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ENDP - Endo International PLC at UBS Global Healthcare Conference

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**Marc Harold Goodman** *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

## PRESENTATION

**Marc Harold Goodman** - *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Good morning, everybody. We're going to get started. Thanks for joining us again for day 2. So Endo, thank you very much for joining us. And Paul Campanelli, who is the CEO and had been CEO now for 8 or 9 months or so, I would say. And I've known Paul a long time, a veteran of the generic business. And he ran Par when it was a private company, and obviously even before that, was a key executive at Par when it was a public company before that, so a long time. And one of the guys who really knows this business well, and we're counting on him to turn things around at Endo.

So he's going to give a presentation, and then we'll have a breakout session afterwards. So Paul, thank you very much for joining us.

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

Thank you, Marc. So good morning, everyone, it's a pleasure to be here. Appreciate your interest in Endo International. Just wanted to pause for a second here to review the forward-looking statement.

As we begin today's presentation, I wanted to give just a quick general overview of Endo, what's happened here over the last quarter here. We reported our earnings a couple of weeks ago. We're pleased. We're off to a solid start here for Q1. As you can see, we generated sales just over \$1 billion. When you look at our segment and how we are -- how we're carved up, we are about 70% generic at this point in time and we're about 24% branded with a small international presence.

If you were to look back about a quarter or so, these numbers were slightly different. We had more of a 64%, 65% presence in generics and a slightly higher percentage, around 29% or so, for the branded. And I think what you're starting to see as some of the generics come to fruition, and specifically we generated around \$99 million of sales for VASOSTRICT last quarter, you're starting to see a little bit of a shift more towards the generic side. But for the most part, this is the way you can start to look at us.

Our vision is quite simple. We believe that we can be a generic company and a highly laser-focused specialty company. There's been a lot of questions about our hybrid model. It's something that we believe. And I think it's something that when we focus on operational execution that we'll be able to deliver on both sides of the business. We'll talk a little bit about that later in the presentation.

But we had to make some tough decisions on the branded side. As most folks know, we had been historically a pain-focused company. We'll get into that in a second. But we believe that we can still remain a generic company and have a nice specialty portion on the branded side.

On the U.S. business, our technology, we do believe that we are slightly differentiated. We want to be very frank, I mean, we do make tablets and capsules. And it's been a core portion of our business over time. But we are introducing new technologies, such as prefilled syringes, nasal sprays, otics, ophthalmics, topicals, creams, ointments, things that are starting to differentiate us, give us longer tails and higher margins.

Pipeline has been strong. We'll show you a scorecard in terms how our first-to-file and our first-to-market as well as our development program is going on the generic side. But we are, in essence, the fourth largest player today in the United States. I think that positions us well to compete with some of the consortiums. I'm sure there's been a lot of -- there'll be a lot of questions on consortiums throughout today regarding some recent changes. But I think we are positioned to compete as the fourth largest company here in the U.S. I think we are able to position ourselves well against some of the larger players as well as some of the smaller players that have been historically known for aggressive pricing.



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On the branded side, as I indicated, we are now highly laser-focused on specialty. We've got about 200 reps specifically focused on a combination of products, such as XIAFLEX in Peyronie's and Dupuytren's contracture as well as SUPPRELIN, NASCOBAL and AVEED. And not to forget about our pain portfolio, while this is not a growing section of our company, it throws off enormous cash flow and EBITDA, so still very important to us. But we just -- it's not an area -- with some of the pressures on opioids and CDC, it's not an area which we can grow.

On the international side, we're taking a very mindful, thoughtful process on how we look at ourselves from an international presence. We want to stay focused on North America, regulated markets, areas that we know. Emerging markets are areas that we are going to move away from. And I think folks know already that we've divested our South African operation, Litha. And over the next 4 to 8 weeks, we should be in a position to have divested our Mexican operation, Somar.

Our priorities are very simple. When I took over about 8 months ago, we had a meet with our executive team. In essence, we had to put in a new executive team in place. From a cultural standpoint, I am incredibly excited and proud on how we've been able to merge these 2 cultures together. What in essence we've done is that we've taken the best of both. We've got a strong presence on the Endo side, a strong presence on the Par side and able to operate our company both from a generic and a branded point of view.

