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# EDITED TRANSCRIPT

ENDP - Endo International PLC at Morgan Stanley Healthcare Conference

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## CORPORATE PARTICIPANTS

**Blaise Coleman** *Endo International plc - CFO and EVP*

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

## CONFERENCE CALL PARTICIPANTS

**David Reed Risinger** *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

## PRESENTATION

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

So thanks, everybody, for joining this session with Endo Pharmaceuticals. It's very much my pleasure to welcome the CEO and CFO. I just need to refer you to disclaimers at [www.morganstanley.com/researchdisclosures](http://www.morganstanley.com/researchdisclosures).

So with me, we have Paul Campanelli to my left. He's the President and CEO. He became CEO in September 2016. And prior to Endo, he was CEO of Par Pharmaceuticals. And he has a long-standing track record in the generic pharmaceutical industry of building companies and creating value. With respect to Blaise, Blaise Coleman is the CFO of Endo. He was named CFO a little bit less than a year ago. He's been with Endo for 2.5 years, and he has extensive experience as a financial executive.

## QUESTIONS AND ANSWERS

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

So with that, I thought that I'd start off with a high-level question. Obviously, there's been a lot to manage at Endo. But it would be helpful before we go into details on what you accomplished recently and some of the opportunities ahead, maybe just state your vision for Endo and how you want to build the company at a high level, and then we'll come back to some more of the specifics on the execution.

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

Sure. Thanks, Dave. So from a vision standpoint, I think since I was asked to take on this role, we've been pretty candid and pretty direct, and we have a vision that we are driving toward. The first part has to do with the generic business. We've taken a very thoughtful, mindful approach with our portfolio and in playing in space that is tied to hard-to-make and technically challenging generic products. So you'll see a lot on a go-forward basis regarding our desire to build out our hospital sales force and injectable sterile products for the generic side. Not that we're going to be moving away from a bit of our core, which is solid oral dosage and always Paragraph IVs, but you're going to see a bigger drive into sterile injectables.

On the branded side, we took a hard approach back in the September, October time frame and we looked at where we were selling to in terms of our pain franchise. So we had to make some tough decisions regarding our sales force into pain. We looked at areas that we could really win and grow and drive, and that led us to our Specialty Branded division. So products like AVEED and TESTOPEL and NASCOBAL and SUPPRELIN are products that are very core to us. So it's a specialty approach. And then, of course, it's our XIAFLEX franchise, which also includes Dupuytren's contracture as well as Peyronie's disease. So you'll see a high focus into specialty. And that's really the driving force as we look to go forward. Yes, I would tell you that we had to make some tough decisions early on people and facilities. We -- but we ultimately rightsize the company to better compete when you look at our company over the next 3 to 5 years.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Great. And maybe you could just talk about the generic pushes and pulls at a high level. Obviously, you've faced, along with the industry, significant price pressure. Is it possible from where your generics business is currently or where it will be in the second half of '17 to grow the top line in the future? Or is it tough to call given price pressure uncertainty?

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

So I'm sure before we're done today, we'll probably talk a lot about consortiums and pressures that we've experienced and how we look at them on a go-forward basis. But to answer that question, to me it always starts with our pipeline. So when you look at Par on the generic side of the Endo business, we've got about 120 products in at the FDA. Our ability to grow that business year-to-year really is dependent upon products that are coming out of the FDA. So every year, you're going to see -- ideally, you'd like to say, you have linear growth. That's just not part of the generic world because we file Paragraph IVs. And depending upon how we settle out or we win cases, you're always going to have peaks and valleys. And I think we saw a little bit of that in 2016 and 2017 with 2 large wins with ZETIA and quetiapine. I think the point here is that we feel real excited about the generic portfolio. We have some nice products in the portfolio. Some we'll bring forward in near term, some will take a little bit longer. But when you look at the sterile injectable side of our business and you look at some of the legacy Paragraph IVs of technically challenging products, I feel good. I do think that we'll see growth, but that doesn't necessarily mean it's going to be year-over-year because you're going to have wins and you're going to have delays in terms of your settlements with the innovator companies.

