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ENDP - Q3 2017 Endo International PLC Earnings Call

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OVERVIEW:

Co. reported 3Q17 GAAP net loss from continuing operations of $100m and GAAP diluted loss per share from continuing operations of $0.45.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Endo International Third Quarter 2017 Earnings Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded. I would now like to turn the conference over to Steve Mock, Senior Vice President, Investor Relations and Corporate Affairs. Sir, you may begin.

Stephen J. Mock *- Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Shannon. Good afternoon, and thank you for joining us to discuss our third quarter 2017 financial results. Joining me on today's call are Paul Campanelli, President and Chief Executive Officer of Endo; and Blaise Coleman, Executive Vice President and Chief Financial Officer. We have prepared a slide presentation to accompany today's webcast, and that presentation as well as other materials are posted online in the Investors section at www.endo.com.

I would like to remind you that any forward-looking statements made by management are covered under the U.S. Private Securities Litigation Reform Act of 1995 and the applicable Canadian Securities Laws and are subject to the changes, risks and uncertainties described in today's press release and in our U.S. and Canadian securities filings.

In addition, during the course of this call, we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used by other companies. Investors are encouraged to review Endo's current report on Form 8-K furnished with the SEC for Endo's reasons for including those non-GAAP financial measures in today's earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in our earnings press release issued prior to today's call, unless otherwise noted therein.

I would now like to turn the call over to Paul.

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

Thank you, Steve. Good afternoon, and thank you for joining us for today's call. I hope that you had a chance to review the company's earnings release that we issued earlier this afternoon.

Endo's very pleased to report another quarter of solid operating performance. This performance resulted from strong operational execution in our core areas of focus and expected future growth. In the third quarter, Endo once again benefited from the impressive contributions of our Sterile Injectables and Branded Specialty Products business units.

Beginning on Slide 2. Here's a brief agenda for today's call.

Moving to Slide 3. Again, we are very pleased with our third quarter operating performance. Strong growth in our Sterile Injectables and Branded Specialty portfolios and lowering operating expenses, including cost savings from previously announced restructurings, drove the increase in adjusted EBITDA and adjusted EBITDA margin, a key priority for Endo. We are reaffirming our 2017 revenue, adjusted EBITDA and adjusted diluted EPS guidance that we provided in August. We now expect to achieve adjusted EBITDA and adjusted diluted EPS that will reach the upper end of our 2017 guidance ranges. Blaise will discuss our financial guidance in greater detail later in the presentation.

Moving to Slide 4. You will see a snapshot of our segment revenues for the third quarter. As expected, the previously communicated, and by now, well-documented, headwinds impacting the U.S. generics industry accounted for the overall decline in the U.S. Generic Pharmaceuticals. Similarly, U.S. Branded Pharmaceuticals' overall performance was impacted by continued generic competition for established products, product divestitures and our ceasing shipments of OPANA ER. I'd like to point out that within each business segment, our core areas of strategic focus, Sterile Injectables and Branded Specialty Products, continue to grow by double digits. International Pharmaceuticals reflects, of course, the previously announced sale of the Litha Healthcare Group at the beginning of the third quarter.

Now moving to Slide 5. U.S. Generic Pharmaceuticals declined 7% to $497 million in the third quarter. The decline in our base business was partially offset by strong double-digit growth in Sterile Injectables. Year-to-date, U.S. Generics revenue grew 6%, driven by strong performance of our Sterile Injectables portfolio and new launches in alternative dosages.

In the third quarter, our Base Generics business declined approximately 27% compared to third quarter 2016, in line with guidance we provided in February. The third quarter performance resulted in part from the annualization of 2016 competitive events, 2017 competitive events as well as product discontinuations. Price erosion in the third quarter continued to be in line with our expectations. New launches in alternative dosages declined 3%, as the impact of lower pricing on our LIDODERM Authorized Generic was partially offset by the continued growth of potassium chloride liquid and powder as well as new Sterile Injectable launches such as ephedrine sulfate and neostigmine.

We're also very pleased with the August launch of vigabatrin for oral solution and the encouraging results achieved so far.

Finally, Sterile Injectables were powered by the continued growth of VASOSTRICT as well as the increasing uptake of ADRENALIN. Sales of VASOSTRICT reached $106 million, a 15% increase versus prior year. ADRENALIN continued its momentum, achieving sales of $25 million in the quarter, a 33% sequential increase. Based on our strong year-to-date performance, we continue to project full year Sterile Injectables revenue growth in the low to mid-20% range.

