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# EDITED TRANSCRIPT

ENDP - Endo International PLC at JPMorgan Global Healthcare Conference

EVENT DATE/TIME: JANUARY 07, 2019 / 7:30PM GMT

## CORPORATE PARTICIPANTS

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

## CONFERENCE CALL PARTICIPANTS

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

## PRESENTATION

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

Good morning, everybody. I'm Chris Schott from JP Morgan and very pleased to be introducing Endo this morning. From Endo, we have the company's President and CEO, Paul Campanelli. After this presentation, we're going to go right over to the breakout room across the hall in Olympic.

And with that, I'll turn it over to Paul.

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

Thank you. Thank you, Chris, appreciate it. So first, I want to thank you, Chris, for allowing us the opportunity to present. We're excited to be here today. I would tell you, Chris invited me here about 2 years ago to speak about the new Endo. And what we want to do today is tell you a little bit about our strategic priorities and what we've executed on, the direction of the company and tell you about some exciting news, both on our Sterile side as well as our specialty side.

So as I said, when we started this journey about 2 years ago, we put a new leadership team in place. And we -- in essence, we locked arms. We had to make some very, very difficult decisions on how we are going to reshape our organization. So we took a new approach in terms of centralizing Endo. And what that really means is, is that we focused on operational execution and having a common denominator in terms of how we operate through our R&D in our manufacturing, our regulatory affairs, amongst other components of our company.

Clearly, we were out to simplify our business, and we were looking to drive improvements on the productivity side and we focused on a new Endo culture. And when we say a new culture, it was really defining core values in which we could operate. We have quite a bit of diversity in our company when it comes to our international business and our retail and our Injectables side as well as our specialty side, but we've really locked in, in our core values and locking in, in our strategic priorities. That said, we had a strong focus in building out our portfolio, and what that meant was we had to make some very difficult decisions on facilities. And when you're touching facilities, you're touching products and you're touching people, but these were difficult decisions that we had to do in order to put ourselves in a better position to compete and focus on efficiencies.

When we started the process, we also indicated it was going to be a multiyear approach, something that goes going to be very important to us that there was a lot of work to do. And I would tell you that while we've made great advancements, we still have more work to do. That said, I think we've positioned ourselves nicely into the areas of strength of our company. Our core strengths right now are going to be focused on our Injectables side. And we'll talk a little bit more about some of the acquisitions that we've made, we'll talk a little bit more on the strength of our specialty business and how XIAFLEX continues to grow and also the trust and confidence that we have in the specialty group, and with that, our next phase of moving into medical aesthetics. So that's something that we're very, very excited about.

Also, when we talk about delevering, we do have aspirations, and we said this 2 years ago that it's a multiyear process. It will continue to be a multiyear process, but we have a foundation that we're excited about in how we can return to growth as a company. And with that, our aspiration is to delever in the 3 to 4x range. Now we haven't defined the specific time, but that is an aspiration of Endo.

With that, we spent a lot of time on playing to our strengths. It would make sense, maybe as I look at the slide, I would probably start to the bottom and talk a little bit about our international side. It is clearly the smaller component of our business. And we had to make some tough decisions on

our international side 2 years ago, moving away from markets such as South Africa and Mexico. But we are playing to our strengths in Montréal, and we have a very efficient and a very agile group in Paladin that's incredibly important to us, albeit a small component of what we do.

You can see the U.S. Generic side taking some pressure in terms of revenue erosion. That's something that shouldn't surprise anybody. These were, again, difficult decisions that we had to make as we culled our portfolio, specifically in our Charlotte and our Huntsville facilities. Again, making difficult decisions but, again, focusing on EBITDA and margin expansion. These difficult decisions are putting us in a position to strengthen our retail side, and we'll talk a little bit more on the retail side as we touch on that.

Branded side, incredibly excited about. We're investing in that. You can see the growth in terms of 2017 versus 2018. We'll share a little more color in terms of what that means. Again, wanting to invest and build out our portfolio. And then one of the areas that we're most excited about is our Branded Specialty & Established products department where we are clearly growing our XIAFLEX as well as some other specialty products.

