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Biogen Idec Management Discusses Q1 2013 Results - Earnings Call Transcript

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Q1: 04-25-13 Earnings Summary

EPS of $1.97 beats by $0.34 | Revenue of $1.42B (9.53% Y/Y) misses by $-0.06M

Biogen Idec (NASDAQ:BIIB) Q1 2013 Earnings Call April 25, 2013 8:00 AM ET

Executives

Claudine Prowse

George A. Scangos - Chief Executive Officer and Director

Tony Kingsley - Executive Vice President of Global Commercial Operations

Douglas Edward Williams - Executive Vice President of Research and Development

Paul J. Clancy - Chief Financial Officer and Executive Vice President of Finance

Analysts

Geoffrey C. Porges - Sanford C. Bernstein & Co., LLC., Research Division

Mark J. Schoenebaum - ISI Group Inc., Research Division

Ravi Mehrotra - Crédit Suisse AG, Research Division

Robyn Karnauskas - Deutsche Bank AG, Research Division

Matthew Roden - UBS Investment Bank, Research Division

Eric Schmidt - Cowen and Company, LLC, Research Division

Michael J. Yee - RBC Capital Markets, LLC, Research Division

Geoffrey C. Meacham - JP Morgan Chase & Co, Research Division

Thomas Wei - Jefferies & Company, Inc., Research Division

Matthew J. Andrews - Wells Fargo Securities, LLC, Research Division

Terence C. Flynn - Goldman Sachs Group Inc., Research Division

Marshall Urist - Morgan Stanley, Research Division

John S. Sonnier - William Blair & Company L.L.C., Research Division

Joel D. Sendek - Stifel, Nicolaus & Co., Inc., Research Division

Operator

Good morning. My name is Sean, and I will be your conference operator today. At this time, I would like to welcome everyone to the Biogen Idec Q1 2013 Earnings Conference Call. [Operator Instructions] Thank you.

I'd now like to turn the call over to Ms. Claudine Prowse, Vice President of Investor Relations. Please go ahead.

Claudine Prowse

Thank you, and welcome to Biogen Idec's First Quarter 2013 Earnings Conference Call. Before we begin, I encourage everyone to go to the investors section of biogenidec.com to find the press release and related financial tables, including a reconciliation of the non-GAAP financial measures that we'll discuss today. Our GAAP financials are provided in Tables 1 and 2. Table 3 includes a reconciliation of our GAAP to non-GAAP results which we believe better represents the ongoing economics of our business and reflects how we manage the business internally. We have also posted slides on our website that follow the discussions related to this call.

I would like to point out that we will be making forward-looking statements which are based on our current expectations. These statements are subject to certain risks and uncertainties, and actual results may differ materially from our expectations. I encourage everyone to consult our SEC filings for additional detail.

On today's call, I'm joined by our Chief Executive Officer, Dr. George Scangos; Tony Kingsley, EVP of Global Commercial Operations; Dr. Doug Williams, EVP of Research and Development; and our EVP of Finance and CFO, Paul Clancy.

I'll now turn the call over to George.

George A. Scangos

Okay, thanks, Claudine. And thanks to all of you for joining us today.

Before I start, I do want to make a few comments on the case reports that appeared in the New England Journal of Medicine today. Frankly, it's hard for me to understand why these old reports were deemed worthy of publication at all. And certainly the timing, coming shortly after approval, is interesting. These are old news, right? The cases described in the New England Journal are 2 of the 4 cases of PML that have occurred in over 19 years and over 180,000 patient years of exposure to FUMADERM. All 4 cases were discussed at the JPMorgan conference in January, and all 4 cases were seen by the FDA, European regulatory authorities and all regulatory authorities months in advance of approval. And I think the TECFIDERA label speaks for itself.

So just to reiterate, there have been no cases of PML or other opportunistic infections with TECFIDERA. The clinical program has involved over 2,600 patients treated for up to 4 years and with a median time of approximately 2 years. So there's been substantial patient exposure with TECFIDERA. The New England Journal of Medicine cases occurred with different drugs; but even if one does assume their optimum rates are the same, which I do not believe to be true, then the rate is extraordinarily low: 4 cases out of 180,000 patient years. Now we've gone through these cases before, we've described the characteristics of these patients before, I'm not going to reiterate all of that stuff now. And fortunately, I believe that the no -- misinformation being spread is transient and will fade. And in a perverse way, it's somewhat complimentary. Importantly, I can assure you that we're well prepared to make sure that physicians and patients have a balanced picture of TECFIDERA.