Now before moving on to the next slide, I know there is some level of uncertainty in the financial community around the durability of VASOSTRICT. I want to tell you that I am very pleased with our VASOSTRICT patent portfolio. We've succeeded in securing 5 Orange-Book-listed patents relating to VASOSTRICT, including 3 in the third quarter. And I note that we have not received a Paragraph IV notice letter with respect to any of those patents.

Separately, while nobody can ever predict the outcome of litigation, I believe strongly in the merits of our pending lawsuits against Cuba and the FDA. It is our firm intention to take whatever actions we consider necessary or appropriate to aggressively defend our VASOSTRICT product franchise and our intellectual property.

Now turning to Slide 6. Year-to-date, Par has launched 14 products, including 2 first-to-market products in the third quarter. We've also submitted nonregulatory filings this year. We expect approximately 20 launches and a similar number of regulatory submissions in 2017.

Moving to Slide 7. Let's discuss U.S. Branded Pharmaceuticals. We continue to be pleased with the strong growth across our specialty product portfolio. Branded Specialty Product revenues grew 11%, driven primarily by XIAFLEX and other products within our specialty products portfolio. As expected, Branded Established Products were impacted by the ceasing shipments of OPANA ER by September 1, the continued decline of our remaining pain products due to generic competition and the 2016 divestitures of STENDRA and BELBUCA. Overall, full year 2017 U.S. Branded pharmaceutical revenues is expected to decline in the mid- to high teens percentage range year-over-year.

We continue to expect our full year Branded Specialty Products and XIAFLEX revenue to grow in the high single- to low double-digits range. We are extremely pleased with the performance of our Branded Specialty Products portfolio and believe additional initiatives, both executed and planned, will continue to grow that portfolio. Specifically, in support of XIAFLEX, this year, we made a commitment to consumer activation for Dupuytren's contracture and Peyronie's disease. Based on the metrics we have seen to date, the results of the initiatives have been very encouraging and we believe indicate the potential for increased demand in both indications. We believe that these investments, along with our increased investment directed toward health care professionals, are helping to drive our year-to-date, double-digit XIAFLEX sales growth.

In addition to branded awareness campaigns, we continue to be committed to disease state awareness for both Peyronie's disease and Dupuytren's contracture. On September 26, we launched our Facts on Hand initiative, partnering with 4-time PGA Tour winner Tim Herron. The focus of this campaign is to educate and activate patients to seek nonsurgical solutions for Dupuytren's contracture, similar to last year's Ask About the Curve PR campaign which was aimed at educating patients regarding Peyronie's disease. We feel that there is ample opportunity to continue to increase disease state awareness as well as diagnosis and treatment rates for both indications.

Lastly, we continue to be very excited about the opportunity to launch into aesthetics and believe that this represents an important milestone for our branded specialty strategy. We intend to initiate Phase III clinical trials in cellulite in the coming months. Our commercial team is already working on preliminary launch planning, and we will be bringing in additional talent with aesthetics experience to complement our current aesthetics commercial team.

Now moving on to Slide 8. Let's briefly review International Pharmaceuticals. Third quarter International revenues of $56 million were down 20% due primarily to the previously announced sale of Litha at the beginning of the third quarter. Paladin's third quarter performance increased 3% due to the continued uptake on Nucynta and XIAFLEX as well as delayed generic competition on certain established products.

Finally, the previously announced divestiture of Somar closed on October 25. We have successfully fulfilled our expressed intention to [divest] noncore assets and have delivered on our commitment to place Litha and Somar with companies that we believe can provide the attention and resources they deserve.

We continue to expect 2017 International revenues to decline in the low 20s percentage range, reflecting the divestiture of these 2 businesses.

Now let me turn the call over to Blaise Coleman to further discuss the company's third quarter financial performance and provide greater insight into our 2017 financial guidance. Blaise?

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

Thank you, Paul, and good afternoon, everyone. First, on Slide 9, you'll see a snapshot of third quarter GAAP and non-GAAP financial results. On a GAAP basis, we had a diluted loss per share from continuing operations of $0.45 in the quarter versus a diluted loss per share from continuing operations of $0.86 in the third quarter of 2016. GAAP net loss from continuing operations in the third quarter of 2017 decreased to $100 million compared to GAAP net loss from continuing operations of $191 million during the same period in 2016. This decrease includes the impact of lower amortization of intangible assets in the third quarter of 2017 and higher third quarter 2016 tax expense.

On an adjusted basis, third quarter results were better than previously guided. Adjusted net income from continuing operations of $204 million and adjusted diluted earnings per share from continuing operations of $0.91 includes the impact of improved adjusted gross margin and lower adjusted operating expenses.

