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PRESENTATION

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Good morning, everybody. Welcome to the session by Endo International. With me is Paul Campanelli, the company's Chief Executive Officer. Let me just welcome all of you guys. The company's obviously had -- has restructured the portfolio quite significantly over the course of the past few years through a bunch of acquisitions. So the last couple of years hasn't been very positive, particularly with respect to the generics business.

But before we get to some of the business highlights, business issues, I would like Paul to address on the developments that happened last week, particularly around the mesh litigation and also around the OPANA ER FDA action. Okay.

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Sure. Thank you, Shubhomoy. So I'll start with maybe the OPANA situation. So I think as most people know, we had an advisory committee in March with respect to the -- whether or not the benefits outweigh the risk of OPANA. And what occurred was, as most people now, last week, on Thursday, we were asked to voluntarily remove the product from market. I would say, while it's not necessarily a surprise, we were probably a little disappointed in terms of the approach. With that said, we are -- our goal was to always in this to collaborate with the agency in order to address the situation. I can probably take it any further if you have any other questions on that.

QUESTIONS AND ANSWERS

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Can you help us understand what the margin profile of this product is and how we should look at the earnings impact going forward?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

So from -- we never get down to the specific gross margin of the product. What I would tell you is that, from a revenue standpoint, it's an important product, but it's not a product that is really a future growth driver. As we look at our pain portfolio, I think we've been pretty clear that we're no longer promoting pain products. So therefore, when you look at Endo in terms of going forward as a company, this product is not a future growth driver. But specifically for fourth -- first quarter, we generated about $36 million in revenue. And I would say that this product is akin to the brand's average gross margin percentage. And the IP of this particular product is domiciled in the U.S., and we do have a partner, Grunenthal, who gets a -- who will get a significant royalty back. So important product, but really not taking us into the future.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Okay. And just to elaborate a little bit more on the regulatory framework that's emerging for opioids. You have a new FDA commissioner, and he's been pretty vocal about solving the opioid addiction issue. Can you talk about any other soft spots in your portfolio, either on the branded side, around the generic side that you think could be potentially subject to additional risk from FDA actions?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Well, I think, right now, I think the focus really needs to be on opioids. When you look at our portfolio, on the branded side, as I mentioned, we still have important products like PERCOCET and OPANA, obviously an important product. Generically, we have a handful of products that still generate meaningful EBITDA, but I think it's going to be pretty much wait-and-see, right. The focus of the AdCom was specific to OPANA. It didn't include oxymorphone, so it was really specifically to be focused on OPANA. So I think what I find interesting, it will be a little bit of a wait-and-see. I think this morning the commissioner made a release that he's putting a special committee together, and there's going to be opinion leaders that are going to be coming out in, I think, July 10 and 11 on opioid use and abuse deterrent formulations and data and statistics generating abuse. So I think that's going to be something that will be very interesting to not only the interest, the whole industry, but obviously Endo in particular.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Great. Moving on to the other development from last week. The judgment around the mesh litigation. Can you talk a little bit about how that provides you additional visibility going forward around the specification?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Yes, sure. So last week, we traveled out to West Virginia to meet with plaintiff attorneys and Judge Goodwin, and we were issued what was called a case management order. I think what that gives -- we truly have wanted to provide visibility on mesh liability. This is myself and Blaise Coleman, being our CFO, have been running Endo. There's still certain degrees of certainty, but what came last week with the case management order is this simple, this determination that the mass portions of the torts are going to slow down. So where you're seeing these high degrees of volume or inventories as they referred to, there is going to be a slowing of that on a go-forward basis. So we don't have the visibility completely solidified at this point in time, but the ability to add large volumes of cases now are going to slow from a natural evolution of any cases that come forward are going to have basically proven out through what's called a fact sheet. So in any mass tort, you're going to have a degree of weaker cases or meritless type of cases. Now there's going to have to be investments made on part of plaintiffs. There's going to have to be investigations. There's going to be fact sheets that are put together with experts. So there's going to be a natural slowing of the process because of the costs associated with bringing cases forward.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Does this have any impact on the 10,500 cases, which have been filed? Or this is...

