

# FINAL TRANSCRIPT

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## **BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call**

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Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

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*Biogen Idec, Inc. - CEO*

**Burt Adelman**

*Biogen Idec, Inc. - EVP of Development*

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*Thomas Weisel Partners - Analyst*

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Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

## PRESENTATION

### Operator

At this time I would like to welcome everyone to the Biogen Idec fourth-quarter earnings conference call. (OPERATOR INSTRUCTIONS). Ms. Woo, you may begin your conference.

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### Elizabeth Woo - Biogen Idec, Inc. - VP, Investor Relations

Thank you. Welcome, everyone, to Biogen Idec's earnings conference call for the fourth quarter and full year of 2005. Before we begin, I would urge everyone to go to the investor relations section of our Website, BiogenIdec.com, and print out the press release and accompanying tables. This will make it easier to follow along when the CFO, Peter Kellogg, reviews the financial results and the reconciliation to non-GAAP financial measures discussed today.

I'll start with the Safe Harbor statement. Comments made on this conference call include forward-looking statements about the Company's expectations regarding future financial results and the potential for TYSABRI, the potential for RITUXAN in RA, plans for the Company's commercial and pipeline products, and plans for external growth and pipeline growth. Such statements are based on management's current expectations and are subject to risks and uncertainties which could cause actual results to differ materially. In particular, careful consideration should be given to the risks and uncertainties that are described in our earnings release and in the periodic reports Biogen Idec has filed with the Securities and Exchange Commission. The Company does not undertake any obligation to publicly update any forward-looking statements.

Today I'm joined on the call by Jim Mullen, CEO of Biogen Idec, Burt Adelman, Executive Vice President for Development, and Peter Kellogg, CFO and Executive Vice President of Finance. I will now turn the call over to Jim Mullen.

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### Jim Mullen - Biogen Idec, Inc. - CEO

Thank you, Elizabeth. Good afternoon, everyone, and thank you for joining us. Our discipline and successful execution in 2005 led to very robust performance of the core business, resulting in strong revenue and bottom-line growth, despite a challenging year. In 2006 we anticipate major approvals for RITUXAN in rheumatoid arthritis and TYSABRI in multiple sclerosis. Let me expand on these few points.

In 2005 we posted revenues exceeding \$2.4 billion, which was topline growth of about 10%; non-GAAP net income of 554 million, which represented 12% growth over the prior year. Revenue performance was driven by RITUXAN and AVONEX. RITUXAN is the number-one selling therapy for non-Hodgkin's lymphoma, and is now a \$3.4 billion global brand. It is growing 16% in the U.S. and over 50% outside the U.S. In rheumatoid arthritis, the sales force has been fully hired. The action date is the end of this month. We and our partner Genentech are prepared to launch RITUXAN for rheumatoid arthritis as soon as it is approved.

For 10 continuous years, AVONEX has been the number-one prescribed therapy for MS worldwide. AVONEX is a \$1.5 billion brand. Over 135,000 patients worldwide choose AVONEX for its lasting efficacy and convenience. Our international business now exceeds \$600 million, growing 22% year-over-year. In Europe, AVONEX has taken share in virtually every market.

We completed our restructuring and have a platform for growth in 2006 with opportunities for RITUXAN in RA and TYSABRI for MS. The past year has certainly been an interesting year, and it didn't exactly unfold as it started. I will review the year here quickly.

Suspension of TYSABRI made 2005 very challenging indeed. The emergence of PML in association with TYSABRI treatment was a serious and unexpected finding that led to the suspension of TYSABRI. Subsequent safety review required a lot of work and significant expenditure of resources as we went through the year. We completed what we needed to do on the TYSABRI work with the safety investigations. We completed the two-year trials and then filed the supplemental BLA at the end of September.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

With the prior review designation, the PDUFA date for TYSABRI's sBLA is in late March, and the Peripheral and Central Nervous System Advisory Committee is scheduled for March 7.

Due to the dozens of patients that have signed up to speak during the public session, the FDA has notified us that the meeting will extend into a second day to allow for a longer session of public testimony. Given the high interest in this event, we expect trading of Biogen Idec stock on NASDAQ to be halted during the Advisory Committee. We look forward to this next step in the process toward making TYSABRI once again available to MS patients.

But beyond TYSABRI, numerous other things were going on in the Company. The RITUXAN RA stage three trials finished up in April, and we filed the supplemental BLA in the third quarter. The PDUFA date is coming up in a couple weeks at the end of February, and we're very optimistic about this opportunity.

We also filed a label extension for RITUXAN in front-line aggressive non-Hodgkin's lymphoma, and just last week the FDA granted this label expansion. As part of our overall plan to expand that label, we will be filing for indolent, front-line and maintenance use, and that's on track for the first half of 2006.

As we looked at the business in the wake of TYSABRI and what was going to be required here, we sold a couple of assets, including the large-scale manufacturing facility in Oceanside, California. We decided we would divest AMEVIVE, and we're in the process of divesting that product. We also made a number of other moves, including restructuring the Company, and in doing so created a lot of P&L space for us to take advantage of external growth.

We recognize the need to increase our long-term growth prospects by significantly augmenting the number of programs in our mid to late-stage pipeline. The PDL collaboration for three products which fit across our key therapeutic areas is an example of the type of deals we seek to pursue to enhance our pipeline.

We have earmarked approximately \$200 million a year for business development and external research opportunities, starting in 2006, and that compares to approximately \$50 million earmarked for business development in 2005. The operating cash flow of our business over the past year exceeded \$800 million. We essentially have a debt-free balance sheet, so we're in a strong financial position with great cash flow to the business and a good foundation to start with.

