

BIOGEN IDEC INC.  
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**CONFERENCE PRESENTATION**

**PARTICIPANTS**

**Jim Mullen**

*Biogen Idec President, CEO*

**Eric Schmidt**

*Cowen and Company Analyst*

**Eric Schmidt** *Cowen and Company*

Okay. Good morning, everyone, and welcome back to the Cowen and Company 29th Annual Health Care Conference. My name is Eric Schmidt. I am one of the biotechnology analysts at the firm, and it's always my pleasure to welcome Biogen Idec to the conference.

We are joined today by several members of management. The Company's Chief Executive Officer, Jim Mullen, is going to be giving the presentation. But also in the front row are Paul Clancy, the Company's Chief Financial Officer; Elizabeth Woo, Vice President, Investor Relations; Rob Jacobson, Director of Investor Relations, is also somewhere in the audience. And the whole team will be here to answer your questions in the breakout session, which will be next door following Jim's talk, in the Tufts Room. If Jim concludes early, we may have time for a couple of questions here as well. So let me pass it over.

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

Thanks, Eric. Good morning, everyone. As always, I will start with the fine print, the Safe Harbor. So I will be making some forward-looking statements. I just have everybody keep updated with SEC filings and our press releases.

Here is what I want to quickly cover today. This was going to be a duet; I had Cecil Pickett doing the pipeline, but he has got laryngitis, so you are going to have to put up with me. So just pretend when I get to the pipeline that I am as smart as Cecil and we will be all set. It may be a little hard to believe, but we will get there.

So let me get rolling. I think most of the people I see are familiar faces, so you are pretty familiar with the Company. Strategy is pretty simple. We are working on first-in-class, best-in-class compounds, taking them to specialty markets with unmet need, and doing that on a global basis. We now have a global footprint that really gives us a direct presence in virtually all the important pharmaceutical markets around the world.

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Just to expand a little bit on the first-in-class, best-in-class, I have arrayed some of the compounds. This is by no means exhaustive about our pipeline, but I really want to make a couple of points.

I have arrayed these late-stage, early-stage, first-in-class and best-in-class, and we focus a lot of our attention on the first-in-class molecules. You know that gives you the opportunity to create a new treatment paradigm and real breakthrough therapies. But with that comes all the risk, with going down unknown pathways and certainly higher technical risk.

We think we have also balanced off that pipeline by going after a number of proven pathways. We all know the many examples in the pharmaceutical industry where the second, third, or the fourth product really becomes the market leader. You take advantage of learning everything that has gone on around that pathway before you and designing around some of the pitfalls of the pathway.

So we think we have got an interesting group of compounds also in the best-in-class. Obviously less technical risk, but then you've got more competitive risk on that side of the equation.

This is just a snapshot of the key metrics since the merger. You can see revenue has grown 17%. Compound annual growth rate, EPS at a growth rate higher than that. EBITDA, we have got expansion on the margins up and down, which is a 22% expansion. And free cash flow stepped up pretty substantially, particularly last year. So I think we feel pretty good about the trajectory of these metrics. We certainly look at these and track these pretty closely.

When you get looking at the revenue, it is obviously driven by our three major products. Over the past five years, the AVONEX business has doubled; the RITUXAN business has also doubled; and you can see the gold bar on the top, which is TYSABRI, is an important contributor, particularly in 2008. It is obviously the major growth engine here for the next couple of years.

So what I really want to do is take the next 10 minutes or so and focus on what does it take to reaccelerate the TYSABRI business, and what are we doing around that?

There's really two major points to focus on. One is we have to continue to tell the story about the unparalleled efficacy of the product. And the second is to put PML and the PML issue in context for the medical community and the patient community.

I think this is an interesting slide to start with. So we have gone back and we have taken a look how did TYSABRI do in the launch relative to three other significant products here - Remicade, Enbrel, and Humira. This is what it looks like, so I think the launch was certainly very strong through the first two years. You can see when we hit the first two cases of PML in late July, that that really hit the - interrupted the momentum of the business pretty significantly. That is pretty obvious from the last six months or so of performance.

Now, we have been doing a lot of things here to really regain that momentum. I am going to go through a few pieces of that, but essentially the challenge is to get back on the curve that we were on about four or five months ago.

It starts with reminding ourselves and everybody else that MS is really a devastating disease. I use this screenshot pretty frequently internally. This is from the Advisory Committee meeting in 2005, prior to TYSABRI coming back to the market. This is a screenshot of patients that paid their own way to come and testify there.

Most of these patients are already at EDSS 6 or above, as you can tell from the fact that they are in wheelchairs and scooters. So these are very well-advanced patients. They came, they paid their own money to really plead with the FDA about the need for new therapies and really put the risk-benefit in balance.

Now TYSABRI is really the first drug where there is any data that it improves multiple sclerosis. We have for years talked about slowing the disease or halting the disease, so slowing the progression of disability. But for the first time we have got real data and evidence about improving the disease.

