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ENDP - Endo International PLC at JPMorgan Healthcare Conference

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PRESENTATION

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. Good morning, everybody. I'm Chris Schott at JPMorgan, and very pleased today to be introducing Endo. From the company, we have the company's CEO, Paul Campanelli. And we're going to be doing a fireside chat format for today's presentation. So first, Paul, welcome, and Happy New Year.

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

Thank you, Chris.

QUESTIONS AND ANSWERS

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

So maybe just to kick it off, it's obviously been a fairly busy few years for Endo. So as we kind of think about 2018, maybe just share some of your thoughts in terms of company's positioning, opportunities and just your kind of look at year ahead kind of look for Endo?

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

Yes. Sure, thanks, Chris, and it's a pleasure to be here. I think, as we look at -- on a go-forward basis, it's probably just worth just to spend a moment in terms of what we've done. When we say it's been a busy couple of years, frankly it's been a very busy last 12 months for Endo when you look at what we've done. So it's a different operating model, I think, as most people know. We centralized the operation in terms of how we actually, in essence, operate as a company. We've made some decisions that have been difficult on people and facilities over the last 12 months and we've communicated those on our generic side, what we've done with our manufacturing plants in Charlotte and as well as in Huntsville. Again, very difficult decisions, but it kind of leads up to, on a go-forward basis -- before I get there, we obviously also had to make some tough decisions on our branded sales force, in pain in particular, given what's happening on opioids and CMS. But these were all things that we really needed to do, Chris, in order to put ourselves in a better position to compete long-term. So we've looked at efficiencies, we've looked at smart product selection on the generic side, and that's where we're headed on a go-forward basis on the generic side. So you're going to see a lot in terms of Paragraph IV on the side of oral dosage, but then particularly on the injectable side that we're excited about. And I think, we've positioned ourselves for an agile, nimble branded division led by Pat Barry, our head of sales and marketing is actually here with us today. But we're real excited about what we're doing on the specialty side of Endo on the brand side.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Great. Maybe digging first into the generics, and we'll transition over to the specialty side. Just maybe just to frame things out initially, maybe key pushes and pulls we should think about, given all the activity last year as we think about 2018?



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

Yes, so in terms of some of the pushes and pulls, I mean, we always -- we would love to be able to shed some color on the pipeline. It always starts with the pipeline. And unfortunately, we hesitate to place color there because we can't place ourselves in a competitive disadvantage. But things that excite me is, is that while we've all navigated, on the generic side, through some rough waters with consortiums and whatnot, one of the things that we're really focused on, we continue to be focused on, is operational execution. We talk a lot about that. And I think we've done a good job in that regard, specifically products like CIPRODEX and AFINITOR, dexlansoprazole, products like that we've developed first-to-file, and we've settled those out. So we're excited about that. On the risk side, it's a little wait-and-see on the consortiums, right? So it's a little bit more of what will 2018 bring.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Yes. And maybe elaborate a little bit more on that. I mean, it seems like we've -- I think, I was remembering this, we were talking before, heading into this conference last year, I think, there was, it seemed like, some concern about pricing getting worse. Your thoughts on just pricing as we're into 2018, we've been through some of these consortiums consolidations, we've got obviously one still ahead, but how are you thinking about pricing this year?