Now I would like to turn the call over to Bert Adelman. Bert?

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**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

Thank you, Jim. Good afternoon, everyone. I'm going to take you through our pipeline, and the format that I'm going to use is to divide the pipeline into our key strategic business units, neurology, rheumatologic disease and oncology, and start with our most advanced programs and then give you some insight into our earlier development activities in each of these areas.

So, beginning with our neurology franchise, and beginning with TYSABRI, taking up from where Jim left off. As many of you are already aware, today the FDA informed us that clinical trial dosing for TYSABRI in patients with multiple sclerosis can resume. And in these regards, we expect to begin dosing in an open-label multicenter safety extension study of TYSABRI as monotherapy in patients with relapsing forms of MS. This will be in the United States under the IND.

Simultaneously, we are in active discussions with European regulatory agencies to reinstate dosing at those sites in Europe that participated in the Phase III trials, also as an open-label extension study of TYSABRI as monotherapy.

The patients, obviously, who will be eligible for these trials are those individuals who previously participated in the Phase III MS program. We already know that a very high percentage of these patients have indicated a strong interest in participating in these trials, so we expect that accrual will be excellent.

Feb. 15, 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

Now, I'm not going to discuss the protocol in detail. I'll give you a heads up on that, because this news is brand-new, and we believe that it is appropriate for us to first communicate directly with our investigative sites, and they with the patients, how the study will be run. But obviously, as I've said, we'll -- this will be a monotherapy trial, and we will be using this as another opportunity to learn as much as we can about testing for PML. So we will be drawing blood from patients to do various tests to continue to learn how best to understand the risk of PML.

Jim has already told you that the Advisory Committee meeting will be extended through March 7th and into March 8th because of the overwhelming patient and patient group interest. We're preparing for that and we look forward to the opportunity to discuss all that we have done to bring TYSABRI back to patients in this important forum.

In addition, as the regulatory process is moving forward for TYSABRI in the United States, it is also actively moving forward in Europe, and we are working closely with the CPMP in our effort to bring TYSABRI to the market for relapsing forms of MS in Europe.

Now I will move on to RITUXAN. I'm sure many of you know that we have, along with our partners at Genentech, an exciting program looking at RITUXAN in both primary progressive and relapsing forms of MS. The Phase III primary progressive trial, which is called [LIMPIS], is completely enrolled. However, it will be sometime before we see the data, as the primary endpoint of that study is a two-year EDSS disability endpoint.

The Phase II relapsing-remitting trial has also completed enrollment, and we expect to have results of that trial sometime during the first half of 2007.

Now, we've already told you about the important progress we've made in our BG-12 oral fumarate program. I'll just very briefly repeat that we announced in January that this oral compound had met the primary endpoint of a Phase II MS trial. The data around these results will be presented at a future medical meeting, and I actually don't know what that venue will be. But we are working actively with our partners and with regulatory authorities to define the path forward for BG-12 in MS. At the same time, we are in discussions with the regulatory agencies in Germany regarding the BG-12 file in psoriasis.

Daclizumab, the antibody to the IL-2 receptor, which we've partnered with PDL, is currently in a clinical trial in MS, and we are working hard to develop ongoing Phase II MS trials for Daclizumab as monotherapy and as combination therapy. Hopefully, we will be starting the monotherapy trial during this summer.

And finally, our oral A2A antagonist program in Parkinson's disease, in collaboration with Vernalis, will hopefully move into Phase II sometime this year.

Now moving on to our oncology franchise, as Jim already mentioned to you, we are very happy to be able to announce that the FDA approved an expansion in the RITUXAN label to include up-front therapy in diffuse large B-cell lymphoma, and we are happy that the FDA has enabled us to bring this important therapeutic approach to patients with aggressive forms of B-cell lymphoma.

We also anticipate filing RITUXAN for indolent front-line and maintenance therapies sometime in the first half of '06, and we believe that these are very strong data supported by trial results from our front-line RITUXAN CVP -- Cytoxan, vincristine and prednisone -- trial, and the ECOG 1496 trial. These supplements will enable us to expand the label for RITUXAN across the spectrum of indications for which well-controlled clinical trials have demonstrated its important efficacy. We're also -- just to finish on RITUXAN, we also continue to accrue patients into a relapse chronic lymphocytic leukemia trial in Europe and the U.S.

Now, moving on to ZEVALIN, we have submitted to the FDA our Phase III protocol for ZEVALIN as a component of therapy to treat diffuse large B-cell lymphoma. And we hope to initiate that trial in collaboration with our partner Schering AG sometime during the second half of 2006.

Feb. 15, 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

Our Anti-CD80 program -- WE have decided to move this antibody into a Phase III trial for relapse low-grade non-Hodgkin's lymphoma, and we hope to start accruing patients sometime in the second half of the year.

Finally, our very exciting early program, the M200 program, an antibody program partnered with PDL that is directed against a protein necessary to facilitate angiogenesis in the site of a tumor bed; we'll be taking that program into a series of open-label pilot Phase II trials, and we look to some important data over the next year or two in this program. There will be some abstracts submitted to ASCO, so hopefully we'll have some exciting data even this year at ASCO.

Our anti-lymphotoxin beta receptor program is in Phase I in solid tumors, colorectal and lung, and our adeno-interferon beta gene therapy program continues to be evaluated as an IV form in patients with advanced colorectal cancer and liver metastases.