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If you look at what I call the pyramid of data on this product, you've got the 54% reduction in disease progression, and the 68% reduction in relapse rate. So those are out of the Phase 3 trials. We also know that at two years, 37% at these patients are free of any disease activity. So that is a composite endpoint of relapses, of MRI findings of EDSS progression.

And more exciting and you will see more of this data at some of the congresses; it has been presented fairly recently: for those patients who had EDSS above 2, they showed a 69% improvement after they had been on product for some time. So this is really the first time that we have seen patients not only halt the disease progression but actually improve physical function. Critical to keep reminding people of that.

Now we've got a very comprehensive marketing and sales program put together. Of course we use different elements of this for different audiences for different purposes, but I am going to work you around very quickly from about 7 o'clock here all the way back around to 5 o'clock.

We've got a lot of customers that are here, a lot of people making the decisions. Clearly the two most important are the physician and the patient. And the patients are very influential in treatment decisions.

You know, patients are very savvy now. If they have got a debilitating disease, they are going to go to a website. We have several hundred thousand people in our direct-mail list. They look at all of the publications coming out of the Company, the press releases in the lay journals, et cetera.

We have got more than 200 people in the call center. We have more people in our call centers answering inbound questions and solving problems for patients daily than we have sales reps in the field calling on doctors. Of course, you have the sales reps, the Advisory Boards, the congresses, where folks like you may go and you may hear a lot of the top-line information.

But a lot of the real influence goes in these peer-to-peer programs and the live programming. So peer-to-peer prescribing physicians, working with their peers in a region. So somebody who is known to their peers working and talking about the product, the advantages of the product, how to deal with patients—that is the most powerful selling tool for physicians and similarly for patients. Patients hearing from other patients is the most impactful.

So we keep working on that and other live programming. We are using webcasts to allow better access to the medical personnel. This is for physicians so they can really get detailed answers around specific medical questions. I think this has all been very helpful to keep turning the tide here.

You can see that this is a trace of market research on physician confidence. Answer to the question specifically TYSABRI's benefits outweigh the risk it poses to MS patients. You can see the fairly—we did a great job building that confidence coming out of the launch. You can see the PML cases really interrupted that. And we are back at the hard work, and it is a nice leading indicator to see that that is starting to climb up to pre-PML levels.

Also, the neurologists increasingly think that they are going to use more and more drug over the next six months. So three-quarters of the neurologists think they are going to use significantly more TYSABRI over the next period of time than in the previous period of time. Now this is the composite; so a snapshot in Europe, late in the year, and a snapshot in the USA at the end of the year.

So that is the efficacy story and some of the leading indicators. Now I want to focus a little bit on putting PML in perspective. When the first PML cases came up in 2005, we were obviously having extensive meetings with our own neurologists and outside experts. And people were saying we don't know that much about PML; we really haven't treated patients with PML since medical school.

So as we worked with the community it was pretty evident that the level of knowledge about PML, JC virus, and the whole evolution of PML from JC virus was pretty poorly understood. So the first thing we had to do was really make sure that the data and what were the supposed effects out there really were true.

So some of the myths. PML is going to be difficult to diagnose. Well, I think we've demonstrated that with standard tools in the physician's office and with clinical vigilance, they can in fact detect PML and detect it quite early. There were papers at the time that the 5HT2A inhibitors might be helpful in the disease. We were not able to replicate that data after a number of tries. But in in-vitro assays we screened hundreds of compounds and mefloquine came up as a hit. So we do have a clinical trial ongoing around mefloquine. Can mefloquine be helpful in the treatment? And in fact, it has already been incorporated in the use by physicians.

PML can't be treated or cured. I think we have now given the tools for physicians to diagnose early and the treatment algorithm to rapidly intervene; and then of course that has changed the outcomes.

And the idea that PML is most often fatal. I think the evidence is going in the other direction—that with vigilance, with rapid intervention, that the outcomes can be certainly not as dire as everybody had initially thought.

So when you think about redefining that experience, I think about it really around these two axes. Making sure people know how to manage the disease and really move the outcomes from the perception of it's going to be fatal to something where it's a manageable outcome and the residual morbidity may be similar to one or two exacerbations of MS. And remember, MS is a debilitating disease.

So they can diagnose it early. We have given them the algorithms and the clinical vigilance, how to read the MRIs, central reading centers to get those to, CSF samples if you have suspicion. And we can pick up an active infection at very, very low viral counts in CSF, less than 100.

Then what do you do with treatment? They know now if you see a case of a patient on TYSABRI that has new neurological symptoms, that in and of itself is unusual enough for a TYSABRI patient that you should work them up and think about—do they have PML? Look at the MRIs quickly. If you have any suspicions, stop TYSABRI. Probably get the CSF sample. If it is confirmed, yes, you probably want to start on PLEX. And many of the people have done the PLEX. We have demonstrated that if you plasmapheresis these patients you can get the TYSABRI offboard fairly quickly.