We changed our operating model from a decentralized approach to a centralized approach. We named Terry Coughlin as our COO. Terry now has visibility across all our sites and all our enterprises, something very different at Endo. And I think that now gives us an advantage. We can put the best minds on all our processes. And as I said, the culture is very strong and we are highly, highly centralized and unified.

We are looking to build our portfolio and our capabilities for the future. Again, what we're really looking at doing is we've made some hard decisions on the generic side. We've mentioned decisions that we've made with our Charlotte facility, having to divest that and taking a deep look at our portfolio, where we eliminated 70 unprofitable products. I think that's going to be -- historically, that's just part of our culture, we have to keep on looking at our portfolio, seeing where we can win, areas that we have strong gross margins, so we make some tough decisions on the pipeline in the portfolio.

At the end of the day, if we have products that are in development and they're not forecasted to be profitable, these are things that we'll make decisions and walk away if we have to, we will do that. Hopefully, that's not the case. But not always do you pick a product so far out in time where it becomes a commercially feasible product. So we want to make sure that we can make mindful, quick decisions on the generic side. On the branded side, I think we made our point, we're going to be highly focused on specialty business and we are divesting non-core assets. So in addition to the Somar and Litha sites, we've also divested our BELBUCA product and we sold it back to its development company, BDSI.

These are things that we can control. And moving forward, we're also focused on things that we're about to control. So areas that we're highly focusing on is driving our margin and expanding and in essence delevering. So we're going to be very, very mindful on how we look at capital allocation on a go-forward basis. But as you see in today's presentation, we are going to be highly focused on margin improvement and driving EBITDA.

On the generic side, our base business generated around \$236 million last quarter. You can see the 32% decline in base erosion. That's something that we have been pretty candid about and we've communicated over the last several quarters. I'd like to point your attention to the sterile side and also the new launches and alternative dosage forms. These are the areas of our growth. This is an area that you're going to see us continuing to invest in R&D dollars. We have a very strong, compliant facility on the injectables side in Rochester, Michigan, very proud about that. On the new launches and alternative dosage forms, you can see tremendous growth, 198%.

Clearly, that is being driven off of our ZETIA and quetiapine first-to-file launches that occurred last quarter. We also got the benefit of those products into Q1. ZETIA will be exclusive with Par for about another 3 weeks or so. And our exclusivity on quetiapine expired about a week or so ago. And we're still holding a fair amount of market share in quetiapine. But you're going to see us continue to focus on Paragraph IVs. And that will be driving our new launches. And obviously, we will be investing heavily into our sterile injectable side.

In terms of our portfolio and how you should look at Par on the generic side, we're pretty proud about how we've expanded our technologies over the last 3 to 4 years. Specifically, when you look at us, we are known for tablets and capsules. But on the modified release side, we have products



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that are manufactured in our Irvine site, such as bupropion, which has been a staple of our company for many years, a very technically challenging product, highly compliant facility. These are areas that we will continue to participate in.

Another area that we're very excited and proud of, we spend a lot of talking about is on our injectable side, we're focusing on 505(b)(2)s. These are where we are launching products like VASOSTRICT, ADRENALIN and ephedrine. These are going to be -- continue to be a part of our portfolio, hoping to get Orange Book patent where appropriate but a high focus of the R&D team. Additionally, products like Aplisol, our BLAs, have been with us for many, many years; very difficult technologies, high barrier to entry, areas that we're going to focus on, on the injectable side. And then on other alternative dosage forms, we have again more 505(b)(2)s, whether it's potassium powder or potassium liquid. These are areas that we're either partnering or developing them ourselves and hopefully having higher barriers to entry and long tails as we could potentially anticipate competition.

From a scorecard standpoint, we have about 120 products on file with the FDA, about \$32 million -- about \$32 billion in IMS brand sales. We have about 105 products at the FDA filed, either ANDAs or 505(b)(2)s. The 2 columns that I'd like people to focus in on is the majority of our portfolio focuses on Paragraph IVs. But the key is clearly are we first to file? So when you look at our 37 confirmed first-to-file and about 4 potential first-to-market products, about 1/3 of our portfolio is what I'd like to call potential first-line product launches. That's where we excel. That's where we drive margin. That's where we're going to drive EBITDA.