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

Yes, so again, if we took a year -- if we took a step back, going to JPMorgan last year, I think, it's where we came here and we, I think, we delivered a strong message in terms of talking about what ClarusONE would mean to the generic industry, and I think we got it right. And in an unfortunate sense, we called out that there was going to be some challenges. Folks are looking a little bit to us in terms of how we see 2018 materialize. And the reality is, is I don't have a clear feeling in terms of whether we're going to see further erosion. I think it's a little bit of a wait and see situation. And that's probably a good thing for the most part. What we have seen is, last year, when we were sitting here, we had 4 consortiums. This year, we have really 3 consortiums. And when Econ just joined with WBAD, and Walgreens and AmerisourceBergen in particular, what we immediately saw was a request for an equalization on the portfolio. So from that standpoint, there was some erosion, and I would almost characterize it a little bit as normal course. What we don't have visibility to is, is will there be a full line bid process similar to what ClarusONE and Walmart did. So it'll be wait-and-see. Now the only thing is, maybe it's a little bit different and I think that's something that we like to shed a little bit color on. When ClarusONE came into formation, what you didn't have was a company like Walmart that was already part of consortium getting perhaps the benefit of a larger buying group where Econdisc already had and already went through a bid process in July. So we just don't know what their motive will be. We got -- we dealt with equalization but it'll be -- time will tell whether they'll come out and do a full line bid, but just a little bit different between ClarusONE and WBAD.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Is it fair to think about, given that dynamic, that the impact this year may be a little bit less than what we dealt with, with ClarusONE dynamics last year?

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

Yes. So at the end of the day, and I'm not trying to avoid the question, it's just that we just really don't know. If we don't see a full line bid, I'm hoping that we can see more stability. And a lot of times, we use this term normalization. I'm not sure what normalization is anymore. I think, we've got a new market here, so it really gets down to what we have as stable market. So fingers crossed in that regard, but unfortunately, it's really going to kind of point to what happens with Econ. I think, the other thing that I -- where my antennas are up a little bit, and I'm not trying to raise any cause for concern, is that over the last year to 2 years, we've talked a lot about ClarusONE, we've talked a lot about WBAD, but let's not forget, Red Oak is still very active, and we've got to be mindful that they're not going to want to see themselves falling into a lag position, not that they are, but you've got to be very aware that it's not just that Econdisc and the WBAD consortium. If that stabilizes, there always could be another ask. I mean, you've got to be mindful of that.

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Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Sure. Maybe just a longer-term kind of thoughts around, in general, with this consolidation you've seen of the purchasers of U.S. generic drugs. I mean, how does this ultimately play out? I mean, do you think we do hit a point of stability where the industry just says, enough is enough, or is this a process of it's going to be ebbs and flows but there's just going to be incremental pressure by these organizations, given how much scale they actually have at this point?

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

Well, there's a couple of different ways, I think, I would look at that. I think, the view that there's stability means that you're going to go months without any asks. And I think that's probably wrong. So I think there's always going to be the (inaudible), right? So you're always going to have some pressures where you're always going to have some change in the market, and that can just simply stem from another competitor coming to the market or somebody falling out. And that, what we're seeing right now is, is even in this stabilized view of the consortiums, that I think (inaudible) are always going to be part of the ask from the consortiums. And then, I think, it just gets down to how generic manufacturers look at their own personal strategy, right? So you've seen a lot of change, consolidation, you've seen efficiencies across-the-board, right? So we know what Endo's done. We heard some of my competitors have done here, more towards U.S. manufacturers. And they focused on efficiencies, right? And I think that's what they're saying is, and what we're saying is, is that we are going to move away from commodities. I think, some of the offshore players continue with their play on volume, and that can create your ebbs and flows that you talk about. So when I look at the offshore folks that have strong positions in API, I think they're going to continue with that approach, where we'll take a more efficiency approach in terms of being very select in our portfolio.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Okay. That makes sense. Last question is on those consortium dynamic. Do you see the opportunity from new entrants, I think, Amazon as an example, has been talked about quite a bit, that might help refragment the channel? Or is that something that's either a low likelihood or it's going to take a while to get to a point where it offsets these other dynamics?