Some have given mefloquine. I don't know that we can demonstrate that mefloquine is helping, but it surely is not hurting, and there is enough evidence that people are willing to do that. Of course, it is a product that is on the market. Lastly, you've got to manage the immune reconstitution inflammatory syndrome. Right? So you have got to manage it aggressively. It is managed with steroids, but it is going to reemerge in six or eight weeks after you get the TYSABRI offboard. And if you manage that aggressively the patients will emerge on the other side of that without PML, and then you can start working on the recovery.

So now looking at the rate, certainly the rate in the label looks like about 1 in 1,000. The experience to date for people with over 12 months of exposure is about 1 in 4,000. And that number will get harder and harder as we just get more experience here with commercial product.

We are doing a lot of work on making sure we can quantify precisely what that risk is with the clinical vigilance. In the US the TOUCH program, which is the risk management program that we are required to run here in the US, gives us visibility down to the dose level on a patient-by-patient basis. So we have got near-perfect visibility of what are all the issues going on with patients in the US.

We did some stuff with the label, initially coming back out to try to reduce the rate. One was patient selection; so we contraindicated patients that have any evidence of immune dysfunction or immune suppression and recommended monotherapy.

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There's a few other things that have come up and bubbled up as theories and ideas over the last couple years. One is, would drug holidays be helpful? I'm going to address that on the next slide. The other one is, are there further ways to stratify patients by risk level and thereby lower the overall rate?

So let me hit first the drug holidays. I think there is an emerging consensus that drug holidays aren't recommended. So the first is, there is data that says once you take patients off TYSABRI, disease reemerges fairly quickly. So there is a consequence to these drug holidays, and you need to get far enough out with patients that TYSABRI is offboard if you have any idea that you're going to somehow improve their outcome on PML.

The second is while it sounds great to talk about the drug holiday, the fact is the rate is so low that when you run the statistics of what does it take to actually test this theory, it turns out you need at least as many patients as we have on product today or three times that. So it's really not a testable hypothesis, and you would have to run it for a couple of years to see it.

So we don't think that that is going to be a very promising avenue at this point. Those physicians that have tried it are starting to go away from it because they are seeing the patients start to have exacerbations and new MRI lesions fairly quickly after stopping the therapy.

This is some of the data. We've got a lot of different cuts of data, but this is probably the simplest one to visualize. So this was a cohort of a little over 100 patients. This is looking at number of enhancing lesions that they had pre-study. When they were on study, they had zero, as you can see.

Then they came back in after stopping treatment, somewhere after two months, anywhere up to after six months. If you just look and drop those in different buckets of two to three months, three to four, four to six, et cetera, you can see they have a fairly rapid rise. Essentially a return to baseline of disease activity for patients that have been off by more than six months. So this goes to there is going to be a real consequence to interrupting the therapy.

We also know that unfortunately we became the tip of the spear on PML, but PML has taken more of a spotlight. It is now starting to show up in a number of other drugs. These are the drugs that have PML on the label today. I suspect more of them will pick that up in the future. These are also some of the other immunomodulatory immunosuppressants that are used by physicians. So this is going to be a characteristic of patients that have immune suppression in the MS market really across drug classes. How it varies class by class I think is impossible to say at this point in time.

It is also clear that we are going to have to do on the risk stratification more and more work on the basic science.

Right? You have got to have three things that come together for JC virus to get into an active replication cycle. So you've got to have significant immunosuppression or immune dysfunction. You obviously have to have the JC virus. But those two in and of themselves are not sufficient, because that is true for at least 50% of the patients. And certainly if you look in the HIV-AIDS area, all the patients have immunosuppression; many of them have JC virus; but still the event is fairly rare there.

So there has got to be some other things—host genetics, viral genetics, or some other unknown factors. And that's where we have focused our attention. We have brought together a research consortium of the companies. You will notice that those companies, if you attach them to the drugs I showed you two slides ago, they all have an interest because they are all working with drugs that have PML in their label as well. So we are pooling the data on the patient profiles, the background characteristics, and how PML evolved for those patients. Hopefully, as time goes on this will yield some interesting results for us.

So the finish on TYSABRI. We are continuing to focus on the efficacy. We have got to put—we are putting PML in context and getting people comfortable with how to look for PML, what the real risk is. And certainly the leading indicators are turning positive now.

So I am going to quickly go through the pipeline. So this is where you have to pretend for a minute that I am Cecil Pickett. So this will all sound smarter if you believe that I am Cecil. If not, well, it is going to sound like it is going to sound. Okay.