So with that, I'll move right into our specialty side, an area that I'm incredibly proud of. When we look at XIAFLEX, you can see that we've grown over 22% quarter over -- Q3 over Q3 '17 to '18. One of the things that I'm most proud of when I look at XIAFLEX is it has 2 components with Peyronie's and Dupuytren's. These are mature products. Dupuytren's was launched around 2010, and Peyronie's was launched around 2013. But we spent an enormous amount of time with our consumer-activation program and investing into XIAFLEX whereby you can see this type of growth. So what we're excited about, these are both orphan indications. The division is led by Pat Barry. Pat is here, and when we break out, we can certainly drill into any specific questions that you might have on the specialty side. But what we're doing here is we're focusing on these orphan indications of Peyronie's and Dupuytren's. So when you look at it from a diagnosis standpoint, these are low level, low percentages of diagnosis in areas that we are really starting to focus deeply in, in our consumer-activation programs is treatment. So when you are treated for Peyronie's or Dupuytren's that we want to convert, we want to be the drug of choice. We are the only drug outside of surgery. So we are making inroads, and I will tell you that and Pat can talk a little bit later at the breakout, this is an area that's very exciting and we're starting to grow our Peyronie's and our Dupuytren's portions of our business.

And at the same time, our specialty side still continues to grow. When you look at these 2 components, these are the areas of which that we promote and we detail into.

With that, the next area that we want to focus in on that we're very excited about is our U.S. Branded Sterile Injectables side. As you can see, we've had, again, more than 20% growth year-over-year. It's anchored by VASOSTRICT and ADRENALIN, 2 products that we're incredibly proud of. Homegrown products, 505(b)(2)s. And when you look at this area, we are reinvesting into our Injectables portfolio. And because of the success in VASOSTRICT and ADRENALIN amongst other products, we've taken the position that we want to get larger in Injectables. And we've made a $190 million acquisition in Bangalore, India, called Somerset, and that deal is scheduled to be closing, hopefully, sometime in Q1. That will infuse us with an additional 13 to 14 commercial products, with an additional 20 products in R&D development and also another 20 products that are on file with the FDA. That is to go along with the 32 commercial products that we already have in our portfolio in an area of growth. I would tell you that I don't anticipate additional costs tied back to our sales and marketing infrastructure, something that also excites me. We have about 15-or-so reps that are calling on high-dispensing hospitals as well as the standard GPOs, the Vizients, the HPGs and, of course, the Premiers. So a strength of the company and an area that we want to continue to invest in.

And lastly, in this area, we also want to start moving into hard-to-make, ready-to-use type product. So we've partnered with a company called Nevakar. We've had some previous success with Nevakar. And in essence, we want to go back to our old playbook and bring back certain types of products that are focused on critical care. And we're hoping that we'll start to see the benefit in late 2020 with respect to the Nevakar opportunity.

As we move into the U.S. Generic retail section of what we do, this is probably an area that while we've taken compression and challenges, it's probably an area that I'm quite proud of because of the tough decisions that have been required to be made over the last 3 years. So again, as I started out, we had to make difficult decisions on facilities and ultimately dialing back to impacting of people. When we started this journey 2 years ago, Endo had about 6,000 employees. Today, we operate with less than 3,000. Hitting all aspects of our company, however, heavily hitting the Generic portion of our segments here. But we're getting back to basics. So when you see a product coming out of the Par portfolio, we really are focusing on hard-to-make, first-to-file or first-to-market type of opportunities. So we're going back to long-acting Injectables, modified-release

products. And we'll show a little bit about some of the type of products that we're focused on. Difficult APIs, small clinical trials in the retail section, these are areas that I think we've built great skill at and an area that we're going to continue to invest in.

And when I say invest, it's really focusing in on efficiencies. So what folks should understand is from a manufacturing standpoint, whether it's Generics, Branded, Sterile or Specialty side, when we centralized our company, it is really falling under the same group of individuals from either a technical operations side, a manufacturing side or a regulatory affairs side as well as an R&D side. Great efficiencies are within our company.

Now we've moved our R&D from New York into Chennai, India, and also into Mumbai. So you're going to see a great amount of efficiencies, many more ANDAs coming out of our facility that are high-quality type of applications. Also, we've expanded our solid oral dosage manufacturing away from Chestnut Ridge, New York, away from the U.S. and into Chennai, India. So also, we're looking at building more efficiencies by expanding our solid oral dosage capabilities outside of the U.S.

When you look at our company, as I said, we're focused on first-to-file, first-to-market. We've got about 90 products on file with the FDA. We launch about 12 products a year. We're not going to be focusing on large volumes of applications. I think if we went back 3, 4 years, you would hear a common statement that a lot of companies wanted to file around 20, 25 applications. That's not what our strategy is going to be. Our strategy is high-quality products, but we're going to still want about 12 to 15 product filed per year.