So with that, we'll move on to the prepared remarks.

Okay, it's been a remarkable quarter for Biogen Idec, our shareholders, for patients, as a result of several major accomplishments over the quarter. First, our core business performed very well. Tony and Paul will go into more detail, but the bottom line is that revenues were up 10% to $1.4 billion and non-GAAP earnings were up 41% to $1.97 per share compared to the first quarter of 2012.

Both AVONEX and TYSABRI had strong growth, driven by AVONEX's life cycle improvement and TYSABRI's powerful efficacy. AVONEX continued to gain market share within the ABCRE class, and global units grew by 4%. So the core business is off to a great start.

Of course, a key event during the quarter was the approval and launch of TECFIDERA in the U.S. as a first-line treatment for relapsing forms of multiple sclerosis. This is a watershed event for our company and for MS patients. We're moving full speed ahead with a great label that allows our commercial team to discuss TECFIDERA in a balanced and broad way to describe the benefits of TECFIDERA, not only on relapse rate, but also on disability progression and MRI end points, both of which are becoming increasingly important for patients living with this debilitating chronic disease.

Also during the quarter, we were able to substantially improve the intellectual property protection for TECFIDERA. The U.S. patent for the 480 milligrams per-day dose that the FDA approved has been issued. The patent provides protection for the 480-milligram dose, which is the only approved dose, until 2028. The European Patent Office also determined that claims to the 480 milligrams per-day dose are allowable. And we expect the European patent to issue sometime in the next few months. The patent also will not expire until 2028. We believe our patent protection for the approved dosing regimen, coupled with existing patents, will provide a solid intellectual property portfolio to support our commercialization of TECFIDERA for many years to come.

Our recent transaction with Elan in which we gained full control of TYSABRI cleared regulatory hurdles and closed shortly after the quarter on April 2. This transaction provides us with full ownership rights and control of TYSABRI and eliminates the change of control provisions that were in the original contract. The operational simplicity should allow us to be more nimble and focused, which we believe will not only help TYSABRI but the overall business in the longer term. As Paul will outline, it is a deal that will give us an increased share of TYSABRI economics going forward. The transaction is immediately and, we believe, sustainably accretive as we move into the future. It's another landmark accomplishment for Biogen Idec and our shareholders.

We also continued to advance our late-stage programs through the registration process, and preparations have begun for 3 more anticipated approvals and launches over the next 18 months. Our 2 product candidates for hemophilia, long-lasting factor VIII Fc and factor

IX Fc, are hopefully our next products to reach the market. These products represent the first major treatment advances in hemophilia since recombinant clotting factors were introduced 2 decades ago. If approved, we believe these products will provide meaningful benefit by addressing a compelling need that these patients have, which is to require fewer injections. Hemophilia is roughly a $6 billion market worldwide. There are entrenched competitors in this market and patients tend to stick with their current therapies, but we believe that, for the first time in a long time, we'll be able to offer patients products that actually give them compelling reasons to change. We have a team with deep experience and relationships in the hemophilia community, and we believe that we have the potential to create a significant hemophilia franchise over time.

Our PEGylated interferon for MS, PLEGRIDY, finished the first year of the ADVANCE Phase III trial successfully. We plan to file for regulatory approval by midyear for an approval decision next year. We hope to be able to offer patients a therapy that's administered once every 2 weeks subcutaneously, with efficacy that appears to be at least comparable to other products in the injectable class. We believe that, with this profile, patients and physicians will view PLEGRIDY as a preferred frontline option. And behind those is a pipeline of compounds on track to reach development milestones in the next few years, including the SMNrx compound for SMA, anti-LINGO for remyelination MS, anti-TWEAK for treatment of lupus nephritis and STX-100 for the treatment of IPF. We believe that each of them has the potential to be a major improvement in therapy for their target patient population.

So in summary, this has been a very productive quarter and year-to-date for Biogen Idec.

So I'll now hand the call over to Tony to discuss in more detail the commercial results.

Tony Kingsley

Thank you, George.

We were pleased with the continued execution of our commercial strategy in Q1. We remained focused on growing our leadership in the MS market, with a goal of maximizing our total patient share across our therapies. The launch in the U.S. of TECFIDERA represents, obviously, a very exciting addition to our MS franchise.

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