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Okay. That's helpful. And you had mentioned it, and I did want to ask about the price pressure that you're experiencing and then how we should think about forthcoming additional price pressure from Econdisc merging with Walgreens' purchasing.

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

So thanks, Dave. I think very early in 2017, we -- Blaise and I had some discussions with The Street, and I think we communicated how we were looking at 2017. And we thought this would be a challenging year because of the fact that Walmart was joining McKesson to create ClarusONE. That played out very similar to the way that we predicted. So we did have base erosion. But ultimately, there were no surprises. So we planned for it. We executed on it. And it basically turned out as forecasted. So the question now is, how do we look at the rest of 2017 now that Econdisc has announced the relationship with WBAD? From the Endo point of view, I don't see any disruption in the market for 2017. Our Econdisc bid was updated and put into effect July 1, 2017. So I think for the remaining part of 2017, we should expect business as usual. Then the question really becomes, what happens in 2018? How should we look -- how should we be looking at going from 4 consortiums down to 3 consortiums? It's early in the process. We have limited feedback from both WBAD and Econdisc. But I think you just have to understand that already Econdisc and Walgreens or WBAD were already receiving favorable pricing. So there'll be an ask, as you would expect with any change in consortiums. But as I see those 2 buying groups, they already had favorable pricing from at least the Par side of Endo's generic business. So stay tuned, but I see no impact for '17 and then we'll learn more in 2018.

**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

And what would you guess in terms of timing for that new combined contracting?

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

So we don't have any direct feedback from Econdisc. I would tell you the way Blaise and I are looking at it, we'll plan for it for Q1. From a planning standpoint, I think it's the prudent thing to do, absent of hearing anything, but that's the way we'll look at it. But we have not heard anything directly from Econdisc or WBAD.



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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Okay. And Blaise, maybe you could just remind us about the current position of the balance sheet, your leverage and the cash flow for 2017 just to frame some of the financials.

**Blaise Coleman** - Endo International plc - CFO and EVP

Yes. So thanks, David. So right now on the balance sheet, we have about \$7.7 billion in net debt. So it's our gross debt less the unrestricted cash we have on hand. From a leverage standpoint, at the end of the second quarter, our net debt-to-adjusted EBITDA was around 4.3x. Our guidance for the end of the year is that we expect the leverage at the end of the year be in the high 4x. And so that's where we are from a debt and leverage standpoint. And as we think about our balance sheet and we think about our capital allocation, we've been pretty clear that one of our key areas of focus from a capital allocation standpoint is debt repayment. And that always comes after we've made the proper investments into those core areas of growth that Paul talked about earlier. And we haven't, at this point, put any exact time frame on exactly when we'll be able to -- or dimensionalize exactly the timing or what level of delevering we can get to. But as we move into 2018, that's something we'll talk more about. When we give guidance in '18, we'll be able to get to in '18.

**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

And can you just frame the cash flow for 2017?

**Blaise Coleman** - Endo International plc - CFO and EVP

Yes. So we have been pretty clear that our cash flow prior to debt repayment for 2017 will be between about \$265 million and \$325 million. So that's where we're ending. From an ending cash balance perspective, we would expect to be around \$800 million of unrestricted cash on the balance sheet at the end of the year if you kind of use the midpoint of our guidance.

**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

And with respect to cash outflows associated with mesh, could you frame those for '17 and '18?

**Blaise Coleman** - Endo International plc - CFO and EVP

Sure. So -- well, let me -- we're -- at the end of the year, the \$800 million is after mesh payments for '17. So if I just take into '18 and '19 for a minute, we'll have about \$760 million left of cash call for mesh in '18 and '19. And we've estimated somewhere between \$500 million and \$560 million for 2018 and the balance in 2019 from a cadence standpoint.

**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Okay. That's helpful. Maybe we could transition to some of the important franchises in your generic segment. If you could speak to some of the more important franchises, the current sales trends, and then I had a couple of specific questions.