Adjusted operating expense favorability was partly driven by approximately $12 million in the quarter of favorable changes in estimates. In addition, there was some shift in spending in the fourth quarter of 2017 and lower underlying operating expenses partly due to better-than-expected efficiency realization. We stated in the beginning of the year that one of our priorities is to drive margin expansion through operational execution and continuous improvement. Our third quarter adjusted results indicate the actions we have taken to date on this front are yielding tangible margin improvements.

This brings us to our guidance on Slide 10. We are reaffirming our full year 2017 revenue, adjusted EBITDA and adjusted diluted EPS guidance. Based on performance year-to-date and better-than-expected operating expenses, we now expect to be at the upper end of our adjusted EBITDA and adjusted diluted EPS respective ranges. The company's financial guidance is based on the assumptions noted on the slide.

Lastly, in terms of projected cash flow on Slide 11, we had $230 million in cash flow prior to debt payment in the first 9 months of 2017 and now expect the full year 2017 cash flow prior to debt payment in the range of $310 million to $390 million. The increase in guidance is primarily due to favorable legal settlements and higher cash provided from changes in working capital. We continue to estimate our net debt to adjusted EBITDA leverage ratio to be in the high 4x range year-end 2017.

Now let me turn it back over to Paul. Paul?

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

Thank you, Blaise. Once again, I'm very pleased with another solid quarter of operating performance for Endo. Efficiency measures are yielding results, and we remain committed to executing on our strategy laid out earlier this year. I'm proud of our vigabatrin first generic product launch through specialty pharmacies, as our hybrid model allow for close collaboration and leveraging of expertise amongst our Par Generics, Par Sterile and Branded Specialty colleagues. I'm also pleased with XIAFLEX-branded campaigns and our unbranded disease awareness campaigns targeting the untreated patient populations for Dupuytren's contracture and Peyronie's disease.

Looking forward, we are excited to initiate Phase III trials in cellulite over the coming months. Over the past year, we've taken significant steps to reshape our organization. As we stated, it will require time to ultimately get to where we want to be. Our priorities haven't changed and we've executed on what we said we would do. We are experienced at transformation, not only as a company, but also as a sector. Through this period of transformation, we will focus on those areas that we can control and we will continue to execute against our priorities. I firmly believe that if we are relentless in the execution of our plan over the mid- to long term, we will be successful in creating value for our shareholders.

Let me now turn the call back over to Steve to manage our question-and-answer period. Steve?

Stephen J. Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Thank you, Paul. We'd now like to open the lines to your questions. (Operator Instructions) Shannon, may we have the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Liav Abraham with Citi.

Liav Abraham - *Citigroup Inc, Research Division - Director*

I have a question regarding margin trajectory. Based on our calculations, and correct me if I'm wrong, your full year 2017 guidance implies an uptick in cost expense as a percentage of sales in Q4. So maybe you can speak a little bit to that, and please correct me if I'm wrong. And how should we think about your gross margin and SG&A and R&D going into 2018?

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

Liav, I'll pass it over to Blaise.

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

Thanks, Liav. Yes. So in terms of our implied gross margin for Q4, it's actually flat with Q3. So that's what we have in our implied guidance. As far as shaping going into 2018, Liav, we're not going to be providing any forward-looking guidance as it relates to 2018. Obviously, as we stated, one of our priorities is to continue to drive margin improvement, particularly gross margin improvement as we move into 2018, and we're on track to do that.

Operator

Our next question comes from Randall Stanicky with RBC Capital Markets.

Randall S. Stanicky - *RBC Capital Markets, LLC, Research Division - MD of Global Equity Research and Lead Analyst*

Paul, you and the management team have been delivering on the guidance that you've put forth. In fact, you're pushing up on the higher end, and the stock continues to drop. So at what point do you step back and say, look we put targets out there. We're hitting them, but it's not just enough given the environmental pressures, and step back with the Board and say, we need to take a more aggressive strategic approach to managing through these headwinds? And as an adjunct to that question, at what point does working with the industry to find alternative distribution or working around the consortiums become a more meaningful part of that conversation?

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

Sure, Randall. So I think it's -- the question in terms of strategic optionality or strategic alternatives, as you would expect, we have fiduciary responsibility. We're always out there looking for ways to create shareholder value. So I mean we're very aware what's happening in the industry, what's happened over the last month or so. So that's always on the radar screen. But it has to be a correct fit, right? So at the end of the day, there are certain things that we control; there are certain things that we don't control. We're not going to lose focus. We are laser focused on what we control, and that goes back to operational execution. We are outperforming because we are doing what we said we are doing. We're going to file and we're going to launch. And I think we've got a good track record. We've proven it over the last -- basically, the last 3 quarters. I feel good about Q4, the way we're -- the way we forecast it. Regarding strategic alternatives, we're always going to be out there looking at ways to improve. And until a perfect fit comes forth, we're just going to continue with what we control, and that's executing on the portfolio, Randall. On the distribution

