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PRESENTATION

Chris Schott - *JPMorgan - Analyst*

Good morning, everybody. This is Chris Schott, pharmaceutical analyst at JPMorgan, and very pleased to be introducing Endo this morning. From Endo, we have Paul Campanelli, the Company's President and CEO. With that, I'll turn it over to Paul.

Paul Campanelli - *Endo International plc - President & CEO*

Thank you, Chris, and thank you all for being here today. On behalf of the Endo team, we all do appreciate your interest in Endo. With that, just take a second to browse our forward-looking statement. And with that, we'd like to just get right into the presentation.

I think as some of you might know, I've been the CEO of Endo since around September. And what we've been doing -- I've been working very closely with the Endo leadership team to really evaluate how we can look at best positioning our company here on a go-forward basis to really create long-term value and sustainable growth. That's going to be the key of our theme here.

Some of the think that we're able to talk about today that we're proud of, we -- back in November, when we had our Q3 earnings call, we were able to talk about and communicate and delivering solid topline and adjusted line results. At that time, we did reaffirm our guidance, and we are also pleased today to once again reaffirm full-year 2016 revenue and adjusted EPS guidance. So, feeling very strong about that. You're also going to hear a lot about operational execution coming out from the Endo leadership team.

And with that, we are very pleased again, later in the month of November, we did communicate the statistically significant positive Phase IIb results for cellulite coming with our XIAFLEX product. So we'll talk a little bit more about that in the presentation. And again focusing operational execution, while we're making some decisions on the direction of the Company, we successfully launched two very important first-to-files that I think everyone is fairly aware of with SEROQUEL XR and ZETIA. Again, we'll talk more about that in the presentation.

When I first became the CEO back in September, we talked about unification of the Company, centralizing the Company, and taking a real strategic view of the Company and focusing on this operational execution. One of the very first things that we did was, we looked at the executive leadership team. One thing that became very apparent to me is that we needed a COO that would have visibility across all three portions of our business, all three segments. Terry Coughlin is an individual who has worked with me for years, had been the Par COO. Terry is now the COO of Endo and having complete visibility on not only the generics, but the brand and also our international business. I think that's going to give us an advantage. I think that's going to allow us to make strong decisions on a go-forward basis.

With that, we also talked about a product-by-product assessment on all our businesses. And one of the items that were a little bit challenging for us, but I think as everybody does know the opioid market, the pain market is a challenging market for Endo right now. And with that, we had to make a tough decision, but we did return BELBUCA to its developer BDSI. And with that, we had to eliminate our 375-person pain sales force and business unit. But it gives us a sharpened focus on our specialty business. We'll talk a little bit more about that again, having successful Phase IIb results on XIAFLEX. We're excited to really put our focus into that. And again, we're going to continue with our strategic review and evaluation on a product-by-product and business segment approach.

And lastly, we will be communicating our Q4 results and 2017 guidance, as well as an update on our strategic assessment in February at our next earnings call.

Just taking a real quick look at some of our financial snapshots, our revenue through Q3, you'll see that our branded division came in at around $877 million. That represents about 30% of the total portfolio, and that realized a slight decline in revenue of 3%. The U.S. Generics business came in at around just under $1.7 billion, represents approximately 60% of the total portfolio, again, benefiting of the acquisition of Endo by -- the acquisition of Par by Endo. And then on the International side, International sales representing around 10% or $209 million.

Further, so in totality for nine months for 2016, our revenue was just under $2.8 billion, our operating income was just over $1 billion and our diluted EPS was around $2.95, again, all benefiting from the acquisition of Par by Endo.

In terms of reaffirming guidance, we're pleased once again here today to reaffirm guidance and showing revenue at $3.87 billion to just over $4 billion and our adjusted diluted EPS around $4.50 to about $4.80, again reaffirming guidance and looking forward to providing 2017 guidance at our February earnings call.

Now, moving to our brand division, we're pleased to talk a little bit about our specialty business where we have successfully had a full year of XIAFLEX. XIAFLEX in essence grew by around 24% to around $134 million, and also SUPPRELIN LA, which is also part of our specialty sales force, grew by around 9% to around $58 million. In totality, the specialty business grew by around 19% for 2016.