This is a snapshot of the pipeline in 2007. I like to pick that point because it roughly coincides with when Cecil came on board. I think Cecil took a lot of great raw material, recruited in some additional folks, put some good discipline in place. And through a combination of organic development – so discoveries out of our own labs put into the clinic licensing, and acquisition programs that we did on the business development side, and then execution on the pipeline, the pipeline looks much broader, deeper and much more advanced two years later. So at this point, I feel like we've got a broad, deep, and significant pipeline.

This is just a quick illustration of how quickly the Phase 3 registration programs have grown. We had four starting in the first half of '08. We added ADENTRI, the IV program, in the second half. We will add the peg interferon program in the first half of '09. And we should add the lixivaptan heart failure, the broader indication, as well as the daclizumab MS program in Phase 3 by the end of the year.

So we will have quite a number of programs in Phase 3, and this does not include the programs we have in the CD20 space in partnership with Genentech. I am going to dance pretty quickly across a couple of these programs and just give you a quick snapshot.

RITUXAN in early RA. We have got the Phase 3 IMAGE results, a couple obviously important outcomes around RITUXAN in RA over the last year. So we've got joint data finally. We've got the early RA data, so the DMARD failures. So this is going to allow really RITUXAN to move up front and expand the label and have a label that is competitive with the rest of the products in this space.

This also gives you really a good demonstration of dose-response and the fact that the 1,000-milligram dose is more efficacious over time. So we are pleased with this. We will see more of this data at EULAR in June.

I will turn to BG-12. Some of you are familiar with that program, so this is dimethyl fumarate delivered orally with an enterically coated capsule. Activates the Nrf2 signaling pathway which interrupts the NFkB and pro-inflammatory cytokine signaling.

We have got Phase 2 MS data that shows 69% reduction in gad lesions; and so we started Phase 3 programs in MS and we have Phase 2 program in RA as well.

The two Phase 3 programs. The first defined as a pretty classical placebo-controlled trial against two doses; primary endpoint is proportion of patients relapsing over two years. That will finish enrollment first half of this year. The second is two doses of BG-12 against glatiramer acetate – also known as Copaxone to you guys – and placebo. Primary endpoint there is annualized relapse rate at two years. This is important. Not only the head to head, but also it is going to allow you to have a data set that can get you an approval in Europe, where you are going to have to have an active comparator arm in one of the trials.

Then lastly, we have got a Phase 2 ongoing in rheumatoid arthritis.

The PEGylated interferon, that is a program that we have had going on for the last couple of years. We didn't start talking about that program until really JPMorgan early this year. Eric, sorry about that; I had to say that. You're not mad at me are you, Eric? Okay.

We wanted to make sure we were finished with the Phase 1; we had good understanding of the PK and the PD of that product; and also that we had met with the FDA and the European regulators and had a defined and agreed-to path forward for registration. And indeed we do.

So this is a PEGylated version of the beta interferon 1a that we market today as AVONEX. We think this could improve convenience and compliance for the patient.

We have started the Phase 3 program – or we are starting the Phase 3 program. We intend to initiate that in the middle of this year. It will be a placebo-controlled trial; primary endpoint is annualized relapse rate at one year.

Again, that is agreed to by the US and European regulators. We are going to test two doses of biweekly and a monthly subcutaneous dose. I think the subcutaneous dose will certainly be received fairly positively by patients.

Lumiliximab is a CD23 monoclonal antibody headed for CLL. The primary mode of action is apoptotic cell death. So we are in a Phase 2/3 for relapsed refractory CLL.

The clinical data on that. A relatively modestly sized clinical trial, Phase 1/2, of lumiliximab plus fludarabine cyclophosphamide and RITUXAN in relapsed patients. It doubled the complete response rate versus historical control; and importantly there was no evidence of additional toxicity or safety or tolerability issues there.

So we are in that Phase 2/3, similar design, FCR plus or minus lumiliximab in relapsed CLL. 390 patients in the Phase 2; 900 in the Phase 3. The primary endpoints in Phase 2 are complete response. In Phase 3 it'll be progression-free survival, and that one is moving along fairly rapidly.

Now I am going to switch gears, go to actually two programs. I just want to set these two programs up and how they fit together here. This is the lixivaptan and the ADENTRI program. There are a huge population of patients in the US and Europe that suffer from heart failure. The one-year mortality is very high from diagnosis, 25%; five-year is 50%. It's a segment that is growing 2.5% per year. In fact, it is really the only cardiovascular segment that really is growing. Hyponatremia and renal insufficiency are common comorbidities in heart failure. You can see hyponatremia is about 25% of the folks, a quarter of the folks have hyponatremia; and roughly two-thirds have renal insufficiency. So lixivaptan addresses the first. ADENTRI really addresses the second.

ADENTRI is a small molecule adenosine A1 receptor antagonist. It disrupts receptors in three different places in the kidney, which disrupts the tubular glomerular feedback and preserves renal function. So you get water off, you retain the salt, and you retain renal function.