And finally -- the list is getting long. And finally, our Phase II anti-CD23 program in CLL is maturing, in that we are collecting the last of the data in that trial, and hopefully by midyear we will be able to make a decision as to whether we're moving that program into late Phase II or early Phase III.

Now, to move on to our new -- our new therapeutic area, rheumatologic disease. Obviously, everyone is aware of our plans for RITUXAN. The history is well-known. We completed a large Phase III trial. It was submitted to the FDA in August. It was granted prior to review. And the expected action date from the FDA will be toward the end of February. And this first indication for RITUXAN is in the TNF inadequate responder group.

At the same time, we have an extensive program to define the value of RITUXAN in retreatment. We are looking at joint erosion data, and we have initiated a large Phase III program for RITUXAN in [D-Mard] inadequate responders. We'll also initiating trials of RITUXAN in Lupus, an obviously very serious autoimmune disease with very limited therapeutic options for patients. So we're very excited about that program. We do have some interesting early Phase I, Phase II data to suggest that there is an important D-cell component to Lupus that can be accessed by RITUXAN therapy.

The second generation CD20 program will -- there will be some results coming up shortly in the Phase II rheumatoid arthritis trial, and we will share them with you when we have them available to us.

Finally, two final early programs, [Lithitoxin] beta receptor program. We've begun enrolling in a Phase II RA study for D-Mard inadequate responders with that fusion protein. And in collaboration with PDL, we've begun enrollment in a Phase II RA program using the HuZAF anti-interferon gamma antibody strategy.

So, to recap expected 2006 milestones -- we're hoping to file six INDs, three are for new molecular entities. The anti BR3 in CLL in conjunction with our colleagues at Genentech. This is part of our expanding portfolio of therapies directed against B-cells, both in malignancy and autoimmune disease. Neublazin for neuropathic pain and the [Alpha-B] beta 6 antibody for (indiscernible) fibrosis. Finally, obviously, we're looking forward to hearing the results of the RITUXAN regulatory process by the end of February, and submitting the RITUXAN front-line low-grade and maintenance in the first half of the year, and of course, TYSABRI in the U.S. and Europe.

Thanks, and I'll now hand the mic over to Peter.

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**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Thank you, Burt. Before I move on to the financials, let me remind everyone that we provide table three of our earnings release as a reconciliation of the GAAP to non-GAAP financial results. Because we recognize the importance of earnings computed in accordance with GAAP, and in accordance with Regulation G, I'd like to remind you that on table three in our press release, we reconcile our GAAP P&L to the adjusted non-GAAP performance that we discuss. This is presented in a tabular manner and breaks out the reconciliation by major driver and by P&L line item.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

The main items excluded from operating non-GAAP EPS in Q4 were -- first, as always, we adjust the purchase accounting charges, which were \$74 million for the amortization of intangibles, and \$5 million in stepped up inventory value in the cost of sales line. Secondly, we have written down \$36 million of AMEVIVE inventory, based on the anticipated sale of that business. Third, we had severance and restructuring charges of \$12 million, which are the fourth quarter's impact from our 2005 restructuring and organizational changes that you have all heard about previously. Fourth, we recorded an impairment loss on sale of assets of \$15 million, driven by the anticipated sale of the NICO clinical manufacturing plant, based on current negotiations with potential buyers. And finally, in addition to the normal tax effect on these items, we have also incurred a onetime tax charge of \$11 million due to the repatriation of approximately \$196 million in foreign earnings, of which \$175 million was repatriated at the reduced tax rate under the American Jobs Creation Act of 2004.

Now, as normal, I will review the P&L operating performance of Biogen Idec and will focus on our adjusted non-GAAP P&L, driven by the reconciliation in table 3. We believe this P&L better reflects the recurring economic characteristics of our integrated business.

Let me begin first by making a few observations about the full-year 2005 P&L performance. We ended the year with 10% total revenue growth and non-GAAP EPS growth of 12%. And as Jim mentioned earlier, some of the key highlights of the year include the fact that total AVONEX worldwide sales grew 9%. Internationally, AVONEX grew 22%, and as Jim mentioned, is now over \$600 million in sales -- quite an accomplishment for this high-performing operation.

Our RITUXAN business continues its strong double-digit growth. In 2005 it grew 15%, despite heavy investment in rheumatoid arthritis and autoimmune trials, and in the buildup of the RA sales infrastructure at year-end.

Finally, we've accomplished these strong results in a year that required a lot of discipline in managing our costs. We maintained our topline momentum, we've done the homework on TYSABRI, we delivered double-digit EPS growth, and we restructured the Company for external growth. So, quite a full-year.

Now let's move through the fourth-quarter P&L results, beginning with revenue. In the fourth quarter, our total revenue was \$633 million, 8% growth over the same period last year. Breaking out the product revenues, starting with AVONEX, which is the number-one MS product worldwide now in its 10th year on the market. In the fourth quarter, AVONEX worldwide sales were \$413 million. In the U.S. the AVONEX product sales were \$242 million. Despite losing some market share in the first half of 2005, we're very pleased that AVONEX has regained some of those losses and remains the market leader in the U.S.

On the international front, our fourth-quarter AVONEX product sales outside the U.S. were \$172 million, up 24% year-over-year. AVONEX's fourth-quarter international sales in local currency was 28%. The corresponding ForEx impact in Q4 was negative at roughly \$5 million, or a 4 point negative impact on growth. Net net, AVONEX had a very strong quarter internationally, driven primarily by its consistent messaging of long-term efficacy and low neutralizing antibodies.