And I think as most of you know, where we -- we had some challenges -- challenges came in our pain segment. So while we declined in the area of around 20%, areas that specifically were challenging, we did receive generic competition on Voltaren Gel, we received additional competition on LIDODERM, and again, we had additional competition or deeper competition on OPANA ER. Just bringing to your attention that we had about three months of brand value in 2016 for V Gel, so this is something that we want to make you aware of.

On the other branded side, we did have a slight benefit of around 11%. Again, that was due to the acquisition of Par by Endo whereby there was three small brands that were brought into the other branded category. That would be Nascobal, Megace and Cortisporin-TC, three products that helped benefit. Again, just pointing out to everybody here that we did have some challenges and we received generic competition on FROVA, triptan, in March. So again, a couple of months of benefit on the branded side, just pointing your attention to potential headwinds for 2017.

Moving over again a little bit into the BELBUCA. Again, this is an area that was a bit challenging for us. Part of pain obviously is a legacy portion of what we do at Endo. So it was a very difficult decision, but as we evaluate all our businesses, we need to put Endo in its position to succeed on a go-forward basis. With that, we ended up returning BELBUCA to its developer, BDSI. And as I said earlier, we ended up eliminating a 375-person sales force. With that, we had restructuring charges around $60 million and we will realize around $90 million to $100 million in annual run rate pre-tax gross cost savings in 2017.

Our intention is to reinvest into our specialty business. We'll talk a little bit more about XIAFLEX from both the cellulite indication, as well as Dupuytren's and Peyronie's disease. Leaving us with a sales force of around 200 individuals promoting, again, XIAFLEX for two indications, SUPPRELIN LA, TESTOPEL and AVEED, as well as NASCOBAL. So around a 200-person sale force remains.

As we focus on XIAFLEX and our specialty sales force, what we are very excited about for the nine months ending in 2016, as I indicated, we realized about $134 million in revenue. With that, the breakdown is about 55/45 between Peyronie's disease and Dupuytren's. So we think this is an area that we're pretty excited about. Vial demands were good with around a 12% year-over-year growth. We do expect that when we finish out and complete our calculations for 2016 that our revenue growth will be in low-double digits. We feel good about the IP going out to the late 2020s.

And then when you look at the potential opportunity on a go-forward basis, in Peyronie's disease, right now there is around 85% to 90% of the patient population that remains untreated. Conversely, in Dupuytren's, there is around 65% to 75% -- 65% to 70% of the patients that remain untreated. So we think this is an area that you'll see additional investment, specifically in direct consumer advertising. This is an area that we want to have additional focus and we think it's a growth opportunity.

Now moving over to XIAFLEX for cellulite, we're real pleased and proud to announce successful Phase IIb results coming out of November. What we are pleased to say -- it was highly statistically significant Phase IIb results for both our primary endpoint as well as all secondary endpoints, so

a good foundation. We have our end of Phase IIb meeting with the FDA later in February. With some success, we will move forward in clinical trials in the June time frame.

If we take a step back and just take a look at exactly the anatomy of cellulite and what we're dealing here with is, when you look at cellulite, in essence what you have is these thick fiber band like material, which ultimately is called septae. What happens over time is as you age, the septae becomes tighter and contracts. And what's happening is, the septae is connected to the epidermis and also connects to the muscle. Over time as you age, the septae starts to shrink. That pulls your skin down and that's the dimpling effect that you see in cellulite.

When you go over to the middle slide here and looking at Subject A, which was a placebo treatment, our study was a 71-day, three-treatment session. Obviously in placebo, there is no obvious difference. When you look over to Subject B that was ultimately treated with our collagenase clostridium histolyticum, which is the name for XIAFLEX, after three treatments in 71 days, you're seeing a significant improvement in cellulite. So good start, we have our end of Phase IIb meeting with the FDA later in February, and we're positioned well to not only develop it, but produce the product.