Phase 2 study tested that with furosemide plus ADENTRI and furosemide alone. We were quite pleased with those results. I don't have them here today. We will have them at the R&D day next week.

We have a couple of large trials ongoing. The first is TRIDENT, which is the IV formulation with 900 acute decompensated heart failure patients. Primary endpoint is change in body weight; and a whole range of secondary endpoints as you can see here. First patient in was August of last year.

And then we started the Phase 2, POSEIDON. We have a real Greek water thing here going. Randomized, placebo-controlled, double-blind. Again, this is the oral formulation. Primary endpoint here is safety and tolerability; secondary endpoints - quality of life, exercise capacity, renal function, and concomitant meds. That one is planned for first patient in the middle of the year.

I will just finish with sort of the teaser on the HSP90 program. So we have several HSP90 programs. We have two oral molecules in the clinic today. They are both small molecule synthetic HSP90 inhibitors delivered via capsule. Those of you familiar with the HSP90, it is pretty exciting, also a very competitive space. It is a chaperone for client proteins involved in tumor cell signaling.

We have data from a Phase 2 GI stromal tumor trial which looks quite positive, and we are now expanding those trials out into other solid tumors during the course of this year. So we are pretty excited about the HSP90 space, not only in oncology but potential applications in the neurodegenerative area.

I will finish by just reminding folks that we have an extensive review of not only some of the programs I just mentioned but really many, many more, as well as some of our early programs and some of our platform technologies, next week on March 25. I hope many of you can make that review. I think you will come away with a lot more information and quite hopefully as excited about the pipeline as I am.

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So, with that, I think we have do we have a few minutes for ? Six minutes? Okay. If I can answer them in two minutes each, I can do three questions. Okay.

**QUESTION AND ANSWER PERIOD**

**Eric Schmidt** *Cowen and Company*

It is early in the year still, but (inaudible)?

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

I only control half of that equation, and that is the half I never comment on. Okay, that was okay. We've got still time for three questions. Okay?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Well, I think that has been presented in congresses. I don't know Elizabeth, it is not on the label yet; so it is something that would really be part of the medical information if you went back to I don't think that is not going to be part of the sales aid for the sales reps. But when you get into the peer-to-peer and you get into the medical information or with the medical affairs folks, they can and do talk about it.

So we are going to have a quiet breakout next door. Yes, sir?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Yes, I'm going to repeat the question because we are doing the thing webcast. I should have repeated yours too, Eric.

So, the question is, from us looking at business development, what would we like to add to the stable, if you will.

If I stepped back from we've got three or four areas where we are focused from a product point of view, obviously.

We've got quite a bit in neurology. We have got an interesting pipeline in oncology. We have a number of things in, call the autoimmune disease area, rheumatology, RA, et cetera. Then we've got this what we call an acute in-hospital setting, which captures the cardiovascular products and probably Factor IX and Factor VIII.

So I would like to see, if we are going to do things that fit in around those categories, I don't think we need any more categories than we already have. If we had things that obviously, we're a company with big powerful products; but that also means it doesn't have as much diversity as you might like. So when we have a hiccup on TYSABRI we have got a ton of volatility around the stock.

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So if we had a way to build out, add to any one of these franchises, and bring in products that either have revenues today or are going to shortly have revenues in the next few years, which would help diversify the revenue base, I think that would be quite interesting.

Philosophically, you know, we always look at all these products and we say can you create a shareholder return here? What is the story that makes us believe that in our hands that we can turn one dollar into two? That is the first economic test, and then we look at all the rest of the things like accretion, dilution, and all the rest of the typical analysis. But I think we have been pretty conservative and disciplined.

Having said that, we all know we are going into a marketplace or we are in a marketplace, we have been there for a while where equity values are at a place where we haven't seen for 10 years or so. So I think there are some attractive assets out there potentially. But we will continue to apply a very disciplined approach to that of can we create a story that not only fits to our strategy, but will create incremental return for the shareholders, add to our growth rate? Yes?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Yes, would I prefer something like late? I'd prefer something late-stage or in-market. I think at this point not only do we have a lot of early-stage, but one of the things that is not really even evident from the pipeline chart is just one of the things that Cecil has done a fabulous job, we did two things.

We realigned our research organization around therapeutic areas. So people like and Evan Beckman is sitting right here. He is one of the therapeutic area heads, and he has got responsibility for that therapeutic area from the bench to the bedside. That has really accelerated moving exciting products from discovery into research.

So we actually have probably more ideas bubbling forward than we have the infrastructure people-wise or the financial capability to advance. So I think we are in great shape on the early side. So I am much more interested in late or in-market products. Okay.

**Eric Schmidt *Cowen and Company***

Last year at the conference, you downplayed the potential for (inaudible).

