to hold up, you've got a completely different efficacy profile and as people get more and more comfortable with the safety profile and as we get thousands of patients beyond the two year point and people can get more comfortable, I think that really becomes the efficacy part to shoot at.

The next thing to look at is really going to be the oral molecule, things that bring a whole new convenience. BG12 I think is in that category. FTY could be there. And we also have a Phase II compound, CDP 323 which is on the same pathway as TYSABRI. So that's where I really think the future is going. I think that could give them a nice life in the interim. But that's not ultimately the strong competitive position. Yes?

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Final Transcript

Yes. Great question. The question is around PML and what happens when we see PML cases. It's always hard to sort of take yourself back in time but you almost have to see the situation at the moment that it occurred. We had no signals in 3,000 plus patients. At that point we had never seen a PML event in the MS sector in AVONEX which we've been in for eight years at that point in time.

And you get two reports in a day. We just launched the product and you had a huge queue of people behind that. That was in the backdrop of the exact time when Vioxx and hearings on the Hill were all in high relief. So I think there was a whole combination of events that come together that cause you to pull back and you say, "Okay, we've got to really study this product."

Now we studied that product and we studied that issue and we determined, in fact, there were three cases. We knew of two. The third one was actually in Crohn's setting, actually much earlier that had been misdiagnosed I think three or four different times.

So that's the background. We now understood at least the outlines of the safety issue. The experts recommended against concomitant administration of interferons or any immunosuppressive with TYSABRI so that's the way it's come back into the marketplace. Importantly, you know, it's sitting there with a warning label and I think that's important. We have now advised everybody that this is a potential. So it's in every piece of communication. It's in every conversation. And the TOUCH program in the U.S. which is the risk management program, literally we have dose by dose understanding and review of every one of these patients.

So if it is to reemerge, it's in a very different category. First, it's in the label. Everybody understands it. We're now past 21,000 patients. We've seen none. I think the question that remains out there is there perhaps some association with time on product and increasing risk. That's why in some people's minds the two year time point becomes important. But I think a case or two or whatever, as long as it's within the label is really not, from a regulatory point of view, a reason that this product would come off the marketplace. It will have an impact in the investment community and it may have a temporary impact in the market.

I think there was "how are we doing? A few minutes? Okay. Yes, sir?"

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Well, I wish I remembered. The question was would sales of TYSABRI equal sales of Betaseron by end of '08? First, I'm not sure I remember doing that but that's not that strange that I don't remember something. That's why we've got an Alzheimer's program that we just started. Boy. I don't look. Here's what I can say because I don't remember the exact Betaseron numbers off the top of my head. I think we're going to have, as we exit this year, to get on this 100,000 plan, we're going to be at \$1 billion plus run rate. So I feel like that's pretty much in reach. I don't remember precisely what the Betaseron sales levels are at this point but it's probably "it's still north of \$1 billion."

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. Well, the 20% of the market actually equates to this 100,000 patients is about 20% of that market at that point in time. So that's probably more what we're talking about.

Okay. I'm getting the cut off signal from Eric. So we're going to go "where? Upstairs? Provincetown? And we can continue. Thank you very much."

Breakout Session

CORPORATE PARTICIPANTS

Jim Mullen

Biogen Idec CEO

PRESENTATION

Jim Mullen *Biogen Idec CEO*

There's a great warning up here which probably more politicians need to read. It says, "Beware. Microphones are live at all times." Questions and answers. This is webcast as well so bear with me because I'll be paraphrasing and repeating questions again. I know that can be a little annoying for you guys in the audience but I want people on the webcast to be able to hear the question.

Unidentified Speaker

Okay. We can do that.

Unidentified Speaker

That wasn't a question, right?

Jim Mullen *Biogen Idec CEO*

Okay. Now we're in front of the curtain, not behind it. Just for the people listening. Okay. Questions? I've got Paul here. Eric? Yes?