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

No, this is -- the way you have to be looking at it is the case management order is on a go-forward basis. So for the most part, you have that 10,000 cases. So I'm nothing to say the 10,000 can't change, but from where we stand, it's -- on a go-forward basis, you're not going to see -- we're hoping that you would not see large volumes of cases coming forward.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

All right. Let's move on to something that's a little bit more uplifting. Can you talk a little bit about the specialty branded business?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

That's a great topic, sure.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

And how do you see that evolving over the next few years? And more specifically, can you talk about the XIAFLEX opportunity? How should we look at existing indications or cellulite indication and also a little bit about the -- what the patent estate looks like for this product?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

So I think the starting point is we'll go back a little bit in time. We look at the entire brand portfolio. When you have to start with the pain side, Endo, clearly, had been historically known as a pain franchise, a lot of history, a lot of legacy, a lot of positive history with Endo. Obviously, with the changes at the government, CMC and CDC and also with the opioids, as we're talking about, it -- we had to shift our focus to specialty. So I think we sent a signal out when we were looking at our BELBUCA product. We ultimately divested the product, and we put it back to its developer, BDSI. It allowed us to reinvest and look at our specialty business. So where we had some cost savings associated with our pain franchise, we reinvested into our specialty business. We looked at the end-market indications for XIAFLEX at Peyronie's and Dupuytren's. So we communicated that we did about $50 million in revenue last -- for first quarter. It should give you an indication of how we see it. We see those 2 indications running at high single digits to maybe low double digits for that end-market indication. Now what we did was with some of the cost savings that we had for BELBUCA, we are reinvesting into the marketing efforts for Peyronie's and for Dupuytren's. So more marketing efforts going there. And also, you'll see later in the year more of a direct consumer advertising program specific to Dupuytren's. So we feel good about where that is -- where that direction of those 2 end-market indications are going. And I think on the cellulite side, obviously a lot of excitement regarding XIAFLEX. And I've been doing this for a series of years and very seldom can you say a product is your R&D pipeline. In particular case of XIAFLEX having the Peyronie's indications and the Dupuytren's moving to cellulite, and we could talk in a second, there's probably other indications that we will focus on eventually. But we're quite excited, and we reported back in the December time frame about our Phase IIb clinical trial and study there. Quite exciting, very favorable. We are advancing to Phase III. It'll -- Phase III is likely to kick off. It's about a 420-, 425-patient study. That'll kick off somewhere around late third quarter to early fourth quarter, so favorable early signs. We are starting our market assessment. And initially, we feel reasonably good and it's quite exciting when we look at potential for cellulite. We're hoping later in the year, we'll be able to provide a little more visibility what we think the value is. But when you look at the population that cellulite touches, there's about 157 million women in the United States. So when you start to synthesize down that pool, there's about another 30 million of self-reporting individuals that have cellulite. And then when you take that pool and you synthesize it down a little bit lower, you've got about 2.3 million users of injectable experience. In a polite way of saying, this is probably about 2.3 million individuals that have some type of experience with Botox. So when you look at the sheer nature, we feel good. It's a little bit early, but we'd like to try to be able to share a little bit more later in the year. Now we talked about investments. We're looking at direct-to-consumer advertising. We're looking to be excited about Peyronie's and Dupuytren's moving forward with the clinical trial. A lot of time and investment, we're preparing for success. With that, comes the point that, at the end of the day, you want to have longevity and it gets back to your intellectual property. So we have 1 patent that's focused on the purity of collagenase. We're real excited about that. That's a very solid patent. I'm not going to get too far into the details, but that patent expires in 2028. So it's a good runway, the way the clinical trial is scheduled. And by the time you pay your PDUFA fee and plan for success, we're hoping that with success that we'll be launching somewhere around Q1 of 2020, give us a minimum of an 8-year runway. But on top of that, we have a series of method and manufacturing patents that are in process.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

What do you think would be the key drivers of -- what do you need to do to get the existing indications to their full potential for XIAFLEX?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