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

So again, I think from a franchise standpoint, we talked a little bit about our sterile facility in Rochester, Michigan. And ultimately, what you'll see in that area is, we like it. It's a more stable environment because we're selling into GPOs. So you're going to see more of a R&D investment specifically

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in injectables. So we're looking at investing in the facility. We're looking at adding technology. So right now, we have capabilities to do vials and prefilled syringes. So we want to be able to invest and expand into that particular franchise that will give us more shot on goal, specifically in Paragraph IV. So different technologies. And it could be things such as long-acting injectables and microspheres, things of that nature you should see us focusing on. Also in that same area, we have had success with polypeptides, and that's where VASOSTRICT falls. But we've also filed a Paragraph IV on a product called GATTEX, which is teduglutide. We're real proud about that because it's a hard-to-make polypeptide coming out of the Rochester facility with a partner, important to say. So that is certainly where we're laser-focused from that particular generic franchise. Also topical creams, ointments is another area that we're trying to now reestablish in our Chestnut Ridge facility. So adding technologies in areas that we have historically done well and in terms of winning, specifically in Paragraph IVs. So those 2 franchises would be the initial technology focus. And then another area that we're starting to invest heavily is when we look at smart product selection, we're looking at ways that we can broaden our marketing efforts outside of the 3 consortiums. So specialty pharmacy is another area that -- well, maybe not a technology franchise, a marketing franchise where we're looking to focus on additional products. So specifically, back 2 weeks ago, we launched a product, a generic version called SABRIL. It's vigabatrin. It's about a \$324 million product. It's got a shared REMS program, high barrier, tough indication for infantile spasms, with a lot of barriers where you have to put up a hub and you're selling to specialty pharmacy. So these are ways that we're really looking at broadening our reach in the generic sector.

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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

Okay. That's helpful. And could you speak to VASOSTRICT? I know that you had some additional patents granted. You had previously said they were pending, and they were, in fact, granted. If you could just talk about your position with VASOSTRICT, the durability, as you see it, why the CP isn't that big of a deal either way, those types of things, that would be very helpful.

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

Sure, thanks, Dave. So obviously, VASOSTRICT is as important as any project or product that we have at Endo. We work very hard with our legal team and our formulators to get timely intellectual property filed. We're very proud and excited of what the team has done. So over the last 12 months or so or maybe 9 months, we were able to file now 5 patents in the Orange Book. For the most part, they're all directed to ranges of pH and as well as impurities and degradants that are tied back to the claims and the patents tied back to our product. So what that means to me is what I'm excited about is, there's been a lot of questions about the durability. So at the very, very least, we feel very excited that we're going to be able to defend ourselves from a 30-month stay. That would be what I would consider to be the worst-case scenario. We're actually very bullish on our intellectual property. We stand behind it for -- from a longevity standpoint. But the reality is, we can say now with confidence that we feel as though a 30-month stay is the very least that we could expect. It's also important to point out, as of today, we have not been noticed. So no Paragraph IV as of today. We've got 5 Orange Book patents, and we have 3 additional patents that have been filed with the PTO pending approval. So we feel good about our intellectual property.

The question on the citizen's petition has been highly visible over the last several weeks. And I think we want to take a -- try to simplify because there are certain things that are misunderstood about VASOSTRICT. When you look at switching within drug product at the FDA, a lot of times it's viewed that there are multiple NDAs. And I think that sometimes gets forgotten in VASOSTRICT because it was an unapproved drug, which we did all the requisite work. And we filed our PDUFA fee and we were approved. There's only one NDA tied to VASOSTRICT. Within that NDA, there was a switch in formulation. And I think that's a nuance that's very important. So while there is a citizen's petition, there's no avoiding the fact that you still need to make a certification on Paragraph IV. That doesn't change. So whether or not a competitor wants to try to circumvent our NDA by filing a -- back towards an ANDA on the former unapproved formulation, you can't avoid having to certify a Paragraph IV. That's Hatch-Waxman, right? So from that standpoint, we feel real, real confident about. So -- and I think we have an example whereby when you look at what occurred with ADRENALIN, the same question arise that there was 2 formulations within an NDA. And we had recently had a competitor file a Paragraph IV utilizing the old formulation. They still needed to make a certification. So you're still tied into the 30-month stay. So from a durability standpoint, I don't think you can hide behind a citizen's petition to get around our intellectual property, 5 Orange Book patents. The fact of the matter is, it's still a hard product to make, polypeptide, and more patents on the way.