QUESTION AND ANSWER

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. You know, when we got into the difficulties a couple years ago, I spent time with Art Levinson and we both felt important that we try to isolate the debate which was turning into arbitration and I'll come back to what that is and isolate that from what's going on in the commercial realm. I think the performance in the commercial realm has continued to be positive and productive and this has had a minimal amount of impact at the operating level. The debate is really about decision making rights. And certainly Genentech has a different interpretation of the contract than we have on that. Given that this relationship is going to go on forever, we think it's important that we get a final reading on what those decision rights are. I also know that there's been some speculation that there's a bunch of downside in this for us but this is really about decision making rights. They've chosen to move forward with all these other programs anyway so there's really nothing that's slowed down from a development point of view that I'm aware of and we continue to progress in those different programs clinically. So if anything we may have a little bit of upside to this if it gets resolved in our favor. At worst, we get clarity on the decision making rights going forward and then what we've agreed is, look, whatever that decision is is how we're all going to behave from that moment on. If it's if the Genentech interpretation is right, okay. And if our interpretation is right, then the relationship will change a little bit.

Final Transcript

But there's every one of these partnerships is going to have a few of these little bumps in the road because they're two different companies, two different objectives, and there's always a little bit of misalignment and it's always hard, in my experience, to predict exactly how one phrase in a contract actually turns out in reality. So yes?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. What the decision making - I mean, the first of the decision making rights and we feel we have a little more influence on that than they believe and we would've made some slightly different choices in some of these development programs. The overriding principle of this contract is maximize on collaboration profit which - so taken literally, which is exactly how we do, I don't sit here and go, "How do I - ?" It's how do we optimize the CD20 franchise across all those products.

A specific example which is not in our - particularly in our corporate interest but I thought was in the interest of the collaboration and the patients is pursuing relapsing, remitting MS with RITUXAN. They terminated those trials in Phase II and decided to skip forward to the next compound. They had an idea that that could be done in an accelerated fashion. The - we did not believe that was going to be true and the FDA has not agreed with them either. And by terminating that trial, that's cost a few years in the development of RITUXAN in relapsing remitting MS, for example. Yes? Yes, sir?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Okay. So to repeat it for the people on the webcast, there's really two sets of comments. One is about the usability of the website with AVONEX or TYSABRI and then the second part of it is really around TYSABRI and why is the website filled with warnings and discouragements if I can put it that way? Is that a fair characterization?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Let's address - on the website side, we periodically get some feedback on that. I'd say by and large I mostly don't get complaints about that or customer service which, of course, if you call our customer service, you'll get a live person unlike if you called AT&T or somebody. So you'll get live people that manage the cases and often know the patients by name. That tends to be a better avenue for patients. I'll take the feedback and we'll take a look at that. I'm in contact with those folks.

The second part, which is TYSABRI, the fact is we have a very regulated set of distribution and everything we put up there or everything we put out, whether it's in print or on a website is reviewed, approved, and regulated by the FDA. And given its history, that's all you're going to see pretty much are the warnings. It's unfortunately that - I heard and I've got piles of letters. We've got piles of anecdotes and you've recited many of them. I think that's probably the most exciting thing about TYSABRI is not only what people report about the disease and how they feel but people that are reporting that they can now do things that they couldn't do before. Unfortunately, we're not able to use any of that from a promotional point of view. Third parties are free to use it but we cannot, given the regulations. It's a little discouraging to patients. That I can appreciate. But that's the answer. That's where we are with the FDA regulations. Yes, sir?

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. The question is about our partnership that goes across three antibodies with PDLI. We're very excited about a couple of those programs. One, of course, we mutually agreed to terminate probably a year ago. That was the HuZAF RA program. I understand there's actually some third party interest in that program and so we're working closely with PDLI to see if that's real because if that's true, that asset should go forward in somebody else's hand. The Volociximab program we're excited about. It's in a few different Phase Is in solid tumors. Obviously we're in the Phase II in ovarian. That would be an exciting outcome. And then the third one is the Daclizumab program which was we've seen Phase II results as combination therapy with AVONEX. We're now in a Phase II trial to establish monotherapy efficacy as the approach going into Phase III with those programs.