So again, we are -- we have a new team in place, a new view in terms of how we're looking at Peyronie's and Dupuytren's. And I think at the end of the day, we're taking a very simple approach. Up until January this year, we were very broad, and we were spending a lot of effort into products that included pain. We've got a very narrow focus. I think the message here is just that, when you look at Endo and you look at us moving forward in the brand side, we are laser focused on XIAFLEX. So it's getting nearly 100% of the attention. So I think that, when you look at our marketing

dollars and you look at our R&D dollars, they're really -- they're tied to a very narrow specific area. So more to come, but we feel that both Peyronie's and Dupuytren's has good growth potentials, and we're very excited about cellulite.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Moving on to the generics business. This year, obviously, you're benefiting from the launches of genetic versions of ZETIA and SEROQUEL . Can you talk a little bit about the pipeline, how do we see the commercial potential for the pipeline beyond 2017 and whether you'll be able to replace some of the revenues from these 2 products? And also talk a little bit about the biosimilar opportunity, if you guys are looking at investing in that part of the business.

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Okay. So the starting pointing point is that, unfortunately, we really can't give a lot of visibility into the generic pipeline post 2017. We don't want to provide guidance at this point in time, and then we don't want to put ourselves at a competitive disadvantage. But that said, when you look at what we've achieved over a series of years, when you look at the Par generic team, we are, in essence, filing about 20 to 25 products per year, and we're launching about the same number of products. And we've been pretty candid about this, what we're interested in pursuing and what we're not interested in pursuing. All products are important, but not all products are equal. So you're not going to see Par come out as a company that is focused on commodity-based products on a go-forward basis. We've been pretty candid about that. We want to stay away from areas that have 4 or 5 or 6 competitors. Sometimes that's inevitable, but that'll happen over time. We're focused on Paragraph IV, it's about probably 75% of our portfolio is focused there. But when you look at our 120 products that are filed with the FDA, about 1/3 of those products are either first-to-file or first-to-market products. So that's the general focus of where you're going to see us going, how we should be looking at the pipeline on a go-forward basis. The other area is the obvious. We've been pretty excited about our sterile injectable side. We acquired a sterile facility 2 years ago in February. We've invested in it heavily. I think it's an exciting time to own and operate a sterile facility on U.S. soil. I think that gives us an advantage from a service level and a compliance level. We've had a lot of successes with VASOSTRICT and hopefully, ADRENALIN and ephedrine are coming. But there are a handful of products that came out of our Rochester's facility like fluphenazine and dexmedotopidine, smaller products that have been historically good drivers of EBITDA for the company. So you're going to see a lot of development in R&D going into the sterile side because we think we have longevity in that regard. Biosimilars are near that we're not going to play in. I think when we look at the cost to entry and the uncertainty around marketing, I think there's areas that we can, as a company, put our R&D dollars to better use. On the branded side, I think it's obvious. We already have a BLA with XIAFLEX. I know that's not what you're really talking about, but we certainly have our fair share of focus on XIAFLEX. We like polypeptides and peptides chemistry, that's an area that we've had success. And VASOSTRICT is a polypeptide. And we recently announced that we had submitted and we were first-to-file on a product called teduglutide, very difficult product to make and manufacture, so we had a manufacturing partner on the raw material side. And that was a product that we developed in-house at Rochester, our Rochester facility. That's where you're going to see us. That's where you're going to see Par play in terms of go-forward basis on R&D.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Can you talk a lit bit about VASOSTRICT? It's obviously being a big driver of growth in the sterile injectable side. It's tracking almost $400 million in annual revenues based on the quarterly run rate. What's the growth trajectory that one should expect? And what's your take around competitive entry products? Even also maybe talk a little bit about the Fresenius copy issue around the API?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Sure. So I think, again, something that we're incredibly proud of, and we've created a $400 million product that's taken a lot of really blood, sweat and tears from the company, a lot of investment in the Rochester facility, a lot of CapEx, a lot of commitments to the FDA. In terms of the size of the product, I think in a max -- the maximum of number of TRxs back in the day, was somewhere around 3.6 million units. I think it may have leveled off to somewhere around 3.2 million, but I think that's about the right number. And the crux of that number really was converting the unapproved drugs to our approved product. That's happened, right, that's happened at least a year, maybe even 14 months ago. So the ability for that market