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

Yes, what is the outlook for future pricing? Well, I never I hate to talk about the outlook because I'm usually wrong, as you just indicated, Eric. Thank you for pointing that out. I guess that is payback for the JPMorgan comment, isn't it? Philosophically, that whole well, look. If there is shareholder value to be gained by getting that, we will do that. I think that has to be balanced off against what does this do to the overall market dynamics.

We are going to have over the next few years more competitors in the marketplace. I think that will again change the dynamics in that marketplace.

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From a business planning point of view, we don't plan on these. All right? So we don't build them into our models, we don't build them into our plans. Where we believe that we can get leverage on pricing we do so whether it's in the US or outside the US.

Thanks. Appreciate it.

## **BREAKOUT SESSION**

### **PARTICIPANTS**

#### **Jim Mullen**

*Biogen Idec President, CEO*

#### **Evan Beckman**

*Biogen Idec SVP Immunology R&D*

#### **Elizabeth Woo**

*Biogen Idec VP Investor Relations*

#### **Paul Clancy**

*Biogen Idec EVP, CFO*

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

All right. Should we get started? So hopefully you are here for the Biogen Idec Q&A. If you are not, you can stay; but you're at the wrong place.

I've got Paul Clancy who is our CFO. I've got Evan Beckman, who is the SVP of the immunology and the cardiovascular therapeutic areas, so we can try to field whatever questions you might have. As well as Elizabeth Woo, who usually bails me out when I miss a detail here.

I will be repeating the questions because this is webcast. So I am not playing for time, although this does help. Who wants to start? Yes, sir.

#### **Unidentified Audience Member**

I wasn't able to sit in on your (inaudible) but I understand that you've got a clinical program underway now in collaboration with Cardiokine and lixivaptan.

Historically, research of the vaptans in heart failure has not led to promising results. I am kind of curious as to why you feel as though this particular molecule in this disease state is going to provide benefit(inaudible)?

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

Sure. Evan, do you want to take that one? That's right up your alley.

#### **Evan Beckman** *Biogen Idec SVP Immunology R&D*

Good morning, everyone. My name is Evan Beckman. The question for those on the webcast was we have a collaboration with Cardiokine on a class of molecules called vaptans. The drug that we are in clinical trials with is lixivaptan. The question was, since there have been some other molecules in the space, how do we feel that we are going to be successful with our molecule?

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So I think first of all, it plays into a strength of ours. As we have gone into the cardiovascular area, gone into heart failure, we have really focused on both our programs, ADENTRI and lixivaptan, work in the kidneys. They have a strong interaction, the kidney and the heart. It's kind of cardio-renal syndrome. Physicians continue to tell us that these are just the most toughest patients to treat in heart failure, and this is where the unmet need is.

The vaptans are well validated in terms of the clinical pharmacology. Have a brisk output in terms of urine volume. Can clearly get patients who have low sodiums, who have too much free water which is part of the disease and that interaction with the heart and kidney and get that water off.

We can raise serum sodiums in those patients who are hyponatremic; those patients who have heart failure who have low sodiums; and those patients who have other diseases which cause low sodium, such as liver failure and some tumors and others.

In terms of the early indications for hyponatremia, we actually think that is very straightforward. We have plans to include additional endpoints to hopefully give us some evidence of clinical improvement in addition to the serum sodium.

So we think that is going to be very important and we hope we can produce that information in our trials. Other trials have not been able to take advantage of some of the insights that we have.

In addition, in terms of them going after the heart failure indication, again we have a lot of insights into the trials that were done by some of the other folks. And we think in the combination of really choosing the patients well, focusing on the endpoint, and also maximizing the dose of the drug and allowing titration to really show the benefit of using lixivaptan as opposed to commonly used diuretics.

So our vision of the future and this is several years out but really we know that furosemide causes a lot of problems in its use in heart failure. We think this next generation of products, lixivaptan for the vaptan and ADENTRI, are really the drugs that should be used in this space and probably not loop diuretics. And hopefully we can show that.

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

Yes?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Have there been changes in the marketing resources dedicated to AVONEX?

Not substantial. Obviously, we are focused both with TYSABRI and AVONEX; but AVONEX is clearly a very important product and still at a number-one used product.

So no, we continue to focus on that both at the marketing level and at the sales level.

This is a tame group. Any more questions?

**Unidentified Audience Member**

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(Inaudible question microphone inaccessible)

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

Yes, so the question is about Phase 3 PEGylated interferon program. So we have been working on that program for a few years. We have not really talked about it until early this year, because I wanted to make sufficient progress that we actually knew it was a real program.

So the PEGylation technology was developed internally, so we don't believe that bears on any of the other patents that are out there at this point.

We have taken it through Phase 1 programs and we think we understand pretty well the pharmacokinetics and pharmacodynamics of the product. It is well behaved. It behaved as we expected it to behave.

We took those packages to the regulators in the US and Europe to ensure that we had agreement on a registration pathway. So we have agreement with the US and the European regulators.