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

So we've been asked that question a lot about what -- can an Amazon break in. And I think, our view is, is that they certainly can break in, right? And they're going to have to align themselves, and we all kind of get this. They're going to have to partner with a PBM, they're going to have to figure out how to adjudicate claims and whatnot. That's doable, right? And I think the market is ripe for an Amazon-like entrant. I think, where we -- we try to get a little bit out and front of that. And what that does mean? So you'll ultimately partner with an Amazon. You'll get part of your portfolio under a contract. And I think, initially, you'll feel good about that, but you just got to remind yourself that terms and conditions will be, what will their ask be, what will happen after you have products under contract because where you lose leverage is once you're under contract, right? So that's the name of the game with consortiums. And my view is, is don't ever underestimate the strength of these 3 consortiums that are controlling tens of thousands of pharmacies, right? So while we want to raise our hands and say that we want to welcome a third entrant, we are. But today, our trade partner -- I mean, the Red Oaks and the WBADs and ClarusONEs, for all the chump, they are our partners, right? And we need to learn to continue to work with them through this assumption that a third-party -- or a fourth-party, rather, will eventually break into the consortiums.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Yes. Now when I think about some of the challenges this space has been through, it seems like on one hand, you had this consolidation of your customers. Also going along with that is we had what seems like a pretty dramatic acceleration of ANDA approvals out of FDA. What do you think this elevated level of approvals, if that further accelerates, what does that mean for the industry? What does it mean for Endo? How do you -- how big of a factor, I guess, is that in terms of how you think about your business and about the opportunities you pursue?



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

Yes, it was a great question, but I think you kind of just hit the nail on head. It really depends on what side of the coin that you're falling to. So industry-wide, obviously, I think there was about 180-or-so approvals in the last 2 months, right? It's about 180, 190. But there was less than 10 new product approvals, right? So I think it's just a matter of where do you play in that game. So again, assuming offshore companies, backward integrated into API, then there could be some value on -- and maybe even its top line sales. The example that I focused in on is, recently, Par launched fluoxetine hydrochloride, Prozac, July in 2001. In 2001, I think, that came off patent. But 3, 4 months ago, I saw an offshore company come to the market, you scratch your head a little bit in terms of do you really a player like that. I will assume that, that player has a rationale where, whether they're backward integrated, that would have value. So from that standpoint and industry-wide, it really just depends on what side of the coin you fall to. Specifically to Par Endo, that's not helpful. We are clearly in the new products game, so we need new products to get out of the FDA, that's where our strength is, that's our focus. So helpful to certain companies but not helpful to companies that are focused on new product approvals.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Sure. Maybe that's a good transition. Just I know you can't talk specifically about pipeline assets. But just in general, when you think about the state of the company's pipeline right now, just talk a little bit about what you're excited about, do you feel you have the right mix of assets for the environment we've kind of found ourselves in at this point?

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

Another good question. I'm pleased with our pipeline, I think, is probably the best way of stating it. And you got to be a little bit honest with yourselves in terms of -- and maybe this is too much honesty, but when you look at companies that say they have 50, 100, 200 products in the pipeline. Well that may sound impressive, but you also got to remember that if you go back to 2014 a little bit, Chris, where the regulations had changed, where back at that time prior to that, you can file with less than 6 months of stability and less than 3 batches, right, so maybe it's a detail, but you had a lot of companies filing applications, and I think everybody was kind of trying to beat that date and for those who follow it, regulations changed somewhere around June of 2014. And then, after that, you're getting a lot of new products that are being submitted by a company. So the answer to the question is, when I look at my portfolio and my competitor's portfolio, you probably have a lot of companies that have some me-toos in there, right? But on a go-forward basis, what we've done is we really have focused on the injectable portfolio, something that we've done well on. We've moved away from commodities over the last couple of years. And I think another area that we spent on a lot of resources and a little bit new to us is broadening our marketing horizons into specialty pharmacy. And what we've done at Endo is we've taken some of the strengths of what Pat Barry's team brings to us on the branded side, and we've coupled that with Tony Pera on the generic side and what we've been able to do is we launched a product called vigabatrin. So it's unusual, right? First time generic coming out of specialty pharmacy. So that's kind of an area that we want to focus in on. So you look at our Paragraph IVs, look at our injectable portfolio, a little bit on specialty pharmacy and also a little bit on 505b2. I think, I'm pleased with the portfolio overall.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Right. Anything in particular you'd highlight to us, I think, about either '18 or '19, that we should be keeping an eye on that you can talk about?