Most importantly, on a patient share basis, AVONEX continues to be the most used international MS therapy. We estimate our leading international market share to be in the low 30s, with Rebif, Betaseron and Copaxone falling behind. In addition, we continue to gain market share internationally in all of our direct markets, and are growing slightly faster than the overall MS market.

Turning to AMEVIVE, in the fourth quarter the AMEVIVE product sales were \$12 million. ZEVALIN had fourth-quarter product sales of \$4 million. And as a reminder, you will recall that in the fourth quarter of last year, which we're lapping, we included \$4 million of international deferred revenue from our distribution partner Schering AG. So, the ZEVALIN performance in Q4 is lapping a big quarter last year.

In the fourth quarter, TYSABRI product sales were actually -\$200,000, and as was the case in the prior quarter, you may recall this represents the amortization of certain product approval milestone payments and credits amortized over the life of the patent of TYSABRI.

Feb. 15, 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

Our royalties in the fourth quarter were \$22 million, and this takes us to our revenues from unconsolidated joint business. Now, on a full-year basis in 2005, as I mentioned earlier, the revenues in this line were \$709 million, up 15%. In the fourth quarter, our revenue from unconsolidated joint business was \$182 million, an increase of 6%.

As we always discuss, this number has several elements. First, we receive our share of the U.S. RITUXAN profits. U.S. RITUXAN sales were \$484 million in the fourth quarter, up a healthy 13%. And our fourth-quarter profit share from that business was \$128 million, up 9% versus prior year. So please note that the profit share growth of 9% was clearly impacted by the collaboration's continued investment in the RITUXAN RA opportunity, both in developmental trials and commercial buildup for the RA sales infrastructure in the fourth quarter.

Secondly, we receive royalty revenue on sales of Rituximab outside the U.S., and in Q4 this was \$42 million, up 24% versus prior year, driven by the impressive growth of (indiscernible) internationally.

Third, we are reimbursed for selling and development costs incurred related to RITUXAN. This was \$12 million in Q4. Please note that this was \$20 million last year, and this reduced level of reimbursement this year also contributed to the lower overall growth rate on the unconsolidated joint business line in Q4.

Now turning to the expense lines on the P&L, in the fourth quarter our cost of sales were \$72 million, 11% of revenue. Our fourth-quarter R&D was \$168 million, or 27% of revenue. You'll notice that our R&D in the fourth quarter was down considerably from the third quarter, but please recall that in the third quarter we incurred \$50 million for the initiation of the PDL collaboration.

In the fourth quarter our SG&A line was \$158 million, or 25% of revenue. And in the fourth quarter our OIE line was \$12 million.

Our fourth quarter tax rate was 33%, which leads us to a full-year tax rate of 31%, in line with prior guidance. And our fourth-quarter diluted shares outstanding for calculating EPS was 345 million shares, which brings us to our fourth-quarter adjusted non-GAAP EPS of \$0.48 per share. And on a full-year basis, our 2005 adjusted non-GAAP EPS is \$1.57, a 12% increase over prior year.

Now I'd just like to touch on a couple of other finance topics before I hand back to Jim. First let me talk about 2006 guidance.

I would just like to again reiterate that our P&L outlook for 2006 has not changed since the third quarter, when we announced the expected financial guidance to be in the range of \$1.95 to \$2.10 non-GAAP EPS. This does not include the impact of FAS 123R.

With respect to the implementation of FAS 123R, please note that this will begin in Q1 2006, but we do not plan to apply FAS 123R retrospectively, so the GAAP income statement for 2006 and subsequent years will not be completely comparable to 2005 and earlier years.

Secondly, the implementation of FAS 123R creates an incremental charge to our GAAP P&L related to the expensing of stock options based on the Black-Scholes valuation methodology. We estimate that this FAS 123R impact for the expensing of stock options in 2006 will be in the order of \$0.06 to \$0.09 per share. These charges will be distributed across the R&D and SG&A lines of the GAAP P&L. Going forward, our current plan is to communicate our financial results with and without stock option expensing, so you will be able to view the numbers both ways.

We have updated our capital spending estimate for 2006. We expect it to be in the range of the 190 million to \$275 million, which is a slight change to what we announced on the Q3 earnings call; we basically adjusted the lower-end of that range.

Our share repurchase -- in the area of share repurchase, we maintain an ongoing stock repurchase program with [Board] authorization to buy up to 20 million shares through October of 2006. Now, during 2005 we purchased approximately 8 million shares under the program. Just fewer than 12 million shares remain authorized for repurchase under this program.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

That's it for the financials. Now I would like to hand back to Jim Mullen for some closing remarks. Jim?

**Jim Mullen** - *Biogen Idec, Inc. - CEO*

Thank you, Peter. In 2005 we took several bold and disciplined decisions to redirect our long-term future. Over the last 12 months, we proved our resiliency. For 2006, we expect continued growth of our core business for the expansion of RITUXAN into RA and the approval of TYSABRI in MS in the U.S. and year. Together these major approvals will provide a platform for Biogen Idec to continue to seek partnerships and collaborations that will further our mission. In addition, we have the resources to develop our promising internal pipeline. While we focus on achieving these vital milestones, we will continue to maintain fiscal discipline.

Thank you, and I will now turn the call to Elizabeth for questions and answers.