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**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

That's very helpful. Why don't I pause there to see if there are any questions from the audience. Okay. So maybe we could just pivot to XIAFLEX. Can you just discuss -- maybe Blaise, you could talk about the numbers first and in terms of the momentum for XIAFLEX. And if you can include some comments on volume and net price, that would be helpful. And then, Paul, if you could talk about the longer-term prospects.

**Blaise Coleman** - Endo International plc - CFO and EVP

Okay. Yes, thanks, David. So in terms of where we guided for the year, we guided that XIAFLEX from a revenue growth standpoint would sort of be in the high single to low double digits, and that's looking at the molecule. And Paul can get into some of the specifics, but all of that growth is really volume-driven. So we've taken a very, what we think, responsible approach to price on XIAFLEX. And so really, what you're seeing there is true underlying demand growth. So we feel really good about the volume growth we see in that product and more importantly, about the untapped opportunity that still exists in both indications. So Paul, maybe you want to hop in there.

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

Yes. So I would tell you -- maybe I'll back up a little bit. So for the last year, when you look at Endo, we talk a lot about some of the challenges that we've had in the resolution with mesh, and we look at some tough decisions that we've made on people and facilities to get ourselves situated to better compete. What I will tell you is that for the first time in the year that I've been doing this job for Endo, I had the opportunity to travel out with our sales reps. And I traveled and I met with about 20 urologists with respect to XIAFLEX in Peyronie's disease as well as some of our testosterone products. And then last week, I had the opportunity to participate in ASSH, which is the American Society of Surgery for Hand (sic) [American Society for Surgery of the Hand]. And what I came back with, I'm incredibly excited about the potential that Blaise was talking about. With respect to Dupuytren's, we're probably only touching around 10% to 15% of the market. With respect to -- I probably said this one. With respect to Peyronie's, we're only touching 10% of the market. With respect to Dupuytren's, we're probably about 30% penetration. There is a lot of opportunity here that, for the first time, that we can focus on as a sales team and put more resources in the marketing aspect of both in-market indications for Dupuytren's and Peyronie's. So these are the drugs of choice for surgeons and urologists. These are the go-to. We're incredibly excited about the indications and the ability to expand our reach. And then when we look at the follow-on opportunities, and one of our partners is here today from BTG, I tell you, we're incredibly excited about our direction moving into cellulite. We are headed into clinical trial Phase III somewhere in Q4, maybe Q1 of next year. But somewhere in that time frame, we should be ready to go with our Phase III clinical trial. We're working with the FDA. We're incredibly excited. We are planning for success. We're building our team around marketing the product ourselves. So we are getting ready for cellulite and being an aesthetics company. I would tell you on top of that, we're strongly considering a host of additional indications. One would be Adhesive Capsulitis, which is frozen shoulder, as well as plantar fibromatosis. So it's basically Dupuytren's nodules for the foot. So 2 additional indications. We also have rights to several other potential indications for consideration that we are working with our partner. But we're incredibly excited about cellulite and then the prospect of moving forward with 1 to 2 more indications for next year.

**David Reed Risinger** - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

And could you just speak to the pricing challenge? So as you think about commercializing in cellulite down the line, obviously, at the current pricing, it would be out of reach for the vast majority of people. And so how do you think through managing that? Can you recreate a new product and price it much lower, but not risk having physicians use it for the existing approved therapeutic indications? How are you thinking about that?