Where we are today in 2017 from an operation side, as I said, a lot of focus on the execution. That's something that we've been incredibly proud of. Right now, we're in an environment that is a bit volatile. We've managed to stay incredibly focused on execution. So we've told The Street that we're going to file and launch about 20 products each year. We are doing quite well. We've launched 8 products to date, about 4 in the first quarter. We submitted 6 regulatory files year-to-date. We are on track to file at least 20.

We were very proud that we worked very hard with the FDA on ADRENALIN. And we are now the only source of a vial ADRENALIN form for 1 mL and 30 mL that is in a vial. We have one source that is in an ampule. But this is a product that we have high expectations and that we're excited about as we near the second half of 2017. And we do expect to have the majority share of the potassium powder. We have one competitor in that market. We should have in excess of 70% to 75%. That's where we believe that we will end up on the potassium powder side.

Over the last several weeks, we've had a lot of success on first-to-file and first-to-market product opportunity, some that we've disclosed here. We talked at our last earnings call about SABRIL. SABRIL is a first-to-market opportunity. It's a very specialized product that requires a shared REMS program. A little bit new for Par, it's going to be an area focused on specialty pharmacy, but you're going to be launching a generic into specialty pharmacy. So this is just another example of how we are looking to broaden and extend our reach as we look at other ways to bring generics to the market.

I'm not going to go through the remaining portion of these products. But just high level, we're just giving you a bit of a view in terms of products like PYLERA and KUVAN, CIPRODEX, MITIGARE, DEXILANT, ZORTRESS, all products that we filed either Paragraph IV, we believe we're first-to-market and positioned well. And the last product is called GATTEX, which is teduglutide. What we're proud about that, we did file Paragraph IV on the NCE date. We would -- we are by definition a first-to-file. At this point in time, we do not know if we're the only first-to-file. But we're pretty proud because this is our first injectable polypeptide ANDA. So this shows again how we are extending our reach into generics.

As we move into the branded side, we are laser-focused again on specialty. As you can see, XIAFLEX generated around \$50 million. XIAFLEX in our specialty group is up in a range of the high single digits to low double digits from a growth standpoint. When we look at XIAFLEX from Q1 generating around \$50 million, the breakdown is around 55-45 between Peyronie's disease and Dupuytren's contracture. SUPPRELIN LA, another product that we're proud of, good growth, up around 11%, generating around \$19 million for the quarter. These are areas that you're going to see us invest in, products that either have patent protection or hard to make products on the branded side.

When we made the tough decision to divest BELBUCA back to its development company, BDSI, we generated about \$100 million in cost savings. We're reinvesting into the brand areas and specifically areas that we believe that we can grow our products. So do believe that there's room to grow in Peyronie's disease. We do believe that there is room to grow in Dupuytren's for XIAFLEX, so you'll see some marketing dollars going there.



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And of course, we're reinvesting into XIAFLEX with respect to cellulite. And we'll talk about that in a second, but again an area that we're pretty excited about.

So a little bit about cellulite. And we've shown this slide here a number of times. But what we'd like to point out here is that we had highly statistically significant positive Phase IIb results. The results came out in the November time frame. And just to remind everybody a little bit about the anatomy of cellulite and what's going on here, when you look at this particular slide on the left-hand portion, you can see in the orange section of the profile, we have the epidermis, and then we move into the yellow section, which are the fat cells. And then we have the muscle tissue, which is defined in the red area.

When you look at this, this slide here and you're seeing this septae or this branch-like figure that is growing into your skin area, over time what's happening here is the septae is shrinking, it's contracting and it's becoming thick. And as you age, that is causing the dimpling effect. What we are proving out in our Phase IIb trial as we move into Phase III, when you take XIAFLEX or our collagenase clostridium product and you inject it into the dimple, over time XIAFLEX is acting like a chemical scissor. And this septae in essence starts to dissolve.

So when you see as we move over to the right-hand side in our Phase II trial, subject A was a placebo patient. After 71 days, obviously no change in cellulite. As you move over to the right-hand section of the diagram, subject had 3 treatment, 71-day treatment of XIAFLEX. And over time, nearly all the cellulite has disappeared. So very encouraging. We've met with the FDA. We've looked at developing our final protocol. We believe we'll be moving into Phase III in the fourth quarter time frame, early fourth quarter time frame.