Now, from a marketing standpoint, we need to keep our optionality open. That's one of the things that we're going to -- that we want to communicate. Over the next several months, we'll continue to assess the potential value of the product. But what we can tell you today is in the United States, we have about 157 million females. For the most part, cellulite affects 85% to 98% of the female population. And for the most part, cellulite starts after the age of 14. So we've got a foundation of around 30 million women that are identified with self-reported cellulite. These are some of the factors that at least will give us an understanding that we have a very valuable asset. But as I said, we are going to continue to assess and continue to keep our options open as we learn more about the potential value of this product.

Moving onto our international side, this is an area where we had some erosion, around 8% in totality as I indicated. It was around $209 million of sales for 9 months in 2016, slight erosion. We kind of break our international into two segments: Paladin, which is our North American International subsidiary focused on regulated markets; and then Somar and Litha, which are in essence our emerging markets. Paladin represented around $100 million of sales, Litha and Somar around $109 million in totality.

Paladin's solid performance across its base business -- we onboarded two products, Nucynta and of course XIAFLEX. We're really pleased about that. We've got a couple of products that are performing very well; Dostinex, Tridural, to name a few. And also we have a clinical trial running in conjunction with Novartis on a product called serelaxin. Serelaxin is indicated for acute heart failure. We will have clinical trial results probably in the March time frame and have an understanding what that potential value would be coming through our Novartis joint venture. That said, it is a bit of an eroding entity, so we are going to be watching it very closely.

On the Litha-Somar side, they are slightly growing. But as I said, we are going to continue to evaluate all our entities and all our products within both international brand and generic. This will be an area that we will be focused on.

Regarding our generics division, so as most of you know, Endo acquired Par in September of 2015. We were charged with at Par, integrating the Qualitest generic into Par. When we did that, we were also charged with really right-sizing and restructuring the company, having to make some tough decisions on the portfolio, facility and some people. So ultimately, what we've done is, we've made Qualitest a very, very strong company now. So historically, there has been some concern that Qualitest was focused on mature immediate release type brand products. I would tell you that when you look at this entity now, it's completely blended into the Par family, per se.

We are focused on size and scale, we're focused on supply chain, and we're highly compliant. We'll talk a little bit about some of our technology opportunities in a second here. But when you lump that together, our total generic positioning in the United States is around 5% of the total IMS sales, putting us as the fourth largest company in the United States. That's important as we are forced to compete with some of the larger players as well as some of the smaller disruptors. Consortiums are getting stronger. I think most of you know that there are four strong consortiums. There's a fifth smaller consortium that is coming into effect. But ultimately, the four large consortiums represent around 90% of the buying and selling in the generic industry, and we think that we're positioned to push back and launch products on a go-forward basis.

So a little bit about our technologies. Again, for those who have followed Par over the years, historically, Par has been known as a company that focused on immediate release products, tablets and capsules. Since 2010, we've really transformed the company in a lot of different ways. Today, we make not only tablets and capsules, we're focused on immediate release products, modified release products, long-acting delayed release type of solid oral dosages. We can make creams, ointments, ophthalmics, [ODECs], nasal sprays. We make vials and we make prefilled syringes, thin films and patches. In essence, it's actually easier to talk about what we don't make. Today, we don't have the capability to make soft gels, although we have some good partners that we can contract with for that capability. And we also don't focus today on metered-dose inhalers.

I don't want to misrepresent. We haven't focused on biologics today, but it's important to say as we centralize the Company and we have visibility through all our businesses, the generic team now has visibility to our Horsham, Pennsylvania plant where we do make XIAFLEX. We do have capacity. And with some smart intelligent product selection, it's possible that we can start looking toward some biologics coming out of Par. So a good set of technology. This is going to be very important as we want to position ourselves against some of the larger players.

So when you look at our year-over-year results for the last nine months, again, generics represent about $1.7 billion in total sales. It represents around a 58% increase year-over-year. Now again, getting the benefit of the Endo acquisition of Par into the Qualitest generic arm. So ultimately, you've got to break this down, you've got to look at the sterile injectables side. Last year, we generated about $387 million for the nine month period for injectables. Around $249 million of that was coming out of our Vasostrict product. Very, very proud of that. I think most of you folks know, it's a 505(b)(2). We obtained Orange Book patent status, something that provides some visibility for at least the near term.