side, if you're referring back to the pressures with the 3 consortiums, there's been a lot of questions on Amazon. I assume that's probably where you're headed. Today is where we are with 3 consortiums. They represent tens of thousands of retail pharmacies. They are our partners and we need to understand how to work with them and continue to launch hard-to-manufacture products. That's our defense for the near term. If, in the future, an Amazon comes to the market, an opportunity to participate in that, that's going to be welcomed, right? To have a -- once again, a fourth consortium, a fourth partner to sell into with new terms and conditions with a fresh look would be a welcome addition for a company like Endo. So I hope I answered your question.

Operator

Our next question comes from Greg Gilbert with Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

A couple. Paul, I know pricing is a very-company specific portfolio -- specific thing to ask about. But if I could ask you more broadly to comment, do you -- I'm not asking you to call the bottom and a big improvement here, but are you seeing signs of some of the pressures that have been hurting price for everyone or at least getting less bad, if I could call it that? And secondly, about testosterone litigation, what would you outline as some of the key milestones as we look ahead? And how do you frame the risk for folks that worry that this could be another mesh-like liability.

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

Okay. So Greg, yes, so in terms of the bottom in generic pricing, I mean it really kind of gets down to how much -- and for us, I'll be specific. I'm going to have to be specific to the Par Generic portfolio. It gets down to how much further do we really want to participate. So we've made corporate decisions on people and facilities and products. So we are -- there's areas that we're no longer going to be participating in. So our defense again is going to be coming out with the hard-to-manufacture products. We have to move away and we are moving away from commodities where you're seeing those larger price points and those larger pressures. So there's no surprises there. For us, we're basically calling out we're at the bottom and we're not planning on going too much further. We'll see where the WBAD Econdisc consortium leads next year, but there's not much room to go on a forward motion for Par. Regarding testosterone, I mean we're not going to be able to comment on ongoing litigation. You're well aware that the first MDL hearing started, I believe, November 6. It'll play out. We've got our defensive strategy at the end of the day. We're just not going to be able to comment on ongoing litigation.

Operator

Our next question comes from Andrew Finkelstein with Susquehanna Financial Group.

Andrew Jay Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

I was hoping you could give a few more specifics about the product launches and submissions you expect before year end. I assume there's probably not a lot of specific products you'll name, but if you can give us a sense, I think it implies 6 more launches this year. Are these approved products or things with good visibility on approval? And then if I could ask specifically about generic Concerta, what your status is with that application and any thoughts on the stability or variability in the outlook for VOLTAREN Gel and the Authorized Generic as we think out over the next 6 to 12 months?

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

All right, so Andrew, in terms of the remaining product launches, we're not going to specifically call them out. They're smaller products. We're not going to place ourselves at a competitive disadvantage because some of these are first-to-market product opportunities, and we just don't want

to put ourselves at risk here. So -- but the way you should be looking at them, they're relatively small products but the company continues to execute. And forgive me, your second question was?

Andrew Jay Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

On Concerta and VOLTAREN.

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

So on Concerta, yes, I mean Concerta, that we do have an application. It is a very, very difficult product to make, as everybody is aware of. We're not going to highlight or put visibility on it. At this point in time, we just don't have clarity. And then on V Gel, your question was?

Andrew Jay Finkelstein - *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

For the brand and the Authorized Generic, is that seen as stable over the next year, or?

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

Yes. So at this point in time, we don't have visibility to any real competitor absent of somebody coming into the market. I think you're going to see status quo with the 2 players plus the brand.

Operator

Our next mission comes from Marc Goodman with UBS.

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

Yes, the line item you call alternative dosages/new launches, can you just give us a flavor for the second quarter to third quarter movement down? I mean obviously, we would expect the ZETIA, the SEROQUEL to kind of come down a little bit, but it just seemed like the numbers came down a lot more than we thought. So just help us with some of the movements. Like did the lidocaine come down a lot more? Did potassium not do as well?

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

I think Marc, you hit the nail on the head. It's the LIDODERM AG. We called that out in the script.

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

How much down was that?

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

About $10 million, Marc.

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

I think that answers your question.

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

And then just a follow-up to the question that was just asked about pricing, and then you responded, "We'll see how WBAD and Econdisc works out next year." Are you basically saying, "It hasn't really kicked in yet. We haven't had negotiations yet?" Where is that? What did you mean by that?