So we will go into a fairly classically designed placebo-controlled registration trial. The endpoint is annualized relapse rate at one year. Did I get that right? Yes, okay.

Now it will take we have got to accrue, and all the patients have to be on a year. But that is what it is.

We are going to take two dose regimens in the trial. So we took three dose groups into the Phase 1s. We chose a dose out of there, and we are going to use that dose both as a biweekly and a once-a-month.

It will be delivered subcutaneously, which is, we think, going to be an important convenience improvement for patients as well. Okay?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Well, the question is around enrollment of placebo-controlled trials. You are absolutely right; enrollment in placebo-controlled trials in MS is getting tougher.

We have got several of them ongoing today. The BG-12 are enrolling placebo patients. We have the ability to do these trials in probably 30 or 40 different countries now, so we know where to go to get placebo patients to run these kind of trials.

It's also important that the duration helps, because it's a year and then they're going to get flipped onto active therapy. So it is not a forever for the placebo patients either.

But I think we know how to get those done. We're spending a lot of time right now doing the feasibility studies and the site selection, to make sure we can get the patient flow we need to actually accrue these trials relatively quickly.

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Yes, okay, so the question well, I'm going to repeat it, too. So the question is really about our views on healthcare reform, follow-on biologics in the US, and potential tax policy changes on corporate taxes. Did I get that right? Okay. So you know follow-on biologics, I have been very active in that. There has got to be a pathway. It is important that it be a well-structured and well-thought-through pathway.

I think the European pathway is a pretty good model for that from a regulatory point of view. And I think that is where most of the bills in the US are going, whether it is Waxman's or Eshoo's or any of the other bills.

There was a building consensus probably in the middle of last year around really all the elements to the bill, inclusive of the date of exclusivity, which was in the 12- to 14-year time frame.

Waxman has come out with an opening bid of five. I don't think it is going to get done at five. I don't know where it gets done at, but it will be a bunch of horse trading.

Interestingly, when Waxman put together the Hatch-Waxman in '84, they picked seven years of exclusivity for orphan drugs. So I think that is just going to get there will be a lot of horse trading behind the scenes and we will come up with a regulatory pathway. I don't know if that gets done this year or next year, but it will get done.

Frankly, I have always viewed it as, look, this is just something that is part of the landscape. It has got to happen biologics as it happened in small molecules. Biologics are more complex. There is going to have to be a little bit more clinical trial data to support it. And it will have to be determined almost on a case-by-case basis as the Europeans have done and I think as the FDA will do. So that is one.

Healthcare reform, you guys are reading all that we are reading. If we are going to go to it sounds like we are going to move more to the European system, frankly, with some version of comparative effectiveness. And then that will be met with access controls to the government programs, and then you can layer on top of that some kind of price controls and some either overt or less than overt or covert format here.

So I think we are just going to end up with a European-style system eventually. Maybe it won't get all the way to the European-style, but that's our outlook.

In terms of tax reform, believe it when I see it. It will be great if they lower the corporate tax rates. I think they are going to need to do that. The corporate tax rates in the US are clearly out of sync with everybody else in the world. It is causing people to shift more and more jobs and everything else offshore. So if they want to bring jobs on shore they're going to have to change the tax rate. I don't know if they will.

**Unidentified Audience Member**

Can you give your latest thoughts on (inaudible) relationship with Elan and any potential (inaudible)?

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

The TYSABRI sharing relation? So the thoughts on TYSABRI sharing relation. So let me just summarize what it is. We have always had from an economics and development decision point of view it has always been 50-50. We are the marketing and sales company on the MS product in the US and outside the US, everywhere. They have represented the Crohn's business in the US.

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We decided to sort of cleanly have lines like that because it made the operating issues much clearer. If there is an opportunity to continue to clarify things, of course we would look to that. But at this point, we don't really have anything that we can report on it.

Any last questions?

**Unidentified Audience Member**

(Inaudible question - microphone inaccessible)

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

Yes, so the oral - the question is really about the oral compounds coming in MS. FTY720 is what people talked about; cladribine and laquinimod being the other two.

I think there is a question with the side-effect profile on FTY720 exactly. Is it approvable, and under what conditions, and how will it be used? I suspect given the safety liabilities that are apparent on that product, it is probably going to get pushed down the treatment paradigm some.

The other products - interesting products. The efficacy is so-so. They have some of their own safety liabilities. We have never been particularly excited about those products.

We took passes on those products during the '90s and I don't know that our view has changed a lot. They may come to the market. I am not particularly - we are not overly concerned about that.

Obviously, we have got two of our molecules in development, one in Phase 3, BG-12. The predecessor product to that one, which is a combination product of monomethyl fumarate, dimethyl fumarate, is the number-one product prescribed for psoriasis in Germany.