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

So I mean, we spend a lot of time talking about the in-market indication versus cellulite, knowing that cellulite is a cash pay product. We're not so concerned about that specific aspect. What I would tell you is, is that we've taken strategic technical moves to alter the product in a manner whereby we believe we should be able to submit a separate BLA. Time will tell. It's not -- I wouldn't say that I'm going to guarantee anything, but I think we've taken a very thoughtful, mindful approach. We're very aware of the situation, but we -- that there are significant technical differences between what is in market as well as what we would be going forward with, with cellulite. So there is a differentiation. And with that, we believe we could



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avoid -- what you're actually referring to as a J-Code challenge. So I think we feel good. Now correct me if I'm wrong, Blaise. But at the end of the day, I believe that if we were looking at a situation where we couldn't get around it, from a Medicare standpoint, it represents maybe only 25% to 30% of the overall market. So while that's important, I would say it's not catastrophic. So I think we have a good handle on it. We've got a strategy. And we are moving forward with a product that we think will be submitted as a BLA in the clinical trial.

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**Blaise Coleman** - *Endo International plc - CFO and EVP*

Yes. Even with that challenge, the cellulite opportunity is incredibly exciting. So either way, it's really -- that will be a fine problem we'd have to deal with.

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

Yes, fine problem. Great way of saying it.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Okay. That's very helpful. And then one final question is just finishing up on generics. So the way that I had thought about sort of the new product opportunity annually was in the ballpark of maybe \$100 million, 20 products, maybe \$5 million each on average. Could you just provide a perspective on how that's going to actually play through in 2017, whether that's in the right ballpark and whether I have the right framework? If you -- or if you could just contextualize the annual new product flow in generics, that would be helpful.

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

So we're not going to really be able to quantify to that kind of detail because there's so many caveats, as you can imagine. But I think that the rule of thumb as I look at our R&D program, we should be able to yield 20 to 25 applications each year on file with the FDA. We should be able to get about 20 products out of the FDA. So when we look at our year-over-year contribution coming out, it's going to be about the same number of ANDAs. The challenge that you have is, it's always hard to predict so early in the process in terms of where your value drivers are going to come from. But I mean, if you want to look at a very, very high dimension, it will be hard to argue with your thought process. We're not going to really sit here today and quantify that for you. But directionally, you're probably in the ballpark. But you got to keep in mind, when you look at the generics division, 75% of what we file are Paragraph IVs, and there's always uncertainties on how you ultimately will move towards -- whether you win or not at a District Court level or whether you go to appeal, whether you win or lose that appeal or when you settle out with the time you've got an appeal. Those are all things that are unknowns, and those all evolve over time as you advance into your litigations. But generally speaking, I would say directionally, you're in the ballpark.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

And then just one final follow-up on that. Within that 20 to 25 ballpark or 20 theoretical potential approvals annually, how would you bucket them? So meaning, percentage of those that would be sterile injectables, percentage that would be 505(b)(2)s, is there any way that you would sort of frame how one should think about those?

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

I -- so I haven't sat there and actually gone through each year by year development target. But I would tell you that we are -- that by far, historically, we have been a solid oral dosage company. So I'm going to -- I mean, large percentage, probably in the 85% to 90% historical solid oral dosage. We are moving away from that. You're going to see more R&D dollars going towards injectables and alternative dosage forms. So I'll start with that. So our bread-and-butter is tablets and capsules, extended release. We do this very, very well. Combination, bi-layer, tri-layer tablets, this is the



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bread-and-butter of what we have been built on. While we're not moving away from that, we're going to be moving away from products that are commoditized, where a lot of people play in. And you're going to see a significant portion of our R&D switch over to injectables and alternative dosage forms, creams, ointments, otic, nasal spray. 505(b)(2)s are opportunistic, right? At the end of the day, I'm not going to sit here and say that I've got a portfolio of 2 to 10 505(b)(2)s. Over time, we create strategies on 505(b)(2)s, right? And in one given year, I could have 4; in one given year, I could have 1. 505(b)(2)s have to be very thoughtful, mindful because it could entail intellectual property, it could entail sales forces. So it's a strategy, but I'm not -- I don't quantify in terms of number of applications.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Okay. Great. Well, we are out of time. Thanks so much for sharing.

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

Thank you, David. Appreciate it. It's a pleasure. Thank you.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Thank you.

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