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

Yes. So again, I mean, not to avoid the question, but I think, right now, what we'll do is when we get to our February earnings, we'll provide a bit more clarity. I know people are trying to understand what our near-term outlook is, but I think we're just going to have to ask people to be just a little bit patient on that regard.



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Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

You've mentioned injectables a few times in the conversation here. Just talk about how we think about kind of trends in that business and maybe specifically as we think about VASOSTRICT, think about ADRENALIN, just how much more opportunity is there for growth in the current portfolio before we consider the pipeline?

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

So I think, we've done our job on VASOSTRICT and in ADRENALIN. I think, in that regard, our regulatory teams and our legal teams worked hard to get the unapproved sources off the market. And I think, for those who don't know, VASOSTRICT and ADRENALIN were unapproved products. We submitted NDAs, and with that, you get to work with the FDA to prove that you have supply and you can consistently provide drug product. And with that, the so-called quid pro quo is that the FDA will work with you to remove the unapproved sources. And I think that's behind us. So when you look at VASOSTRICT, we, in essence, have garnered that market. ADRENALIN, I think, we've done a pretty good job. We have about a \$25 million run rate. I think we've maximized that. There is one competitor with an ampoule in ADRENALIN. But I think those 2 markets are, in essence, maximized. And I forget the rest of your...

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

So -- and I guess, well, maybe dig into VASOSTRICT a little bit. At this point, durability of the asset, can you just talk a little bit about your confidence in how much line of sight you have at this point in terms of that important business?

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

Right. Sure. So there's obviously -- there's a beacon of light on VASOSTRICT from a couple different angles. I think, the starting point is -- so from a potential generic competitor on a Paragraph IV standpoint, there's been no notice to Endo. So what I can tell you today is that, to the best of my knowledge, there hasn't been a Paragraph IV filed with a notice. We have 5 orange book patents. We've got 11 pending. We are very bullish on our intellectual property. So over time, we only strengthen our position on VASOSTRICT. So that's probably item #1. Item #2 and #3 are a little bit more difficult to talk about because they're surrounded with pending litigations. So we have a situation with a compounding company that is tied back to some trade secret theft, and so I'm not going to go into the details of that, but we feel pretty good about our position regarding that. And then, the larger question is in compounding, in general, which is VASOSTRICT amongst other products. And I think, folks are well aware that we, in an unusual move for Par, we, in Endo, we don't bring suit against the FDA, something unusual, but that was something that was necessary to deal with some compounding issues that we just feel are unlawful, and I'll probably have to leave it at that.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

And just on -- without taking too much, just time lines around when we should think about potential clarity on the FDA side of things?

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

So in a lawsuit, there's a couple of things that are going on. So it's probably less than a year for a decision. And then, I think, depending upon which way it goes, you can always assume an appeal. Appeal's typically 10 to 12 months, so that kind of gives you your time line there. In the meantime, I think, the FDA's been pretty vocal that they're acknowledging that they're going to have to make some changes to the DSQA and -- I'm sorry, DQSA and with respect to how they're handling compounding. So that's going to be a little of wait-and-see. And who knows, right? So depending upon how they settle it -- settle the -- settle their interim policy, that could impact how we look at the litigation.



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Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Last question on generic side. Teva announced a significant restructuring recently. I think they're talking about optimizing their portfolio. I know you went through a significant portfolio optimization last year. I mean, how do you think about, as kind of one of the larger players in the industry having now going through a similar process, does that make you more optimistic in terms of market dynamics? Is it just a different strategy that they have relative to where you are? So maybe just comments about what you think about...