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

So I think with -- there has been -- there had been some initial requests coming from both Econdisc and WBAD. So there was some initial, what I call, calibration or equalization. That was part -- when we called out 27% base erosion, that included that. So we feel good with respect to this equalization of portfolios. What I meant by next year is, time will tell whether they plan on having a portfolio bid like a Claris one or is this it. So time will tell. We have not had any feedback or communication. What I will say is I don't believe that the generic sectors is going to support too deeply another round of bids, considering we just came out of a round with Econdisc in July and we really finished up probably less than a year ago with Walgreens. So it's going to be a very interesting 2018.

Operator

Our next question comes from Chris Schott with JPMorgan.

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

Just 2 questions here. First, maybe on XIAFLEX and cellulite. Can you just elaborate at bit, since we're getting close to starting the Phase III, just in terms of the size of the study, the duration of the study, any major changes in the way you're approaching this relative to that successful Phase IIb data that you had earlier this year? And the second question was just coming back on the base business, that $600 million or so of annualized revenue. How profitable of a business is that for the company at this point? So as we think about sales erosion going forward, is there still a lot of margin associated with this? Or are we kind of reaching a point where the profitability is kind of elsewhere in the portfolio?

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

Chris, it's Blaise. On the second part there, that second question, it is meaningfully below our gross margin that we've gotten to for the generics segments in 2017.

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

Yes. And we didn't disclose the number of patients, did we? No. So I think right now in terms of the XIAFLEX trial, Chris, we haven't disclosed the specific number of patients. I think right now what we say, it's going to be similar in nature to the Phase II -- I mean, and we're still discussing the overall Phase III program with the FDA. So we're going to ask for a little patience, but we feel good about it. But we're still in discussions with the FDA.

Operator

Our next question comes from David Risinger with Morgan Stanley.

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

I wanted to ask actually a high-level follow-up question. So it's not that I'm trying to be negative or not be supportive, but Paul, when you say the industry won't support much lower pricing, yes, the thing that comes to mind is that U.S. generic margins are still higher than they are ex U.S. And so I guess you've taken action to exit certain products that are unprofitable, and I think some other industry players have exited a very small number of products. But my question is do you think the industry will take action to exit a larger percentage of volume and SKUs in the country such that the Street can see more clearly exiting which causes pain for the buyers when they can't get the supply that they need? And then second, more specifically to Endo, the cellulite opportunity is quite exciting. There's been a lot of speculation for years that Endo would partner with an aesthetics company to help to fund development and commercialize in a significant manner. Could you just speak to whether that is still a possibility on the table or whether you're currently planning on going it alone?

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

So David, in terms of the high level on the generics side, my statement is very broad. I think -- there's a couple of ways that I'm looking at it. I don't believe that the measures that Endo has taken regarding Par is isolated to only Par. I think other companies are dealing with products and people in plants. And when you make those decisions, you just don't just come back and turn it back on, right? So when you look at a lot of -- and I'll speak for a lot of U.S. manufacturers. When you're producing product primarily in the U.S. and you make these decisions, it's very difficult just to come back into a product. And I think when you walk away from a product, you're sending a message. You may have some offshore companies that are looking to drive on volume, but these price points are getting to the point where they're so slim that while you can say that the margins are still high, it's -- ultimately, it's hard to grow your business in that regard. I think it wouldn't surprise me that you start to see drug shortages come out in the future on commodity products that you might have seen 10 years ago because of the price pressures that you're getting from some of these consortiums. That's just my view. I think it's a possibility. Regarding cellulite and partnering, I think I've been pretty clear. We're always going to be open to optionality. We will talk to folks or people that will talk to us and want to partner with us to be able to maximize XIAFLEX or CCH, as we're calling it, for cellulite. Of course, we're going to listen, but it has to be fair. At this point in time, we are incredibly excited about the Phase III trial. We are in the process of recruiting talent to bring the product forward. And all I can tell you is we are planning for success.

Operator

Our next question comes from Irina Koffler with Mizuho.

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

The opioid litigation tends to be pretty scary to people, and quite frankly, I just wanted to see if we can just get our arms around what is it that the range of risks is. And so is it just off-label marketing on your branded opioid products such as OPANA and PERCOCET over a particular period of time? Is it something else? Is it something more punitive or criminal? Can you kind of help us understand a little bit more and put it into buckets? So that's the first question. And the second question is on XIAFLEX, are you still coming out with a different formulation? And if so, will you need to do any sort of bridging work before you start your Phase III?

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

So Irina, I think simply put, on the opioids, we are headed into pending litigation. With that respect, we're not going to be able to speculate and it's not our policy to comment when we're moving towards litigation. Your specific question on what the allegation is, in terms of marketing practices, that's out in the public domain. So that's known. Regarding XIAFLEX, the formulation is basically -- I would say, it is a new formulation. It's a bit different that was used in the Phase IIb but I do not believe that there's going to be any bridging requirement.