In terms of changing the relationship, we made some minor changes. There's certainly been a lot of discussion as they've gone through their difficulties and so we've tried to work with them in a close partnership to make sure that these programs continue to advance forward. Obviously those are critical programs to them. On a relative basis, more critical than they are to us. But they're important programs to us. We are doing all the manufacturing and a lot of the heavy lifting on Volociximab and Daclizumab at this point even though Daclizumab was being manufactured by them. We've changed some bits of the relationship. We've really not changed the economics to any significant degree but of course we're open to that. But we're not necessarily pressing for that. Yes?

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Yes. So this is a question on the 2010 goal, 100,000 patients around TYSABRI. So I think the first thing is it is 2010. And I didn't select that I selected that because that's sort of the time horizon to see really where the rest of the pipeline and the typical time horizon the analyst has worked on is three years. Now most of the new competitors, competitive products, whether they be ours or others really come into the scene after that timeframe. I've seen a lot of programs about to blow us up in MS and, you know, over ten years I guess I've become a little bit jaded on that and I'd like to actually see the final data before I conclude how terrible it's going to be.

But in terms of the assumptions behind the 100,000, it's really just it's fairly straight forward. We need to see continued depth and breadth of prescribing. We are expecting, we continue to warn people, we're anticipating there will be some cases of PML. We'll see how that safety profile really unfolds as we go through this year and we see a significant number of patients that are on therapy for 18 months or two years. I think that's sort of the remaining large safety questions that physicians and patients can sort of better understand really what the incidence is.

What we've seen is certainly a shift in the psychology in the marketplace where initially when we went back out they were reserving patients that had failed everything else that were fairly late stage. Those are the patients we sort of call the train wrecks. Those are also the patients we would've thought might be at higher risk of PML given their exposure to immunosuppressants over long periods of time. But that's all theoretical. We are seeing people move it forward in the treatment regimen and in some countries, Germany being one, for example, there's a fair amount of initiation of therapy on TYSABRI. More so than we see in some of the other markets.

So specifically what we're expecting is we watch the weekly accrual rates in the U.S. and outside the U.S. Those have accelerated fairly steadily over the past year. And we're assuming that will continue to accelerate as we see more prescribers which we're seeing and more depth and really it's the patient's psychology. And you heard the anecdotes from the gentlemen a few rows back. We hear those everywhere we go and we hear them by the dozens. That's really what goes around the patient community and when the physicians see in front of them what I call the two dimensional data that we send out and New England Journal of Medicine articles or whatever turn into people with real clinical

response, the whole mindset around a risk benefit starts to shift.

Final Transcript

So we are expecting that we're going to see PML. That's what we've continued to warn against. No doubt because of the history of this product, that will cause a lot of excitement in the short term. I think it really is what are the circumstances around the cases and how many are there over what period of time. Yes, sir?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen - Biogen Idec - CEO

Yes. If we get a couple of cases of PML, it's what do you learn from those cases? One of the objectives - there's a couple objectives for the risk management program that's been installed in the U.S. Number one is to ensure that only patients that are appropriate to receive therapy receive therapy. Second is that these patients are fairly closely monitored. So every time they go in for an infusion, they actually get a questionnaire from the healthcare provider. Have they seen any changes in symptoms and whatever? And if the answer to any of those boxes is yes they get recycled back to the treating neurologist.

And so a lot of it - and so the second is to have a very high quality database on who's received product, what's their medical history, what other products have they been on, how long have they been on the product, how many infusions have they gotten, and then what do you learn from the cases you get? It would - the wisdom of the experts was avoid patients that are immunosuppressed and avoid giving patients concomitant therapy - concomitant immunosuppressants. That's what we've been doing. Does that hold up over time and what do we learn about the specific cases? But for a few cases that are within the incident rate that's in the label, I see no particular regulatory issues. I see a lot of investment concern and I think we'll get a reaction to that in the investment community. And I think it may take a couple weeks or a month or two for the prescribing community to digest whatever information we learn from that. But a few that are within the label, both in the U.S. and Europe and I don't think that poses any particular regulatory problem. Yes, sir?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen - Biogen Idec - CEO