to grow is unlikely. I think we've maximized that, and I think we've done a good job. So from a share volume standpoint, that product is maximized. Then what we've done is -- I think you should look at it as Endo approving mindful, thoughtful price increases. It is a brand, it's an NDA. So when you say that run rate's around $400 million on a go-forward basis, that's about the max that you'll see that. And then you should just anticipate maybe just typical mindful increases on an annualized basis. In terms of competition on that particular product. As of today, we have not received any notifications of a Paragraph IV. So that's encouraging from our standpoint. So we -- there's nothing blocking anybody from filing an application. So it's basically every day that we wake up, we come to work and there's no Paragraph IV, that's a good day, right? We are continuing to watch. And then your question on Fresenius, we don't -- we typically don't get into or talk a lot about ongoing litigation. I think, in this particular case, what we're simply saying is there is -- I believe the suit against us is tied to API contracts and who we partner with. I think we've been pretty candid throughout the last 6 or 8 months that we have 1 exclusive agreement in place. So let's see what happens within discovery, we'll move forward. But today, we -- as I had said several months ago, we have a single contract that's exclusive. And I don't believe that to be any unusual, specifically for brands, it's not unusual to have exclusive arrangements. And there are other sources out there that companies can contract with, and today, there's multiple sources.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Okay. Going back a little bit on the -- I suppose the base genetics business is concerned. Where do you -- do you see this business inflecting at some point? Or is it something that -- is this -- is the downdraft that you've seen in the last 2 years more cyclical? Or is it secular? And how should one look at the trajectory going forward?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Okay. So on the base business, we just try to tie it back to changes in consortiums, and I think that is something that we've communicated. We've been pretty candid about. So where we had seen challenges in our, for the most part, our commodities business and a little bit of our pain business was through the consortiums. And then actually, that also was magnified by additional approvals on scheduled products. But to answer your question, as you start to see changes within consortiums and in particular you have the ClarusONE consortium, which everybody now knows that Walmart is now a part of, that's part of the base erosion that we talked about for Par. A lot of that doesn't surprise me, only from the standpoint that, for years, when you looked at the 4 consortiums that included Red Oak and WBAD and Econdisc and -- Red Oak, who am I missing? I'm missing one more, WBAD, Econ, McKesson, thank you. So that's a OneStop. So what doesn't surprise me is that Walmart always dangled out there, and they ultimately had to make a decision, were they going to try to go as the solo fifth player representing around 6 or 7 share or join with a consortium. So some of the erosion that you see is because of obviously Walmart joining with OneStop and now ClarusONE. On a go-forward basis, what I had said and I still believe this is that base erosion will continue absent of really normalization within the consortium. So if there are additional changes within consortiums, there's going to be an ask. Whenever a major players switches in or out, historically, the consortiums ask for an ask and your portfolio could, in essence, get bid out. Our view was having 4 solid players that things would normalize, absent of a chain. So about 2 weeks ago, Econdisc announced that they would be joining WBAD. So now it's going to be wait and see what happens there. We had been in contact with Econdisc, and they had sent out a notification that, stay the course, they typically have a 2-year bid cycle and their bid kicks in, in July. So that has been determined. We already know the impact to that. So I think to answer your question from a base erosion where the market's headed is it should be kind of status quo. We'll deal with ClarusOne for 2017. You'll get through 2017, knowing that you're going to deal with ClarusONE. You're going to get to 2018, and you're going to have to deal with Econdisc becoming part of WBAD. Econdisc bids go for 2 years. WBAD goes for 1 year. Next year, the WBAD contract is going to be up. Let's see what happens, I'll speculate. I don't know this, but I'll speculate that Econdisc will join WBAD, and there'll be an ask in 2018.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

But this will primarily be a pricing impact, right? Or is it going to be a mix of pricing (inaudible)...