Operator

Our next question comes from David Amsellem with Piper Jaffray.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

So just a couple on the injectables business. So just going back to VASOSTRICT. Obviously, you have IP and you've had it in the Orange Book. But is there anything beyond just IP that you can -- any reason why you would think you have not been certified against on P IV? I mean, is there something inherent about the product beyond just the patent protection that we should be aware that might be a barrier for generics? And then just secondly, on ADRENALIN, when do you think we might see companies that exited the market come back? Amphastar alluded to filing on their adrenaline vial product. They exited the market but they're looking to come back. So I wanted to get a sense for when you think competition may start there.

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

So on ADRENALIN, we already have a Paragraph IV filed. So with respect to that, we already know that we're in litigation with one company. Anybody that wants to make a submission and come forward on ADRENALIN, outside of the intellectual patent -- intellectual property as filed in the Orange Book patent, you have to file it a Paragraph IV. We are, obviously, aware that there is a company that had filed an application before our Orange Book patent was listed, and there's no barrier there. And I think we've been pretty clear with that. And as I indicated, Hospira had filed a Paragraph IV and we're in litigation. So if any other company, the company that you named wants to come forward on ADRENALIN, they will have to file a Paragraph IV. Regarding VASOSTRICT, your question, I believe, was how do I know if somebody hasn't notified me. At the end of the day, the process is, if you're going to file a Paragraph IV and you made a submission at the FDA and you're challenging the patents, you have to make a notification of a Paragraph IV. So there's a period of time that it has to come back to the innovator and, in our case, us and we would be notified. We've got 5 Orange Book patents listed. We've got 11 pending applications that will also enforce our intellectual property. So we feel very confident in that regard and we're saying at this point in time, nobody has noticed Endo regarding VASOSTRICT.

Operator

Our next question comes from Elliot Wilbur with Raymond James.

Elliot Henry Wilbur - *Raymond James & Associates, Inc., Research Division - Senior Research Analyst*

Just a couple of quick follow-ups. Paul, appreciate going to the bottom in the generic pricing cycle, at least, for yourself. With respect to that, though, obviously, while things may not get much worse, deflation is still very elevated. And I'm just wondering if you think this is kind of the new norm or whether or not we're -- at some point in time, and hopefully, that's a distant future, we'll actually see deflation levels ease. And then a follow-up to the Amazon question earlier, Teva owns a captive distribution business by the name of Anda which has about 10% share of the market. And earlier today, the other generic's Paul suggested that his company may also look at owning a captive distribution network as a way to get more direct control over product going to patients and, obviously, capture more of the margin. Is that something that you guys would consider at some point in time?

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

Yes. So Elliot, regarding the distribution question, of course we would consider it, but we have to be very careful here. As I said -- and we all know the situation, the consortiums represent tens of thousands of pharmacies. When you make that decision, you better be prepared for pushback. At the end of the day, we all know the math and the consortiums are controlling 91%. So while I have a lot of respect for Anda and smaller distributions, they represent right now tenths and halfs of percents. Again, I'm being -- I'm the master of the obvious here. When you take that turn and make that decision, you best be prepared for what could occur. So you need a very diverse and strong portfolio. Would we consider it? Sure. But you

better be ready to back it up. Regarding the deflation question, we don't know the answer to that definitively. I can only hope and speak for Par. There's just -- frankly, there's not much more room for where we're going to go. We're looking forward, we're looking at bringing new products to the market that are hard to manufacture, and that's our strategy and that's our defense.

Operator

Our next question comes from Annabel Samimy with Stifel.

Annabel Eva Samimy - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD*

So I understand that the impact on the alternative dosage forms was really LIDODERM and then we're, obviously, seeing some downtick from SEROQUEL and ZETIA. But can you tell us whether alternative form, which we typically saw as a more protected class, is falling into some of the same dynamics that you're going to be seeing -- that you've seen in the base business? Have you seen more competitors into this area? And should we see some of these trends going forward? And then separately, on XIAFLEX, do you have any kind of breakdown or can you give us a sense of the breakdown between Peyronie's and Dupuytren's, and Dupuytren's is an old -- an older indication. So how much of an impact can this new awareness campaign generate?

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

Yes. So Dupuytren's is -- we feel that actually, Dupuytren's is a growing indication for us, right? So regarding the demand of vial growth, we're seeing volume increases of around 7%. So we feel pretty good about that. For the quarter, I think we saw Peyronie's specifically grow about 10% and we saw Dupuytren's grow about 2%. So year-to-date, we called out the 7% overall growth. Then with respect to the other question on the alternative dosage forms, the other area that we had some pressure was on -- in addition to LIDO was on both forms of just the potassium powder.