**Elizabeth Woo** - *Biogen Idec, Inc. - VP, Investor Relations*

Thanks, Jim. We're ready to begin the Q&A session, and I would ask participants to ask one question and one question only, and to reenter the queue if you have subsequent follow-up questions, to allow more of your colleagues to be able to ask their questions. With that, operator, please open the line for the first question.

## QUESTIONS AND ANSWERS

**Operator**

(OPERATOR INSTRUCTIONS). Adam Walsh, Jefferies & Co.

**Unidentified Speaker**

It's actually (indiscernible). Regarding the TYSABRI trials and the [mess] that will begin soon, I was just wondering, how will you monitor these patients for PML, and will TYSABRI-naive patients be eligible to enter the trial in the future?

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

First of all, this -- as I said, this is a trial, it's an open-label safety trial for patients who were in the Phase III program. Obviously, there will be other studies of various kinds that will be available for naive patients, but this study going forward is for patients that were already part of our clinical development program.

We are evaluating -- with respect to PML, we are reevaluating a whole series of potential approaches, most of which are based around using PCR-based assays to look for evidence of (technical difficulty) DNA in plasma, serum or perhaps associated with buffycoat cells. That's the most advanced technology. That technology does -- is used clinically to make the diagnosis on CSF specimens or tissue specimens. So we are basing our strategies on the use of that technology.

**Operator**

Ian Somaiya, Thomas Weisel Partners.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

**Ian Somaiya** - *Thomas Weisel Partners - Analyst*

Just a follow-up. Maybe specifically, did the FDA ask you to -- ask for any sort of specific monitoring techniques or frequency in terms of how frequently the patient should be monitored for PML or JC virus in these open-label studies? How do they correlate with some of the recommendations you might have made in your filing for the drug?

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

A clinical trial is different than the commercial environment. As we have discussed, there will be a risk map as part of the overall strategy for bringing the product back into the market. I won't discuss the details of the risk map now until all of that is fully worked out with our colleagues at the FDA. Clinical trial manages risk through defined inclusion exclusion criteria, so we'll be deciding patient eligibility based upon that. We will -- as I said already, we will undoubtedly be continuing to examine the usefulness of plasma, serum and buffycoat-based PCR assays for the presence of JC virus. But I'm not going to go into any greater detail at this point in time, because this is new news, and we believe the appropriate first audience for this information are the investigators who will be accruing patients into this trial, and ultimately the patients. And perhaps at a later date we will be able to discuss trial designs and findings.

**Operator**

Joel Sendek, Lazard Capital Markets.

**Joel Sendek** - *Lazard Capital Markets - Analyst*

Without really describing the trial design or anything, can you tell us whether you are going to have an efficacy endpoint on the open-label study, or if it will only be safety?

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

I would say that this is an open-label study where all patients are receiving treatment, so it will be difficult to actually have strict efficacy outcomes. This is not an efficacy-based study. This is primarily an open-label safety extension study.

**Operator**

Mark Schoenebaum, Bear Stearns.

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

Maybe I missed this; can you give us ex-U.S. AVONEX market share now, and how that's changed year-over-year? And also, can you refresh us on the market share data for U.S., please?

**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Outside the U.S., obviously, as you know, we have to do some triangulation. We estimate our market share to be in the low 30s, very low 30s in terms of percentage. And quite frankly, the other two interferon products are just behind us, not too far behind. So the three are pretty close, and Copaxone follows that.

Feb. 15, 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

In the U.S., our market share is roughly 40%. And again, we are the market leader in the U.S.. In the U.S., obviously, that's based on [self-reported] sales that all the companies do, so it's pretty closely triangulates to the IMS data that you see, but it is the final shipments that we also all have to report back to IMS. But I don't think it's usually available to normal sources.

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**Operator**

May-Kin Ho, Goldman Sachs.

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**May-Kin Ho** - *Goldman Sachs - Analyst*

Based on what you have indicated about the extension study, right now it's only with monotherapy. Is the FDA concerned about the combination in terms of the risk profile? And if indeed that's true, and TYSABRI reenters the market with just monotherapy indication, how should one use it? Because the refractory patients, obviously, have been treated mostly with combination therapy.

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**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

Again, I'm not going to go into detail about label negotiations that are ongoing, but what I will say is that we have incredibly strong data supporting the efficacy of TYSABRI as monotherapy in patients with relapsing forms of MS. We believe that the mechanism of action of TYSABRI is relevant at all times, at all stages, in all patients who have relapsing forms of MS. So I think that our belief is that the biologic relevancy of TYSABRI is strong at all points in the course of relapsing MS.

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**Operator**

Geoffrey Porges, Sanford Bernstein.

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**Geoffrey Porges** - *Sanford Bernstein - Analyst*

Just a follow-up, Burt, on something you said earlier. You mentioned other trials being initiated later in the year. Could you give us a sense of what type of trials we should expect from you? Would you be looking at more experienced -- treatment-experienced patient population, safety studies, or would they have efficacy endpoints as well? What would that look like?

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**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

I would say all of those are possibilities. Obviously, we are waiting anxiously to complete our label negotiations with the FDA and the EMEA, and undoubtedly there will be some post-approval requirements. So those will form the basis, probably, of any ongoing clinical development program.

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**Operator**

Craig Parker, Lehman Brothers.