The major component of that is dimethyl fumarate. We have got a ton of safety experience with that product, so we know that that is safe and tolerable, probably more so than these other products. And we will see what the efficacy profile looks like in Phase 3.

Then the other one is we have the Phase 2 program in conjunction with UCB on the VLA-4 pathway. So that is sort of the oral version of TYSABRI, if you will. You know, I think certainly the VLA-4 pathway is the bar people are going to have to jump over in terms of the efficacy profile of TYSABRI. Yes?

**Unidentified Audience Member**

(Inaudible question - microphone inaccessible)

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

Yes, the question is on the pricing environment here in the US for products.

Well, I think as the healthcare reform comes, we get comparative effectiveness, we get all these other government programs. It looks like it marches down the lines of the Europeans, so we are going to see versions of access controls and price controls certainly through all the government programs.

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It depends on how big a piece of the pie the government programs are. They are not a huge piece of our business in the MS space. They're bigger pieces of our business obviously in the oncology space.

We generally would say there is going to be more pricing pressure, more access control pressure in the future the way things are going. We never really plan on trying to take price increases as part of our base business plan. We build the business around running the business as it is.

But if we have the ability to take price increases, we will. We will try to do that, if we don't think it is going to be harmful to the business long-term.

I think the other thing you will see as the environment gets more competitive is what is the list price and what is the discounting strategies? And contracting strategies may start to evolve and change over time as well. I'm not predicting anything on that, but that will be the other what typically happens in these different categories. Yes?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Yes, Cecil's retirement. Let's go back to what was when Cecil was recruited in, it was with the understanding that it was a limited period of time. We asked him to do a number of things, right?

One was help build out the R&D organization, recruit some new folks, and he has done that. Help develop the folks we have in the organization that were very talented; he has done that. Really improve the thinking, the discipline around the programs and the execution; and he has done that.

So now is a good time and so we will start looking both internally and externally. We just decided we are going to look broadly.

What are we looking for? Somebody that is a high-impact R&D leader that also can integrate the business elements into the R&D.

In the highlight, now how long might it take? I don't know. It will take as long as it needs to. So Cecil is going to remain on board. There is no definitive endpoint, other than we needed to announce publicly both for external reasons and internal reasons that we were going to do that.

We are going to look and evaluate the internal candidates and the external folks. Yes?

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Well, yes, the pitch for coming back to town for the R&D day is not this hotel. It's the R&D.

We haven't gone through a detailed R&D pipeline discussion in a couple of years. It is an opportunity to not only get into some of the products in the pipeline that you have heard around before, but to talk to people like Evan and Al Sandrock and Greg Reyes, who lead those programs, as well as some scientists underneath that, and some of the early programs.

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I think it allows you guys to get not only a lot more data and insight into specific programs, but really to walk away with a touch and feel about what is the culture, what is the enthusiasm, what is the excitement within the R&D organization.

And I think you'll be impressed. Frankly, there is a lot more stuff to talk about than there is going to be time to talk about it. As we prepare for that, we are doing a lot of how do we make sure we go in depth enough on the important things, but make sure people get a good feel of the breadth of things? And we are going to have a lot of scientists there.

**Elizabeth Woo** *Biogen Idec VP Investor Relations*

But we will webcast (inaudible).

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

Yes, we are webcasting.

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

**Unidentified Company Representative**

We haven't, but we don't intend to. That would be (inaudible) which I think has been pretty consistent with what we've done for, gosh, 10 quarters.

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

Yes.

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

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

Back to the mic. Repeat the question.

**Unidentified Company Representative**

Chris asked if I could reconcile leap year to leap year and number of holidays, et cetera, et cetera, but just for the first quarter.

I think the only thing I would point everyone to is what Genentech said at their Monday R&D day. They kind of itemized the RITUXAN shipping dates, which will have a meaningful effect.

If you looked at that slide that they did, it probably lines up with the way we are thinking about the business, which will have an impact unfavorable in the first quarter.

We don't see it on RITUXAN. We don't see it as any kind of an issue as it relates to the full year. So that is the closest thing I can give you.

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

I think we are running out of time here. Do we have are we? What do we have? Got a couple minutes. Any last questions? No. Going once okay. See, you got to put the pressure on people. Okay.

**Unidentified Audience Member**

(Inaudible question microphone inaccessible)

**Paul Clancy** *Biogen Idec EVP, CFO*

Those were two milestone payments. The question was, there were two milestone payments that Elan paid to Biogen Idec as part of the collaboration agreement. One was sometime in 2008, one was in the first quarter of 2009.

We are taking those and amortizing those over the life of the asset essentially. So I think what you will end up seeing is a favorable impact that is relatively minimal of that combined \$125 million that gets spread over our estimation of the life of the asset.

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

Any more? Once, twice, okay. Thanks. Thanks for coming. Hopefully we will see a lot of you next week at the R&D day