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

So at the end of the day, I really don't have any specific insight as to Teva. But I would tell you that, if I just looked at it from a very simplistic approach and what we did and the magnitude of Teva, what they did based upon just the sheer nature of the size that they are, it's very similar to -- I mean, to me, it appears to be very similar to what Endo did. And it was really to build on efficiencies. And I think, it kind of goes back to a little bit, Chris, on the question that you asked earlier. I mean, when you start to see these companies with these portfolios and saying that you have 100 or 200 products on file at the FDA, but as long as there's going to be -- I mean, there's 100 generic companies out there, depending -- and if you want to get into the nitty-gritty, there's probably 300 generic companies that have 1 ANDA filed. So as long as people are bringing ANDAs forward and you have 3 consortiums, that's going to put pressure on companies that are highly focused on margin expansion or EBITDA expansion. I think that's the message that Teva is sending, they're going to become more efficient. And I think that's the message, clearly, that we've focused on, so not surprising.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Okay. Maybe the last for me is just transitioning over to branded side. Maybe first question, just how do you see the specialty business fitting in with the Par business as you think about operating these 2 franchises within the broader structure?

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

I love that question, and I'll be honest with you, I'm so excited about what we're doing. And under this centralized model, I mean, I have one R&D team, I have one regulatory team, one legal team, it's been proven. Really, when you look at the operations, where we differentiate ourselves is almost purely on the sales and marketing side. So from a structural side and operation side, I absolutely love it. What I love about our branded division is that we're not trying to be all things to all people. At the end of the day, we've got some really interesting assets that are -- I mean, when you look at what we've achieved at -- and I hate to keep on going back to Par, but when you look at our generic division, we've been successful because we played in arenas where we had little competition. Paragraph IVs, 505b2s, things of that nature. When I look at our branded division, and XIAFLEX in particular, we are focused as the only pharmacological product in Dupuytren's and Peyronie's, right? There's no other drug. So I think there's opportunity. It's, in essence, in my view, similar, small, nimble and agile. And I love the prospects for CCH and cellulite, again, the only known pharmacological product. So I think, from an operations standpoint, I like it a lot. From an ability to grow margin and EBITDA expansion, it fits in well.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Another question, just in terms of the existing indications when you think about XIAFLEX, how much more room to run do you feel you have in those 2 initial indications?

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

So I think, when we look -- again, with Pat's expertise and coming over to join us taking a fresh look at it, XIAFLEX has been on the market for about 7 years. So it's got a lot -- it's got some history. I would tell you that we guide to high single digit, low double digits for last year, and in essence, what we delivered was high double -- sorry, low double digits. So I think, there's certainly room to grow. I think, what I've learned quite a bit is that



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there's a lot of unmet need in both the indications. So from the ability -- from a diagnosis standpoint and a treatment standpoint, we are the go-to drugs when it comes down to treatment. So we're highly focused on patient awareness. And that's where I think we're going to see ourselves invest. That's why I think we have the ability to grow this product. And again, the patents go out to 2028, so we've got a nice runway.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Excellent. Maybe last question as we're wrapping up here. When you look at the leverage situation of the company, do you feel you have the cash access you need as you think about whether it's BD or being able to kind of invest properly in the business? Or how do you think about that because it's obviously a significant part of the story, it's been like...

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

Yes, I think so. I mean, when you look at where we -- what we guided to for the last quarter, for 9 months, I think, we had indicated that our -- we're at about \$7.5 billion with respect to debt. And I think we were at around maybe the high 4s for leverage. But on a go-forward basis, I think we are -- I mean, we're going to have to navigate through some choppy waters, there's no denying that. But in terms of what we need to do to invest on our R&D side, to invest in smart potential bolt-on acquisitions. We do have capital. Again, it would have to be in areas that would be in market indications for XIAPLEX, like a urology or an orthopedic area or smart injectables. I think, we have some room to consider things. And we're always going to be laser-focused on reducing our debt.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Great. Well, I think, that wraps up our comments here. We'll continue the dialogue across the hall in the breakout session. Thank you.

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

Thank you. Appreciate it.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Thank you.

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