Annabel Eva Samimy - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD*

And so what does that mean going forward?

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

Ultimately, if we take on more competition, there's nothing stopping anybody with respect to coming to the market on either the powder or the liquid, and we've call that out and we've said that from previous conference calls, that those 505(b)(2)s behave like sole-source generics but there's no intellectual property holding back competition. So those products could receive competition at some point in time.

Operator

Our next question comes from Dana Flanders with Goldman Sachs.

Dana Carver Flanders - *Goldman Sachs Group Inc., Research Division - Research Analyst*

My first, just on the decision to sue the FDA preemptively on VASO compounding, and I know you referenced this in your prepared remarks, it's not something we see as often. So just could you talk a little bit about what went behind that decision? And did something happen or change to make you feel like you needed to take that action? And then secondly, on the international business, a lot of progress you've made reshaping it. Are you done at this point? Or is there still action you plan to take going forward?

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

Dana, on the international side, I mean, it's a very -- at this point in time, it's a very small part of our business. So I think we've done a great job of putting Somar and Litha into better owners' hands to grow those businesses. But in terms of what remains in Canada and a little bit in the U.K., I think these are so small at this point in time. We've got bigger challenges that we're focused on. So this is not our highest of priorities. Regarding the decision to bring a suit against the FDA, I would tell you that was a painstaking decision and a lot of thoughtful, mindful approaches went into communicating and attempting to dialogue with the FDA. So I do agree with your statement in terms of it's not something that you see that much. We exhausted every means possible to resolve what we think is something that is incredibly unlawful. To take a product that we spent millions of dollars on to develop, to bring to market under an NDA and then have a category 1 compounder come to the market where the requirement is to fill out 1.5 pages application with no notice period, without any definition around a medical need, was something that was unacceptable to us and we needed to have a dialogue. It didn't happen and we exhausted company means, political means. And ultimately, after a period of time went by, we need to protect our intellectual property and our product, and that's why we went forward against the FDA. Thank you.

Operator

Our next question comes from Gary Nachman with BMO Capital Markets.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

I wanted to come back to the spending levels that were a lot lower than we expected. Could you review what that favorable change in estimates was? And where are the additional efficiencies coming from? What areas are you scaling back on? And then, Paul, any new updates on mesh? Any new cases that have surfaced? Are you comfortable enough with that situation where you would consider doing some bolt-on deals if those opportunities presented themselves?

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

So I'll take the first -- I'll take the last question. I'll let Blaise handle the financial question. Regarding the mesh question, I guess the easiest way to comment on it is, frankly, I just don't have an update. And I think that's good news. So when we talked about last quarter the accrual, there's just nothing material to talk about. So we feel pretty good regarding that. Regarding your comment on bolt-on deals, that's a question that we're going to make a little bit later this year, early next year. We're going to -- we've got to look at what type of cash that we end the year with. We always talk about delevering. We're laser-focused on that. But if we find a small deal that makes sense in areas that we're highly focused on, whether it's aesthetics or injectables, that's something that we will strongly consider as well. But I don't want to leave you with a wrong impression. We are committed to being laser-focused on delevering. With that, I'll pass the next question to Blaise.

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

Yes. Sure. So Gary, on the spend question, the favorability we saw in Q3 and then you're seeing play through in terms of our full year guidance, a piece of that is what we mentioned up front, which is we had some favorable changes in estimates in Q3 of about $12 million, and that's in OpEx and that's playing through in the quarter and that's going to play through on a full year basis. The other piece we had is around just the timing of spend in the quarter and that -- and how that's moving forward into Q4. And the last element in terms of underspend, true underspend, is in 2 areas. One is around legal spend, where a legal spend can be a bit lumpy. And then we're seeing that change for the year. We're going to have some savings there. And then also just from a selling and marketing standpoint, we're going to see some favorability as well. So last component we mentioned is around efficiencies, and we did see some realization a little bit quicker on some of our efficiency initiatives that we have going on that we realized in Q3, and that's going to contribute to the full-year benefit as well.

Gary Jay Nachman - *BMO Capital Markets Equity Research - Analyst*

Okay. So those are good run rates going forward, both SG&A and R&D?

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

Well, listen Gary, I'm not going to give you anything right now in 2018 in terms of what we're going to do, but we'll give you that guidance during the year-end call.

Operator

Our next question comes from Louise Chen with Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

First question I had was, why haven't we seen more pushback from the other companies to these consortiums? It sounds like now you're getting to that point, but why hasn't there been up to now? And then secondly, is the potential entrance of players such as Amazon positive or negative to the generics industry? And particularly on pricing, how do you think about that?