And in essence, we are very proud to present data at the Aesthetica Super Symposium as well as the American Academy for Dermatology. So again, moving forward to Phase III in the second half of 2017. I'm assuming it'll probably be more like the October time frame. And we are in essence preparing for success. At the end of the day, by the time we complete the trial and get through the PDUFA time frame, we are looking at about a 2-year window. So somewhere around fourth quarter of 2019 to first quarter of 2020 would be a potential launch date. And as I mentioned, we are in essence preparing for success with respect to XIAFLEX in cellulite.

A little bit on the international side. As I indicated, when we took a step back and we redefined and reshaped our company, we wanted to be very focused in where we excel. And clearly, we know our U.S. market. We're focused in regulated markets such as Europe. And we took a hard look at Canada. We do believe that when we look at Canada, it's an area where it can augment our EBITDA. It's not an area in which we are going to put enormous resources. But I think if we take a thoughtful, mindful approach, we want to stay focused on Canada. And as you can see here, we generated about \$29 million in revenue.

But I think the message here is that we're finding that the gross margins in Canada can generate in the high 50% ranges. And for us, we're able to populate Canada with some of the work that is coming out of our Chestnut Ridge facility in New York. So from a logistics standpoint, we're close by. We're going to start moving into filing generic applications in Canada, ANDSs. And we'll be doing that work from our Chestnut Ridge and a little bit of our Chennai facility. So stay tuned, but you're going to see a little bit more mindful investment in Canada.

And then on the Litha and the Somar standpoint, I think we made ourselves pretty clear. These are emerging markets. This is not the strength of Endo. These are areas that we're going to move away from while they're still generators of revenue. We don't see these as areas that are going to be places where we can invest to grow. So stay tuned. But I think you'll look at us from a standpoint highly focused on the generic side, highly focused on specialty, a little bit of Europe, and we're going to take a mindful and thoughtful process when we look at our Canadian international side.

So in brief, just a high level from a financial side. And when we do the breakout, we can certainly go into as much detail as you want with Blaise Coleman, our CFO, who's with us today. But again, high level, we'd just like to point to the revenue side, just over \$1 billion for Q1. Gross margins are running just a little bit higher than a year ago at 61%. That's an area that we want to focus in on obviously. Operating income of \$437 million, and then also just to point to the effective tax rate increase of around 15.7%. So a quick overview of Q1.

And then moving to our financial guidance. At our last earnings call, we did in fact reaffirm full year guidance for 2017. We don't see any change at this point in time. As a reminder, our revenue range is in the area of \$3.4 billion to \$3.6 billion. Our adjusted EBITDA is in the range of \$1.5 billion



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to \$1.58 billion and adjusted EPS of around \$3.45 to around \$3.75. Again, a couple of bullets here, high level from a guidance standpoint in terms of the assumptions that these -- the guidance will be built around. Our gross margins should be in the range around 62.5% to 63.5%. And also our tax rate should be generally in the area of around 13% to 14%. So this deck will be on the website. You'll be able to view it at your leisure. But this should give you some of the assumptions around our full year guidance.

So in closing, I just want to reiterate there's been enormous change at Endo over the last 8 to 9 months. We're very proud of the team. The team that we put in place is a team that has a proven track record of success, highly focused on centralizing and unifying the company, not afraid of making some tough decisions. We're going to be very select on intelligent product selection, where we put our dollars and how we're going to build out our portfolio and our capabilities. And we are in essence we are committed, we've said this time and time again, to delevering, driving margin expansion, driving EBITDA.

Now we're not going to walk away from potential acquisitions. But we want to be very mindful, right? We're going to have incredible discipline from a capital allocation standpoint. We're committed to delevering, so something would have to be exceptional. But we have a pretty skilled business development team that's out there looking for opportunities. And if there's a product opportunity either on the generics side or the branded side, we'll take a look at that. But again, these are usually mindful types of investments, so committed to delevering and driving EBITDA and margin.

So with that, that concludes my presentation. We are in breakout room -- Alvin/Carnegie if you want to join us for Q&A. We've got about 1.5 minutes. Marc, should we just break out or -- okay. So folks, we'll just go right now to the breakout room. Thank you very much.

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