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**Craig Parker** - *Lehman Brothers - Analyst*

Burt, this is not a backdoor way to ask about the safety study, but I'm interested in a broader question -- your thoughts on alternative dose and schedule strategies with TYSABRI, both lower dose, less treatment dosing, or perhaps even drug holidays.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

We're thinking about all of those. They're appropriate questions. I will say that the general thinking about developing antibodies to integrin receptors, be it TYSABRI, or say [Reacrol] -- our sense has always been that to get any level of efficacy, you have to saturate the receptors at somewhere between a 70 to 80% level. So if you reduce -- it's almost a yes/no phenomenon. So if you drop the dose, you probably lose all the efficacy, rather than sort of have a graded loss of efficacy. So we don't believe that alternative dosing strategies would make a lot of sense, because right now we know the efficacy profile.

Now, whether or not drug holidays might make sense, that's an interesting question. And fortunately we have a portfolio of product opportunities to treat relapsing forms of MS with, and it may well be a logical approach to treatment to consider having patients on one treatment for some period of time, and then moving to another treatment. So I think the good news is that we've got just the kind of portfolio of approved and products in development to address that kind question.

**Operator**

Eric Schmidt, SG Cowen.

**Eric Schmidt** - *SG Cowen - Analyst*

Peter, I think your partners at Elan have made a comment as to the sales levels with TYSABRI you need to achieve in order for the collaboration to be profitable. Could you just give us your views on that?

**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Actually, I'm not going to disagree with them, per se. We usually don't break out our product lines' breakeven points and all that. Obviously, in our launch here we're spending more money than we likely will have as revenues. That's always our standard watch-out. And of course, how we spend money against the program will be a function of how it develops, obviously. So if this thing is -- continues to be really exciting, then we will obviously (indiscernible) pretty well. Elan and Biogen Idec work together very closely in the collaboration. We have joint committees for all the different areas, and we sort out a budget together and work closely. So we are not going to disagree with anything Elan laid out. Elan, obviously, does (indiscernible) a little more information on TYSABRI as it's one of their core products. And so we generally don't try to get into talking about product's P&Ls at this point.

**Operator**

David Witzke, Banc of America Securities.

**David Witzke** - *Banc of America Securities - Analyst*

Question regarding AVONEX pricing. I believe the last increase was 8% last May. How should we think about timing, and if you can, magnitude of increase in U.S. this year? Then I guess, ex-U.S., what's the competitive intelligence on BioPartners on generic beta and when that could be on the market, and how that could change pricing dynamic in Europe? Thank you.

**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Let me take the first part of that question, and for BioPartners maybe I'll pass it over to Jim. It's kind of more of a speculative question really.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

In terms of pricing in the U.S. for AVONEX -- I'm assuming that's what you were talking about. We did take a price increase in December of 9%. So that you'll see rolling through our financials going forward. So I think the question is resolved in terms of what's coming forward in that. I'm sure it takes care of things for a while. And quite frankly, that leaves us in a very competitive position with all the other products on the market, with the exception of one which is at a premium to ours, which as you know is Rebif. But the rest are all very closely aligned in terms of pricing when you look at it on a per-year basis. Relative to BioPartners, let me, if I can, turn that over to Jim. That's sort of an open-ended question really, in terms of anything that's been developed that we are aware of or (indiscernible) influence on pricing.

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**Jim Mullen** - *Biogen Idec, Inc. - CEO*

It's hard to speculate on actually even the dates as to when BioPartners could get a product into the market in Europe. A lot of that will revolve around both what they did from a clinical trial basis, as well as how the Europeans are moving on approval of bio generics. So they have, as you guys all know, recently put out some guidance on a few products. So clearly, they're thinking about it. But they're also very cognizant of matching us in safety efficacy issues. As a practical matter, the trials that the BioPartner has run have been 22 micrograms three times a week. So I don't think we see that actually as a very strong profile coming into the market, but I think the timing -- we don't expect it to be very soon.

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**Operator**

Jason Kantor, RBC Capital Markets.

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**Jason Kantor** - *RBC Capital Markets - Analyst*

You seem to have a lot of confidence in the RITUXAN priority filing, having hired everybody. Could you comment on what if any data you have submitted in the interim, if there's any chance that that gets credited as a major amendment, and how we should be reading into the fact that there is no FDA Advisory Committee for this one?

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**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

In answer to the last question, of course, that's entirely up to the FDA. They don't take us into their confidence as to how they decide whether or not to have an Advisory Committee meeting. But I would assume that they felt the package was strong, and that the issues were pretty clear, and the intention of the companies and how to use the product seemed very appropriate and in line with the data that -- the safety and efficacy data that we had. We haven't changed our guidance to you about the PDUFA date and our expectation to get a decision from the FDA. So that's how I would answer the first part of the question.

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**Operator**

Elise Wang, Citigroup.

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**Elise Wang** - *Citigroup - Analyst*

I just wondered if you had a little more elaboration on the guidance for the year. Specifically, I know in the past, the last quarter you mentioned operating expenses would be in the range of 1.4 to 1.5 billion. I did want to get an update on that, as well as any details you can give us in regards to -- I believe, again, your partner Elan made some comments about spending levels for TYSABRI as a group, and then also in addition to that, what might be spent in the collaboration with Protein Design Labs.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

So, you're right; in the third-quarter earnings call we gave a range for operating expenses in our guidance, and that hasn't changed at all. So that's still true. And just as a key point, that covers R&D, SG&A, and it also includes what Jim and I have often referred to as the \$200 million that's been set aside for external growth activities. So that's all embedded in that guidance. So basically, on the P&L there's no real update to our guidance at all, so that's still true. Coming to the fourth quarter, I think you can see that makes a lot of sense.