And maybe just a soundbite in terms of where the environment is on the Generic side. While we have been cautiously optimistic, we say that quite a bit, we're seeing stability in the Generic environment. And I say that because I'm seeing little movement within the consortiums. And I think that's a good thing for Par, in particular, I think it's important to point out that as we approach 2019 and get deeper within the year, some of them, more valuable applications are more towards the end of 2019. I think that's more of an awareness for the folks in the room to just think about when you start modeling your views on Endo and Par. We will have our fair share of launches, but again, the products that we are depending upon in terms of from a value standpoint, would be more towards late Q4.

With that, we're in a shutdown with the FDA and always creating some uncertainties around approval time lines. That said, I think we're well positioned from an efficiency standpoint, and you can see where we rank within IQVIA data within the U.S.

Just to recap a little bit on the key growth drivers, again, what we're incredibly excited about is the work, the good work that Pat Barry and his team has done on XIAFLEX, 22% growth. I'd probably move to what we're doing with Somerset. Again, bringing and building more breadth to our organization that were incredibly excited about. The Nevakar licensing agreement. And then maybe just taking a quick look at some of the recent products that we can speak to when we look at our Generic portfolio tied back to first-to-file or first-to-market products. We list out products that we're able to speak about. Again, we file predominantly Paragraph IV. So whenever we settle, there are a lot of times that the terms and conditions do not allow us to provide color on whether we settled or a date -- these are products that we can talk about. And I think the message here is, when you look at every product in this list, whether it's a DEXILANT, which is a very, very challenging proton pump inhibitor; or an AMITIZA, which is a soft gel requiring a clinical trial; each story -- each product has a story. Each product has a technical challenge. And when you look at the Par portfolio as it matures, you're not going to see a lot of commodity-based me-too products in areas where you're agree to see 6, 8, 10 or more ANDAs. So very selective in where we play, very technically challenging types of products, whether it's a formulation challenge, whether it's an API challenge or whether it's a marketing nuance that takes specialty pharmacy into consideration in the case of SABRIL. So that's the way that I'd like to have you folks focus on that Generic portfolio.

And then may be moving back to the last point, and it's really the bullet #2. As we move to the future, I'm incredibly excited about what we're doing here at Endo with respect to CCH for the treatment of cellulite. Again, we are preparing for success. Our BLA is scheduled to be submitted at the back half of 2019. And upon success, if successful with the FDA, we would have a commercial launch about 12 months later at the back half of 2020. So we are preparing for success.

With that, we also have international rights. We're here today. Our business development team is out exploring. We have individuals in this room as we speak, also looking at ways in which we can partner for ex U.S. rights.

So staying on the cellulite theme, I wanted to take this opportunity to talk a little bit about the positive results that we had for Phase III. We call it RELEASE-1 and RELEASE-2. These were 2 large trials. We'd like to start out by saying this was the largest trial ever conducted in cellulite, 845 women were enrolled. And I think an important factor that we don't want to get lost in this particular clinical trial was that we took all comers. There were no limitations on BMI, weight or cellulite severity. So we took all comers. Now that's a nuance and that's a little bit different than we had in Phase IIb. Phase IIb was about a 425-patient study. And why we took all comers, there was a governor on cellulite severity, so a little bit of a nuance.

When you move over to the right side of the slide, this is a photonumeric cellulite severity scale. As you can see, there are 5 levels of severity. It starts with no cellulite, all the way over to severe cellulite. Our clinical trial only focused on the more challenging cellulite, the moderate to the severe cellulite. I think that's an important point that we make sure everybody is aware of. And also, when you look at our trial, it was not focused on a dimple specific, it was focused on a quadrant. It just talks to the vigor of the trials. We were so proud of the trial and there was so much rigor tied back to the trial that, ultimately, the trial was accepted and presented at 5 prestigious peer review congresses, something that really shows to the integrity of the trial.

That said, the next slide here is a slide that you've seen before. This data is a slide that we presented back at our last earnings call. It shows that our primary endpoints, a 2-points composite, was highly statistically significant. And on the right side, it talks to single point secondary subjects whereby we had success also in the global aesthetics improvement as well as patient assessment. And I think what's important on this particular slide, as we look back at the primary endpoint results that when we stratify the data on the primary endpoint side and we look at it in the same way as we did for Phase II with respect to BMI and weight and cellulite severity that the percentages do increase and that, ultimately, the trial -- the Phase III trial is consistent with our Phase IIb trial, something that we're proud of.