This is about our Alzheimer's disease program. We actually have a few different programs in Alzheimer's disease, most of which we haven't really spent a lot of time discussing externally. The one we have talked about is in licensing that we did in the fourth quarter with Neurimmune. And so this is an antibody approach but I think the different piece of this is it's an auto-antibody so it's coming out of patients that have had positive responses or positive evolution if you will of the disease of Alzheimer's. There's a couple of other technical hooks which I'm not qualified to even talk about. We also have some more standard programs like gamma-secretase modulators and things like that. So we're obviously interested broadly in neurodegenerative diseases. I'd say as the HSP-90 field moves forward, we're pretty excited about that as a potential as well because these misfolded proteins and chaperoning were always thought to be part of the mechanism there. So we think there may be a way to cross over the HSP-90s into Parkinson's and Alzheimer's. But that's a little ways off still.

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen - Biogen Idec - CEO

Final Transcript

So the question is on TYSABRI. Will we see an inflection point because people starting now really can see the results for people that have been on it for a year or two years in front of them and therefore have the ability if there's events to change their medication, if you will, before the risk goes up?

I've heard that theory out there a few times. Actually recently I've heard it. We think that's not a marketing message that we can be going out and talking about. But that's the kind of thing that will get driven through the opinion leaders in the medical community. I don't know that I hear that among those folks. But the logic is interesting. I've heard that logic actually several times just in the last couple weeks. I hadn't heard it being discussed before that. Maybe people are thinking about that.

What we can say is the psychology as the months go on, as the numbers go up of patients and as the cases are treated in front of the physician's eyes, that's why we're seeing this gradual acceleration of accruals. Is there a magic inflection point? We're not assuming there is one. It could happen though. We'll all know it looking in the rearview mirror probably. I don't think there's a magic switch out there. But that's when you're going to be accusing me of being just low balling the 100,000 patients. Which would be great because everybody's laughing at me three months ago. So I'd love to be wrong, on the high side. Yes, sir?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

The question is isn't it a high probability that the risk of PML goes up with time? I think the answer is nobody really knows that. I think that's kind of the last theory that can be out there. But there's no real mechanistic or scientific basis

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

As I said, it's the only one that's left out there but I wouldn't say that there's any underpinning scientifically. Importantly, because I want to point people over to the other thing; we haven't been just sitting on our hands around PML. We have been looking at risk mitigation. We've done flex studies which is to get TYSABRI rapidly off board. We have screened lots of different compounds to see what compounds might have efficacy against J.C. virus. There are some hits of approved drugs. So we're actually going to do some work in the clinic in the HIV patients with those populations. So we're actually looking at it a number of different ways. Can we predict it? Can we know who's at risk? Can we do something about it if we saw it to address those? I think any or all of those together also help I think mitigate the risk in reality and particularly in the minds of treating physicians. Yes, sir?

Unidentified Audience Member

(Inaudible question - microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

So the assertion is that there's no history of PML in monotherapy. If you only looked at the two patients with MS, your statements are true but unfortunately there was a third patient which indeed was actually chronologically the first patient which was in Crohn's disease. And they'd actually been - they were on monotherapy. They had a long, long history of immunosuppression but they were not on concomitant immunosuppressants at that time.

Unidentified Audience Member

Final Transcript

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Alright. This is the situation we're often in in the drug development business which is proving something is never going to occur, never happen, is an almost impossible task. So we're associated with what we're associated with. I think by and large the medical community understands that and that's certainly where we try to talk about that.

Unidentified Audience Member

(Inaudible question microphone inaccessible)

Jim Mullen *Biogen Idec CEO*

Those kinds of conversations can occur between medical professionals and medical professionals in our Company. They cannot happen at the sales force level because it's just illegal. It's just that happens to be the fact. It arguably isn't true, either, depending on how broadly you want to draw the definition.

Believe me, we'd love to be out there more aggressively doing this. What we have done here has been taking a very careful approach, a very responsible approach, and we have the trust of the regulators, the physicians, and the patients. I think that is very important to how we continue to move this business forward, that they feel like they've got the full safety update. That's probably the most critical thing that they look for and that we're going to be as conservative as they are. I think that has, more than any other thing, helped us bring this product and get it back to where it is. Any other questions? I think that's it. Thank you very much. Appreciate your time.