Relative to the question of the TYSABRI spending for 2006, again, Elan covered a couple of points on that. We always stand back from that and don't get into spending collaboration by collaboration. The PDL spending is embedded in the operating expenses that we've talked about. It is something that we planned for, obviously, as we went through the year, so that's all embedded in the guidance as well for operating expenses.

In terms of magnitude of the PDL spending, we don't really, again, break that out. But obviously, we're moving forward with some of the trials and so forth, so there are expenses related to the collaboration, and that's all been baked into our R&D thinking.

So basically, at this point I think we are really on course. We did a lot of work this year, restructuring some of our costs, looking at some of the strategic assets that we had or assets that we decided were not strategic. And we've been in the process of selling some of those off. And I think it sets us up in a really good position to drive into '06. Jim, do you have any other comments there?

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**Jim Mullen** - *Biogen Idec, Inc. - CEO*

Yes, just a comment. The reason we don't go through trying to break out each program is we don't find that to be terribly valuable. We're managing the whole business. You can see what occurred last year. We react to the product events that are in front of us. Some of them turn out to go one way, others go the other way. We're going to manage that very actively as we go through the year, so I don't see that there's a lot of value in us parsing out in great detail what we think is going to be the spending on a program when we're sitting here in early February.

What we do have fairly high confidence is that we will be able to advance our internal programs and all those in collaboration, and that we've got sufficient money and resources to do so. And we've got a very active and robust pipeline. And it advanced very nicely last year, and we expect good progress this year, as well as to put a few more products into that pipeline.

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**Operator**

Eric Ende, Merrill Lynch.

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**Eric Ende** - *Merrill Lynch - Analyst*

With respect to RITUXAN in RA, I'm assuming you guys have extensively reviewed the Orenzia data at this point, and the amount of data that they have. I was wondering if you guys can kind of go through and compare the amount of data that you guys have relative to what Bristol submitted for Orenzia, with respect to really the safety side as well as retreatment. So in other words, really the number of patients that you have at different points in time for each of those.

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**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

I don't think I've got all of those numbers in my head, but what I will say -- we are looking for an initial indication in TNF refractory patients, and we ran a fairly large trial there. We have -- in the context of the 120-day safety review, we were able to submit additional data on patients who have received retreatment. And we have a very extensive safety database from the use of RITUXAN for many years in oncology. So, I think we actually have a bigger safety database that is germane than perhaps even

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

the Orenzia database. And we will, obviously, be continuing to update that database because of the extensive ongoing clinical trial program.

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**Operator**

Gene Mack, HSBC.

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**Gene Mack - HSBC - Analyst**

First, I was just wondering is there any -- in the agreement with Elan, do you have any sort of best efforts criteria in the U.S. in terms of depending on what kind of label you get, especially if it's something that's -- where we're going to see use in the front-line, and we need to now start to think about this? Is there a best efforts agreement with Elan that might run counter to your interest with AVONEX, given the higher profit margin there? And just real quick, Elan seemed pretty optimistic about starting up a trial or restarting development in Crohn's disease, and I was just wondering if you share that optimism.

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**Peter Kellogg - Biogen Idec, Inc. - EVP, Finance and CFO**

Let me take the first crack at that one. Without getting into details of the contract, clearly, we have spent an enormous amount of money on TYSABRI. We have considered it a core part of our MS franchise, as well as one of our really big opportunities to move into Crohn's and other areas. And we and Elan are very much aligned on all details of how we move forward, whether it be the commercial activity or the clinical activity, or the financial commitments we make. So I don't think it's really a topic that is one that needs to be worried about at all. We are extremely committed to moving TYSABRI forward and making it a big part of the therapeutic choices in the MS community, and all the other areas where it can be used appropriately.

And clearly, we had good Crohn's data that you've seen in the past. So that's another area that we would be moving forward on. What we have done at the collaboration is agreed post-suspension to zero in on getting back in front of the FDA and the EMEA with the MS information and focus on the MS piece first, really get that taken care of, and then to move on to other indications, including Crohn's. So that, clearly, has been the work that we've been doing so far. So it's probably not to say that Crohn's is kind of [off], it's just the more we really zeroed in on getting MS rolling first.

And I think we don't -- as Jim mentioned earlier, we don't break out all the financial spending and so forth that we do on TYSABRI, but I can tell you as the CFO we've spent a whole lot on TYSABRI to get it here, and we fully intend to make it a tremendous success. We are very committed.

In terms of the contract, there's lots of joint management of this collaboration in the contract, so there's all kinds of areas where we agree on budgets and long-range plans and everything. It's a very close collaboration, and we and Elan are completely locked together on this one in terms of how we look at the opportunity.

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**Operator**

Bret Holley, CIBC World Markets.

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**Bret Holley - CIBC World Markets - Analyst**

Burt, I had a question on the extension study. These are prior Phase III patients. And presumably, since the suspension of TYSABRI, those patients have been receiving other therapy. And I was just wondering how you're going to handle that in bringing them back onto TYSABRI.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

Good point, and that is undoubtedly the case. And we will have developed, in collaboration with the FDA in this protocol, an algorithm for patients switching to TYSABRI. And I'm sure that it will be something that we will discuss, perhaps in the context of the Advisory Committee meeting. But again, as I said earlier, I'm not going to discuss the details of operating this protocol until we have had an opportunity to make sure that all of our investigators and the eligible patients understand the details directly through us.

**Operator**

Ron Ellis, Prudential.

**Ron Ellis** - *Prudential - Analyst*

Just a question about the panel. You mentioned that it's going to extend into March 8. Do you think that the questions to the panel will be posed on the 7th or the 8th now?