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

So Louise, the question for -- I'll start with the second question on Amazon. As I've said before, any time that you can bring another major buyer into the sector, I'm going to view as favorable, right? So that just -- that opens up competition. That's just another outlet. I think that's the way I would look at it initially. And in the future, you just have to look at what types of terms and conditions that would result to that. Now I would tell you that the 3 other consortiums aren't going to just allow that to happen. And we see what's already happening in the market, and I think we're all aware of the CVSs and the Walgreens making communications about increasing their 24-hour delivery services. So at the end of the day, they're going to try to put themselves in a position to compete against Amazon, as you would expect. But whenever you have an ability to go to another major buyer in the generic industry, that's a positive. And then your first question, I apologize, was?

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

Yes. Why haven't we seen more pushback from generic drug companies on these consortiums and their pricing?

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

So pushback from the consortiums, at the end of the day, they're controlling 91% of the market. They're controlling tens of thousands of pharmacies. So whenever you have multiple players in a product and somebody is willing to lower price, you have to decide whether you want to stay in a product and compete, and that's what's obviously occurred here. In our particular case, we've made certain decisions on commodity products where we've decided we can't compete or we don't want to and no longer compete. And hence, we made decisions on people and products and facilities. But to answer your question, as long as there's multiple players in the product and they're willing to drop price, that -- it's very difficult to push back on the existing consortiums as we know today. And you have a record number of ANDA approvals coming and a lot of those record ANDA approvals are not first-time generics. These are on older ANDAs. So there's plenty of new products -- I'm sorry, plenty of new ANDAs coming to market on older products.

Operator

Our next question comes from Douglas Tsao with Barclays.

Douglas Dylan Tsao - *Barclays PLC, Research Division - Director and Senior Research Analyst*

Just first, in terms of the generic business, I mean when you look at your portfolio, Paul, in terms of some of the hard decisions that you sort of referenced, do you feel like, at this point, you've sort of gotten out of the products that are most vulnerable? Or when you look through your book, are there some -- in terms of some of those pending ANDAs at the FDA that, that could be a little problematic? And then just a second question, in terms of the Sterile Injectables, you've had some -- a lot of success with VASOSTRICT and obviously, you're sort of capitalizing on the FDA's sort of unapproved drugs program. But there has sort of been called out some of their recent sort of drug pricing hearings as sort of having some unintended consequences. And does that potentially change how you look at those as an opportunity for the company and the investment you want to make behind them?

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

Yes. So Doug, the answer to the second question, it does. And I think the way you have to look at it is we have a 505(b)(2) strategy. We feel good about it. We're going to continue with it, but you have to be thoughtful and mindful on how your price things today. I think that's very important. But you have to take into consideration that it can be incredibly costly to take an unapproved drug, do the requisite clinical trial work, submit an NDA, pay the PDUFA fee, and if you're going to pursue intellectual property, the cost that comes with it, knowing that you're maintaining, in our case, a sterile injectable facility in the United States. That comes with a price, but you've got to be mindful and thoughtful on how you price products and that's always been the case. When we look at our generic portfolio, I would tell you that your first part was when we look at our commercial products, I think that's probably where you're headed, we've made tough decisions already on commercial products. Going forward, I would say that we're probably in a normal course process where every quarter, every 6 months, you're always looking at your portfolio. So there's probably going to be a handful of ins with product launches and a handful of outs, but nothing, nothing along the scale of what we've gone through over the last year. Regarding the R&D, similar question. We have over 100 -- we have about 100 products on file with the FDA. So you're going to have a similar question there, that not every product is going to fall into a perfect category. And we'll have to be very thoughtful and mindful that, do we want to enter into a market with 4, 5, 6 competitors. And that's just -- there may be a percentage of our portfolio, as you would expect with anybody, that you're going to fall into that category. And we'll make some decisions at the time of product approval. We may or may not go forward with a handful of smaller commodity-type products. But I want to leave you with the soundbite that we're pursuing, for the most part, difficult-to-manufacture products. That's the focus of the R&D side of Par.

Stephen J. Mock - *Endo International plc - SVP of IR & Corporate Affairs*

Shannon, that's going to have to be our last question. Paul just has a few closing remarks.

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

Thank you, Steve. Before we conclude, I do want to thank our dedicated employees for their hard work and commitment to our company. I'd also like to thank our investors for their patience and continued support. We appreciate your continued interest in our company and we look forward to providing you with updates. Thank you for joining us this afternoon, and good evening.

Operator

Ladies and gentlemen, this concludes today's conference. Thanks for your participation and have a wonderful day.