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

At this stage of the game, it's all price. I mean, price volume, the way you look at the commodities business, to me, it's -- if it's volumes because you can't support the price at this stage of the game.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Right, right, right. I mean, I wanted to move on to the balance sheet. Obviously, you've given a commitment to reducing levels at 3x to 4x of the business trends have pushed that out. How do you see this playing out, particularly in the context of some of the commitments towards the mesh litigation results, possible of constraining your free cash generation?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Yes. And again, I think we've been pretty candid here that when I took over as the CEO of this company and I've said pretty candidly, if people are looking for a fix in 2017, I am going to disappoint you. If you want to be patient, then we can weather through some of the rough waters here. We will get to a position to be able to delever. We can't quantify the exact date, but we're here saying that we are committed to delevering and we're going to take a very, very mindful approach to capital allocation. So you're going to have to be patient. It's a multiyear process. I think the case management order is a positive step, but it's not -- it doesn't bring resolution. So our goal is, hopefully, we can bring closure to mesh, but that's yet to be seen. But we'll be pursuing very mindful, thoughtful capital allocation, and we are committed to delevering.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Could you just talk about what do we see -- I mean, what's the best way to model mesh-related cash flows going forward?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Sorry?

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Mesh-related cash flows going forward.

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

I think at this point in time, we just -- we don't have visibility. So I think -- I'll apologize for saying this, but you're going to have to be just patient in that regard.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Just want open it up to the audience if there are any questions that they would like to ask.

Unidentified Analyst

I was just wondering if you could talk a little bit more about the process (inaudible) going forward?

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Sure. So the situation with OPANA was we -- when we came to the follow-up meeting last Thursday, the intent from the Endo side was to talk about collaboration and talk about ways that we could work with the FDA in terms of keeping our product on the market in an area that we could focus on things, such as labeling, REMS and/or perhaps a formulation change. So the decision for us to come off the market, while not a surprise, we knew that was always the case, the timing of it was probably slightly disappointing because the intent was more of a collaborative approach. That said, there's a lot of specifics tied to this product. There's about 50,000 scrips per month, and we've got to be very mindful about those patients that use the product as it is prescribed pursuant to the clinical trials. So the request to voluntarily remove the product is one thing, but it comes with a lot of other questions that are unanswered. So we need to -- we are attempting to communicate with the FDA to find out what they like us to do. At the end of the day, there's 50,000 scrips per month. You've got drug-drug interaction issues. There's a lot of moving parts to it. So while the communication to voluntarily remove the product, it comes with more questions. So that's -- we're working through those issues. There is a formal process if we choose to pursue. It's called a notice of opportunity hearing. We're not there as a company. It is an option that we could consider, but I think our starting point is, is that we need to understand what the FDA is thinking, what they'd like us to do about certain other commitments that we've made such as Phase IV trial commitments as well. There are some other -- there are open questions that we still need to understand. We got a little more time.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Any other questions?

Unidentified Analyst

Can you talk about the FDA approval process that (inaudible) accelerated and whether or not the company that's (inaudible).

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Okay, so that's a great question. So I think there was an announcement yesterday that last month was the second highest both approval and tentative approval process from -- since PDUFA 1 had been implemented. So I think that's viewed -- that's obviously viewed very favorably. So I think when you have to look at that from an industry-wide perspective, that's obviously very good. You're going to see more applications. You've heard Commissioner Gottlieb make his comment that he wants to see quicker approvals. He wants to see 3 approvals per drug. So from an industry point of view, I think that's very favorable. When you look at Par from the generic point of view, I'm not sure that it's technically a huge benefit one way or another. A lot of our portfolio is tied to Paragraph IVs. So as I said, about 1/3 of our portfolio is confirmed first-to-file or first-to-market but about 75% or 80% of our portfolio contains a Paragraph IV. So while PDUFA is speeding up the process, you got to also calculate companies that Paragraph -- that file Paragraph IVs, you're in a 30-month stay. If you're victorious or you lose, there's an appellate process. So it kind of neutralizes the -- that process. If you're filing Paragraph IIIs, that's a benefit, but that's not really our business model.

Shubhomoy Mukherjee - *Goldman Sachs Group Inc., Research Division - Research Analyst*

I think we're just out of time. I want to thank Paul for his time, and thanks to all of you for attending. Thank you so much.

Paul V. Campanelli - *Endo International plc - CEO, President and Director*

Great. Thank you so much. Thank you.