**Burt Adelman** - *Biogen Idec, Inc. - EVP of Development*

I think the format -- the panel gets the questions, obviously, at the beginning of the meeting. And the format -- the meeting is being extended to allow for more public presentation. And that comes in between the FDA and the sponsor presentation, and then the actual panel discussion of the list of issues. So, I suspect the discussion of the list of issues will either complete or may not even start until the second day.

**Ron Ellis** - *Prudential - Analyst*

So then, the stock would be held on both days?

**Jim Mullen** - *Biogen Idec, Inc. - CEO*

The stock will be -- we expect the stock to be held as long as the Advisory Committee is still in session.

**Operator**

Mark Augustine, Credit Suisse First Boston.

**Mark Augustine** - *Credit Suisse First Boston - Analyst*

I wanted to ask about Q4 results over in Europe with AVONEX, because the growth was pretty high relative to where you had been in Q4s over there, so whether it's a reflection of inventory price or any other unusual (indiscernible) let us know. Thanks.

**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Always in the international there's things moving around up and down and so on. There was very strong volume growth, just first of all, just to start. However, a few things that are a little different in Q4 versus Q4 a year ago, just to mention.

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

One of them is, and I think we commented on this during the Q3 earnings call, and that is that as we have reviewed our FIN 46 accounting approach for some of our joint ventures, we concluded over the summer that our joint venture in Italy should go through a FIN 46 consolidation. It should be a consolidated entity. You may recall in Q3, as a result of that, we had slightly lower revenue in Italy, because we pushed these sellthrough points a little further out. In other words, we used to book revenue when we sold into the joint venture, and then once you decide to consolidate that, you book revenue when the joint venture sells the product onto the market. So in Q3 our revenue was slightly suppressed from that. But then in Q4, now we have a full quarter of accounting for the joint venture on a consolidated basis. So that actually helped our revenue a but; not a major factor, but that was one kind of anomaly.

But we've got very strong volume growth, we have some pricing benefit overseas, and then that's been offset slightly by the foreign exchange. So really it's a very healthy business performance in both the direct markets and the distributor markets around the world. So it's just a great quarter.

And I think what we like to look at, because international is complex with all the mix and so on, is we do like to focus on just how we're doing against the competition in terms of market share. And the team overseas has been consistently posting volume growth in excess of the market growth. And they've been gaining share. And that's just great performance, because in a number of markets they compete in, Copaxone was just launched in the last year or two. So to gain market share in that setting is really solid. There's probably not a whole lot more complexity to that. We had a little bit of product sold for some clinical trial activity that's anticipated by another company, but that was very small relative to the overall volume. So basically, a very strong performance really -- volumes, some pricing benefits, offset a little bit by ForEx.

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**Elizabeth Woo** - *Biogen Idec, Inc. - VP, Investor Relations*

Operator, I think we have time for one last question.

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**Operator**

Steven Harr, Morgan Stanley. Your line is open.

Okay, we'll move to Alex Hittle, A.G. Edwards.

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**Alex Hittle** - *A.G. Edwards - Analyst*

I was wondering if you could fill us in on where the pricing now lines up in terms of what comes back to Biogen between a patient who for a year is on AVONEX, as opposed to a patient who would be on TYSABRI, per the price before TYSABRI was pulled from the market.

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**Peter Kellogg** - *Biogen Idec, Inc. - EVP, Finance and CFO*

Just so you understand, this is a complex question. I think you're saying as a patient is on AVONEX versus as a patient is on TYSABRI, how does that affect our financials. So let me answer it that way.

First of all, TYSABRI was launched at a higher price than AVONEX, in line with the clinical results (indiscernible). And so it really is first of all not really comparable one-to-one to AVONEX. Secondly, it is a new mechanism of action, and the clinical profile I don't need to speak to; I think you've all analyzed it very thoroughly in all of your reports, but very exciting clearly. And I think everybody who looks at that expects us to grow the market considerably. And remember that MS -- of the patients that one might think would be on therapy, maybe 55% or 50 to 60% of them are actually on therapy. There's a great number of patients

Feb. 15. 2006 / 5:00PM, BIIB - Q4 2005 Biogen Idec Inc. Earnings Conference Call

who are what we refer to as off therapy or quitters, or in the middle of switching. And they're dissatisfied with the current therapies for a variety of reasons that we've all talked about, whether it be tolerability or a perceived efficacy, or whatever.

So, we expect that innovations -- what the MS market has been screaming for, clearly, is some form of innovation in terms of a new product. The last -- TYSABRI was really the first new significant product to be launched into the MS market since 1996 or '97. So a long time since anything major has been launched. And so we really think that TYSABRI will be, first of all, a premium product; number two, it will expand the market; and number three, relative to our portfolio -- we've shown this many times over the years in different presentations -- clearly, it's going to expand our portfolio and be very positive for both the top line and the bottom line of Biogen Idec.

So we, obviously, looked at that very closely. And likewise we've looked at other products that are potentially coming into the MS area, and we're excited about all of those. We think the MS market is ripe for innovation, and TYSABRI is, we think, a major innovation for the market. So we are quite comfortable with all of that.

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**Elizabeth Woo** - *Biogen Idec, Inc. - VP, Investor Relations*

Thank you, everyone, for joining us on the call today.

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**Operator**

Ladies and gentlemen, we do appreciate your joining us today. This does conclude our Biogen Idec fourth-quarter earnings conference call. You may now disconnect.

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