New product launches in alternative dosage forms, again, that's an area that we're going to be spending an enormous amount of focus on, and that kind of goes back to our technology breadth that we talked on the previous slide. In totality, we've got over $350 million in sales, representing around a 3% increase in this particular segment. This is an area, along with the injectables, that you should expect Par to invest more on the R&D front.

But I want to bring your attention to base business. Now, what we did at our last earnings call, we talked a little bit about our base business declining quarter-over-quarter in the area of around 20% and we also talked a little bit about on a year-over-year basis that we saw around a 30% decline. And we just want to point out that the consortiums are still concerning. On a go-forward basis, when we called this out at our Q3 earnings call that there have been some challenges. And it wouldn't surprise me, as we look at our base erosion in 2017 year-over-year, if we don't see similar results in terms of the 30% base erosion. We've yet to see the impact of McKesson with Wal-Mart. And any time you see a change in consortium, there's going to be an ask. So we're gearing up for that. We're forecasting for it. But you just need to be aware that we believe that it's possible it may continue.

That said, like anything else, our best defense is our ability to launch products and file applications. 2016, we launched approximately 20 new products, represented around $11 billion in market value. Two key first-to-files, again, was the SEROQUEL and the ZETIA products. You'll recall that SEROQUEL XR was in a settlement agreement with AstraZeneca. We have 180 days of exclusivity. Also in ZETIA, we launched ZETIA on December 12, again with exclusivity under a settlement agreement with Merck. For the most part, these products have behaved according to forecast and to plan. And recall, we will get the benefit of the carry-over of launching these products in the fourth quarter and also getting the benefit of a partial Q1 benefit from the first-to-file positioning.

We filed 27 products in 2016. We're very proud of that, specifically with the new stability requirements. 21 of those were ANDAs, two European dossiers. We still have a small European presence. We filed one 505(b)(2). We're still strong in 505(b)(2). It will continue to be a focus. And we have three Prior Approval Supplements. And the reason we call it the three Prior Approval Supplements is, all of these submissions are going to be creating value for Par and Endo on a go-forward basis.

We completed the restructuring to rationalize the generic product portfolio, and we're going to estimate around $60 million in annual net run rate savings to be fully realized in 2017. Again, some very difficult decisions coming out of Par, looking at people and facilities, specifically and our Charlotte, North Carolina manufacturing facility.

Now, a little bit about the pipeline. When you look at Par, it's robust, which we believe it to be. There's about 117 products on file with the FDA. They represent about $32 billion in sales. We've got several research and development platforms that are working on about 88 products. We've

got two internal R&D sites, one in Chestnut Ridge, one in Chennai, India. We're focused on injectables and modified release products in our Chestnut Ridge facility. And on the external side, we are also focused on business development, all three platforms giving us a robust R&D pipeline.

Clearly we're focused on Paragraph IV and first-to-file. When you look at our first-to file and first-to-market opportunities, we've got about 39 products. When you look at the total files, it represents -- about a third of the portfolio are in line first-to-market products, something that we're very proud of.

A bit of a snapshot on our pipeline that we're anticipating product launches between 2017 and 2019. This is not meant to be at all all-inclusive, but I think it gives you an idea that we are not just a company focused on immediate release products. We've got injectable products here. We've got some REMS programs that are quite challenging here. We've got patches. We've got thin films. We've got in essence products that take small clinical trials. And I think these are -- we're showing you the barriers to entry that we're clearly focused on at Par Pharmaceutical.

In closing, I just want to reiterate some of the key highlights that we accomplished in 2016. We are clearly focused on operational execution. We've got a new leadership team. This is a proven team, focused on execution. We've centralized the Company. We've got a new COO. We've got a new CFO in Blaise Coleman. Blaise is here with me today. We'll be answering your questions on our breakout. We've made some tough decisions and quick decisions on BELBUCA, as well as our Charlotte manufacturing facility. We've reorganized and at the same time, we're clearly focused on operational execution. XIAFLEX remains a core focus. We continue to launch products and we filed 27 total submissions in 2016.

So in closing, we have a strong focus on our strategic evaluation. We're going to continue with our product assessment, and we look forward to providing you more visibility in February at our earnings call.

So with that, that's concluded my presentation. And we will be doing a breakout at the Olympic Room, Chris? So thank you all for being here today.