When we move forward in terms of showing some data that we have not spoken about before, another nuance to the trial, somethings that we're pretty proud of is on the left side, were talking about and showing cellulite for -- CCH for cellulite patients who saw improvement were substantially happier. Seven out of 10 patients were substantially happier. Now this is the patient reporting study. This is a 1-point improvement from the patient. And in essence, what we're seeing here is new data in the eyes of the patient on the happy scale, on the patient perception scales that they were happy more than 7 out of 10 times. Very important point. Again, reminding everybody that we've taken all comers, right? No limitations on BMI, no limitations on weight, no limitations on cellulite severity.

On the right-hand side, again, this is simply stating that the patient saw improvement after the first injection, right. Another important factor that after just 1 injection -- keep in mind, it's 3 rounds, 21 days apart, 12 injections per buttock, that after 1 treatment, the patients saw improvement. Again -- and as we move deeper into 2019, we will be able to show and speak more to enormous amount of data generation again on this 845 patient trial. That's something that we look forward to. We'll be presenting around 25 to 30 congresses in 2019.

Now getting really down to what does it all mean in terms of what some of the actual results should look like. So what we're showing here is a Phase III, 2-point composite. And on the left-hand side is baseline, it's day 1 prior to the injection. And you can see, on the bottom aspect of the buttocks, you can see the undulations, you can see the cellulite, you can see the fibrous septae pulling down, creating the dimple. Again, 2-point composite. After day 71, so that's 28 days after the third injection, you can see that the -- that there's a great deal of smoothness and elimination of the fibrous septae.

The next slide here is more of same subject, a rotational view as to what's going on here. Again, on the left-hand side of the slide is your baseline right before the first injection. And on day 71, again, 28 days after the third injection, you can see the impact of our CCH, 2-point composite.

Now again, moving to a 1-point composite and why we think that this is meaningful, you can see in Phase III, 1-point composite improvement again on the left-hand side at baseline. You can see the dimpling, you can see the undulations, you can see the cellulite and the fibrous septae. Day 71, while not complete perfection, you can see a remarkable improvement with a 1-point composite change, something that we're quite proud of, showing the product works after 1-point composite change.

So getting a lot of questions in terms of trying to quantify what we're working at, and we have intentionally not quantified the value. We're continuing to refine and think about what this could impact and what it could mean to Endo, but maybe some starting points. What we do know is the U.S. aesthetic market is about $15 billion. What we do know is, is that the Injectable aesthetic market is around $3.5 billion. What we're doing is enormous

amount of market research and we're going to continue to do so. But we start with a cohort in the U.S. of women between the ages of 25 to 51 -- I'm sorry, 25 to 54. When we start with that cohort, that leaves us with about 64 million women. And then what we do is we take -- we try to take an approach of who the users would be. And ultimately, you can see that we're using a target BMI around 18.5 to just below 30%. That, in essence, is normal to slightly overweight females. When you take that cut, we're down to around 42 million individuals. And then it really gets down to what's your household income. So we're looking at household incomes of greater than $75,000 per year. You can see that takes you to around 20 million. And then what it really gets down to is -- with our market research is, individuals that self-identify, very important, right, who's going to self-identify from that standpoint, it gets you down to around 10 million individuals. And at the end of the day, cellulite doesn't bother everybody. So we take a cut of the cut, and we end up with, if you're bothered by cellulite, it leaves us with a healthy base of around 6 million individuals. We think that is very important. And then ultimately, if we were to broaden that by ages 21 to 59, we could increase by about 2 million to -- rather to around 11 million.

So in closing, I just wanted to kind of recap in terms of some of the successful execution on what we've done over the last few years. Difficult decisions on people and facilities, but I think we've made significant progress. I think ultimately, we've made it very clear. It's a journey, it's a multiyear journey. We're investing in our core areas of Sterile, specialty. We're excited about growing out CCH. We have aspirations to delever in the 3 to 4x range. And we have a strong liquidity profile and a disciplined approach to capital allocation, and shown by our investment in CCH, Nevakar and Somerset.

And with that, I want to thank everyone. Our breakout is going to be in the Olympic Room, and we look forward to answering any questions you might have. Thank you all.